Check Sheet

Company Name: KEY PHARMACEUTICALS
Permit Number: AC 13-129891, -129893, -129894, -129895, -129897
PSD Number:
Permit Engineer:

Application:

- [x] Initial Application
  - [ ] Incompleteness Letters
  - [ ] Responses
  - [ ] Waiver of Department Action
  - [ ] Department Response
  - [x] Other

Cross References:

- [x] AC 128475
- [ ]
- [ ]

Intent:

- [x] Intent to Issue
- [x] Notice of Intent to Issue
- [x] Technical Evaluation
- [ ] BACT Determination
- [ ] Unsigned Permit
- Correspondence with:
  - [ ] EPA
  - [ ] Park Services
  - [ ] Other
- [x] Proof of Publication
  - [ ] Petitions - (Related to extensions, hearings, etc.)
  - [ ] Waiver of Department Action
  - [ ] Other

Final Determination:

- [x] Final Determination
- [x] Signed Permit
- [ ] BACT Determination
  - [ ] Other

Post Permit Correspondence:

- [x] Extensions/Amendments/Modifications
- [ ] Other

SENDER: Complete items 1 and 2 when additional services are desired, and complete items 3 and 4.

Put your address in the "RETURN TO" Space on the reverse side. Failure to do this will prevent this card from being returned to you. The return receipt fee will provide you the name of the person delivered to and the date of delivery. For additional fees the following services are available. Consult postmaster for fees and check box(es) for additional service(s) requested.

1. ☒ Show to whom delivered, date, and addressee's address. *(Extra charge)* 2. ☐ Restricted Delivery *(Extra charge)*

3. Article Addressed to:	4. Article Number
Mr. Thomas W. Flachmeyer, Mgr. Environmental Engineering and Waste Management Key Pharmaceuticals, Inc. 50 NW 176th Street Miami, FL 33169	P 794 947 068
	Type of Service: ☐ Registered ☐ Insured ☒ Certified ☐ COD ☐ Express Mail
	Always obtain signature of addressee or agent and DATE DELIVERED.
5. Signature – Addressee X	8. Addressee's Address *(ONLY if requested and fee paid)*
6. Signature – Agent X	
7. Date of Delivery MAY 3 1988	

PS Form **3811**, Mar. 1987 ★ U.S.G.P.O. 1987-178-268 **DOMESTIC RETURN RECEIPT**

P 794 947 068

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED
NOT FOR INTERNATIONAL MAIL
(See Reverse)

Sent to Thomas W. Flachmeyer, Mgr. Environmental Engineering	
Street and No. Key Pharmaceuticals, Inc.	
P.O. State and ZIP Code 50 NW 176th Street Miami, FL 33169	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt showing to whom and Date Delivered	
Return Receipt showing to whom, Date, and Address of Delivery	
TOTAL Postage and Fees	$
Postmark or Date Mailed: 04/29/88 EXT. AC 13-129894	

PS Form 3800, June 1985

Florida Department of Environmental Regulation

Twin Towers Office Bldg. • 2600 Blair Stone Road • Tallahassee, Florida 32399-2400

Bob Martinez, Governor Dale Twachtmann, Secretary John Shearer, Assistant Secretary

April 29, 1988

Mr. Thomas W. Flachmeyer
Manager, Environmental Engineering
and Waste Management
Key Pharmaceuticals, Inc.
50 NW 176th Street
Miami, Florida 33169

Dear Mr. Flachmeyer:

Re: Permits Operate/Construct Air Pollution Sources

The Department has received your March 15, 1988, letters requesting the expiration dates of construction permit Nos. AC 13-129894 (2 Tablet Presses) and AC 13-129897 (1 Granulator & Dryer) be extended to June 30, 1988. The District has informed the Bureau that they are currently processing the applications for permits to operate the 2 Tablet Presses and 1 Granulator & Dryer. As these permits will probably be issued before the Department could grant the requested extensions, the Bureau has chosen not to process your requests. By policy, Key Pharmaceuticals, Inc. can assume they have the timely request for the extension unless it is denied by the Department.

Another policy within the Department is that permits to construct minor sources (less 100 TPY) are processed by the Districts. As Key Pharmenticals, Inc. is currently a minor source, any new permit application should be sent to the Southeast District for processing.

If you have any questions on this matter, please call Willard Hanks at (904)488-1344 or write to me at the Department's Tallahassee address.

Sincerely,

C.H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality
Management

CHF/plm

cc: Stephanie Brooks, SE District

PM
3.17.88
Miami, FL

File Copy

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

March 15, 1988

Mr. W. Hanks
Florida Department of
Environmental Regulation
Twin Tower Office Building
Blair Stone Road
Tallahassee, FL 32301

RE: Permit AC 13-129897

Dear Mr. Hanks:

Key Pharmaceuticals would like to request an extension of the expiration date of the above referenced permit. The requested expiration date is June 30, 1988.

Should you have any questions or comments, please don't hesitate to call me at 305-654-2240.

Sincerely,

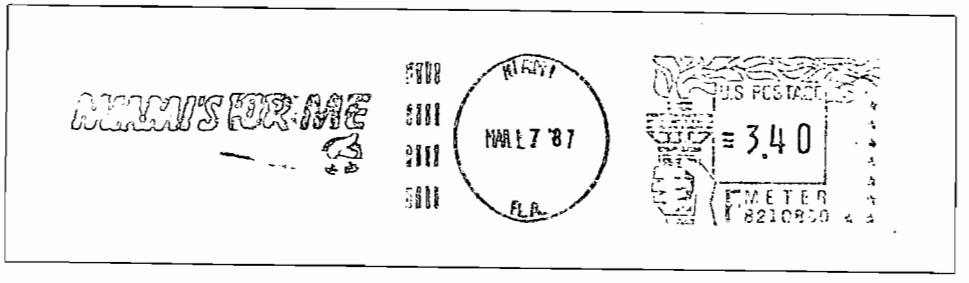
Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

enclosure

cc: Mr. P. Wong (DERM)
Ms. S. Brooks (DER)

Copied: Willard Hanks
CHF/BT
3.22.88 mr



RETURN
TO

FROM
KEY PHARMACEUTICALS, INC.
P.O. BOX 693670 - NORLAND BRANCH
50 N.W. 176 STREET MIAMI, FLORIDA 33169

to

MR. W. HANKS
FLA DEPT OF ENV REG
TWIN TOWER BUILDING
BLAIR STONE ROAD
TALLAHASSEE, FL 32301

FIRST CLASS

CONTENTS: MERCHANDISE - RETURN REQUESTED.
POSTMASTER: This parcel may be opened for inspection if necessary.

CERTIFIED
P 083 539 346
MAIL

PM
3.17.88
Miami, FL

File Copy

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

RECEIVED

MAR 21 1988

DER - BAQM

March 15, 1988

Mr. W. Hanks
Florida Department of
Environmental Regulation
Twin Tower Office Building
Blair Stone Road
Tallahassee, FL 32301

RE: Permit AC 13-129894

Dear Mr. Hanks:

Key Pharmaceuticals would like to request an extension of the expiration date of the above referenced permit. The requested expiration date is June 30, 1988.

Should you have any questions or comments, please don't hesitate to call me at 305-654-2240.

Sincerely,

Thomas W. Flachmeyer

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

enclosure

cc: Mr. P. Wong (DERM)
Ms. S. Brooks (DER)

Copied: Willard Hanks
CHF/BT
} 3.22.88

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

March 15, 1988

Ms. S. Brooks
Florida Department of
Environmental Regulation
Southeast Florida District
3301 Gun Club Road
P.O. Box 3858
West Palm Beach, FL 33402

RE: PERMIT TO OPERATE AC 13-129894

Dear Ms. Brooks:

Enclosed please find the completed application for a "Permit to Operate" two Tablet Presses at Key Pharmaceuticals 50 N.W. 176th Street facility. This permit application differs from that of AC 13-129894 in the fact that separate Torit Dust Collectors were installed for each Tablet Press. This allows for independent operation and material recovery.

I trust you will find this application in order. Should you have any questions, please do not hesitate to call me at 305-654-2240.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

enclosure

cc: Mr. W. Hanks (DER)

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

SOUTHEAST FLORIDA DISTRICT
3301 GUN CLUB ROAD
P.O. BOX 3858
WEST PALM BEACH, FLORIDA 33402

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

ROY DUKE
DISTRICT MANAGER

APPLICATION TO OPERATE/CONSTRUCT AIR POLLUTION SOURCES

SOURCE TYPE: Air Pollution [ ] New[1] [X] Existing[1]

APPLICATION TYPE: [ ] Construction [X] Operation [ ] Modification

COMPANY NAME: Key Pharmaceuticals, Inc. COUNTY: Dade

Identify the specific emission point source(s) addressed in this application (i.e. Lime Kiln No. 4 with Venturi Scrubber; Peaking Unit No. 2, Gas Fired) 2 Tablet Presses

SOURCE LOCATION: Street 50 N.W. 176th Street City Miami

UTM: East 57987 North 7868445

Latitude 25 ° 56 ' 03 "N Longitude 80 ° 11 ' 42 "W

APPLICANT NAME AND TITLE: Thomas W. Flachmeyer, Mgr Environ Engr & Waste Management

APPLICANT ADDRESS: 50 N.W. 176th Street, Miami, FL 33169

SECTION I: STATEMENTS BY APPLICANT AND ENGINEER

A. APPLICANT

I am the undersigned owner or authorized representative* of Key Pharmaceuticals, Inc.

I certify that the statements made in this application for a Operation permit are true, correct and complete to the best of my knowledge and belief. Further, I agree to maintain and operate the pollution control source and pollution control facilities in such a manner as to comply with the provision of Chapter 403, Florida Statutes, and all the rules and regulations of the department and revisions thereof. I also understand that a permit, if granted by the department, will be non-transferable and I will promptly notify the department upon sale or legal transfer of the permitted establishment.

*Attach letter of authorization

Signed: Thomas W. Flachmeyer

Thomas W. Flachmeyer, Manager Environmental Engr & Waste Mgmt

Name and Title (Please Type)

Date: 3/14/88 Telephone No. 305-654-2200

B. PROFESSIONAL ENGINEER REGISTERED IN FLORIDA (where required by Chapter 471, F.S.)

This is to certify that the engineering features of this pollution control project have been designed/examined by me and found to be in conformity with modern engineering principles applicable to the treatment and disposal of pollutants characterized in the permit application. There is reasonable assurance, in my professional judgment, that

[1] See Florida Administrative Code Rule 17-2.100(57) and (104)

* See Note Page 2

I HAVE REVIEWED THE CALCULATIONS USED TO DETERMINE THE STATED LEVELS OF PARTICULATE AND VOC EMISSIONS AND FIND THEM TO BE ACCURATE BASED ON PROJECTED MANUFACTURING LEVELS OF THE PRODUCT.

the pollution control facilities, when properly maintained and operated, will discharge an effluent that complies with all applicable statutes of the State of Florida and the rules and regulations of the department. It is also agreed that the undersigned will furnish, if authorized by the owner, the applicant a set of instructions for the proper maintenance and operation of the pollution control facilities and, if applicable, pollution sources.

Signed John N. Wells, P.E.

John N. Wells, P.E.
Name (Please Type)

Key Pharmaceuticals, Inc.
Company Name (Please Type)

50 N.W. 176th Street, Miami, FL 33169
Mailing Address (Please Type)

Florida Registration No. 33917 **Date:** 3/14/88 **Telephone No.** 305-654-2200

SECTION II: GENERAL PROJECT INFORMATION

A. Describe the nature and extant of the project. Refer to pollution control equipment, and expected improvements in source performance as a result of installation. State whether the project will result in full compliance. Attach additional sheet if necessary.

Tablet presses are utilized during the manufacturing of various solid dose (tablet or capsule) pharmaceutical products. Room dust control and tablet dedusting is provided for tablet press. Due to constraints a loss of product of less than ½ of 1% can only be tolerated.

B. Schedule of project covered in this application (Construction Permit Application Only)

Start of Construction _____ **Completion of Construction** _____

C. Costs of pollution control system(s): (Note: Show breakdown of estimated costs only for individual components/units of the project serving pollution control purposes. Information on actual costs shall be furnished with the application for operation permit.)

$50,000.00

D. Indicate any previous DER permits, orders and notices associated with the emission point, including permit issuance and expiration dates.

(1) Consent Order No. 83-0373 (Closed)

(2) Permit to Construct for mfg GUANIDINE & QUINORA AC 13-115383

(3) Permit to Construct for mfg K-DUR AC 13-100437

E. Requested permitted equipment operating time: hrs/day 24 ; days/wk 7 ; wks/yr 52 ;

if power plant, hrs/yr_____; if seasonal, describe:_____

F. If this is a new source or major modification, answer the following questions. (Yes or No)

1. Is this source in a non-attainment area for a particular pollutant?	YES
a. If yes, has "offset" been applied?	NO
b. If yes, has "Lowest Achievable Emission Rate" been applied?	NO
c. If yes, list non-attainment pollutants.	OZONE
2. Does best available control technology (BACT) apply to this source? If yes, see Section VI.	NO
3. Does the State "Prevention of Significant Deterioration" (PSD) requirement apply to this source? If yes, see Sections VI and VII.	NO
4. Do "Standards of Performance for New Stationary Sources" (NSPS) apply to this source?	NO
5. Do "National Emission Standards for Hazardous Air Pollutants" (NESHAP) apply to this source?	NO
H. Do "Reasonably Available Control Technology" (RACT) requirements apply to this source?	NO

a. If yes, for what pollutants?_____

b. If yes, in addition to the information required in this form, any information requested in Rule 17-2.650 must be submitted.

Attach all supportive information related to any answer of "Yes". Attach any justification for any answer of "No" that might be considered questionable.

SECTION III: AIR POLLUTION SOURCES & CONTROL DEVICES (Other than Incinerators)

A. Raw Materials and Chemicals Used in your Process, if applicable:

Description	Contaminants		Utilization Rate - lbs/hr	Relate to Flow Diagram
	Type	% Wt		
solids	particulate	100	238 per unit	"A"

B. Process Rate, if applicable: (See Section V, Item 1)

1. Total Process Input Rate (lbs/hr): 238 lb/hr

2. Product Weight (lbs/hr): 238 lb/hr

C. Airborne Contaminants Emitted: (Information in this table must be submitted for each emission point, use additional sheets as necessary)

Name of Contaminant	Emission[1]		Allowed[2] Emission Rate per Rule 17-2	Allowable[3] Emission lbs/hr	Potential[4] Emission		Relate to Flow Diagram
	Maximum lbs/hr	Actual T/yr			lbs/yr	T/yr	
particulate	0.025	0.1	N/A	N/A		10.8	"A"

[1]See Section V, Item 2.

[2]Reference applicable emission standards and units (e.g. Rule 17-2.600(5)(b)2. Table II, E. (1) - 0.1 pounds per million BTU heat input)

[3]Calculated from operating rate and applicable standard.

[4]Emission, if source operated without control (See Section V, Item 3).

D. Control Devices: (See Section V, Item 4)

Name and Type (Model & Serial No.)	Contaminant	Efficiency	Range of Particles Size Collected (in microns) (If applicable)	Basis for Efficiency (Section V Item 5)
Torit Dust Collector	particulate	99%	2 micron or larger	supplier's design

E. Fuels

Type (Be Specific)	Consumption*		Maximum Heat Input (MMBTU/hr)
	avg/hr	max./hr	

*Units: Natural Gas--MMCF/hr; Fuel Oils--gallons/hr; Coal, wood, refuse, other--lbs/hr.

Fuel Analysis:

Percent Sulfur: _____ Percent Ash: _____

Density: _____ lbs/gal Typical Percent Nitrogen: _____

Heat Capacity: _____ BTU/lb _____ BTU/gal

Other Fuel Contaminants (which may cause air pollution): _____

F. If applicable, indicate the percent of fuel used for space heating.

Annual Average _____ Maximum _____

G. Indicate liquid or solid wastes generated and method of disposal.

10.8 tons per year of solids are collected in approximately 60 drums. All solid waste is disposed of off-site at an approved facility.

H. Emission Stack Geometry and Flow Characteristics (Provide data for each stack):

Stack Height: OFF ROOF 11 ft. Stack Diameter: 12" x 12" ft.

Gas Flow Rate: 4000 ACFM _____ DSCFM Gas Exit Temperature: 70 °F.

Water Vapor Content: 50-60% % Velocity: 67 FPS

SECTION IV: INCINERATOR INFORMATION

Type of Waste	Type 0 (Plastics)	Type I (Rubbish)	Type II (Refuse)	Type III (Garbage)	Type IV (Pathological)	Type V (Liq.& Gas By-prod.)	Type VI (Solid By-prod.)
Actual lb/hr Incinerated							
Uncontrolled (lbs/hr)							

Description of Waste _____

Total Weight Incinerated (lbs/hr) _____ Design Capacity (lbs/hr) _____

Approximate Number of Hours of Operation per day _____ day/wk _____ wks/yr. _____

Manufacturer _____

Date Constructed _____ Model No. _____

	Volume $(ft)^3$	Heat Release (BTU/hr)	Fuel		Temperature (°F)
			Type	BTU/hr	
Primary Chamber					
Secondary Chamber					

Stack Height: _____ ft. Stack Diameter: _____ Stack Temp. _____

Gas Flow Rate: _____ ACFM _____ DSCFM* Velocity: _____ FPS

*If 50 or more tons per day design capacity, submit the emissions rate in grains per standard cubic foot dry gas corrected to 50% excess air.

Type of pollution control device: [ ] Cyclone [ ] Wet Scrubber [ ] Afterburner

[ ] Other (specify) _____

Brief description of operating characteristics of control devices: _____

_____

_____

_____

_____

Ultimate disposal of any effluent other than that emitted from the stack (scrubber water, ash, etc.):

_____

_____

_____

_____

NOTE: Items 2, 3, 4, 6, 7, 8, and 10 in Section V must be included where applicable.

SECTION V: SUPPLEMENTAL REQUIREMENTS

Please provide the following supplements where required for this application.

1. Total process input rate and product weight -- show derivation [Rule 17-2.100(127)]

2. To a construction application, attach basis of emission estimate (e.g., design calculations, design drawings, pertinent manufacturer's test data, etc.) and attach proposed methods (e.g., FR Part 60 Methods 1, 2, 3, 4, 5) to show proof of compliance with applicable standards. To an operation application, attach test results or methods used to show proof of compliance. Information provided when applying for an operation permit from a construction permit shall be indicative of the time at which the test was made.

3. Attach basis of potential discharge (e.g., emission factor, that is, AP42 test).

4. With construction permit application, include design details for all air pollution control systems (e.g., for baghouse include cloth to air ratio; for scrubber include cross-section sketch, design pressure drop, etc.)

5. With construction permit application, attach derivation of control device(s) efficiency. Include test or design data. Items 2, 3 and 5 should be consistent: actual emissions = potential (1-efficiency).

6. An 8 1/2" x 11" flow diagram which will, without revealing trade secrets, identify the individual operations and/or processes. Indicate where raw materials enter, where solid and liquid waste exit, where gaseous emissions and/or airborne particles are evolved and where finished products are obtained.

7. An 8 1/2" x 11" plot plan showing the location of the establishment, and points of airborne emissions, in relation to the surrounding area, residences and other permanent structures and roadways (Example: Copy of relevant portion of USGS topographic map).

8. An 8 1/2" x 11" plot plan of facility showing the location of manufacturing processes and outlets for airborne emissions. Relate all flows to the flow diagram.

9. The appropriate application fee in accordance with Rule 17-4.05. The check should be made payable to the Department of Environmental Regulation.

10. With an application for operation permit, attach a Certificate of Completion of Construction indicating that the source was constructed as shown in the construction permit.

SECTION VI: BEST AVAILABLE CONTROL TECHNOLOGY

A. Are standards of performance for new stationary sources pursuant to 40 C.F.R. Part 60 applicable to the source?

[ ] Yes [ ] No

Contaminant	Rate or Concentration

B. Has EPA declared the best available control technology for this class of sources (If yes, attach copy)

[ ] Yes [ ] No

Contaminant	Rate or Concentration

C. What emission levels do you propose as best available control technology?

Contaminant	Rate or Concentration

D. Describe the existing control and treatment technology (if any).

1. Control Device/System:
2. Operating Principles:
3. Efficiency:*
4. Capital Costs:

*Explain method of determining

5. Useful Life:

6. Operating Costs:

7. Energy:

8. Maintenance Cost:

9. Emissions:

Contaminant	Rate or Concentration

10. Stack Parameters

a. Height: ft.

b. Diameter: ft.

c. Flow Rate: ACFM

d. Temperature: °F.

e. Velocity: FPS

E. Describe the control and treatment technology available (As many types as applicable, use additional pages if necessary).

1.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

2.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

3.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

4.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Costs:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

F. Describe the control technology selected:

1. Control Device:

2. Efficiency:[1]

3. Capital Cost:

4. Useful Life:

5. Operating Cost:

6. Energy:[2]

7. Maintenance Cost:

8. Manufacturer:

9. Other locations where employed on similar processes:

a. (1) Company:

(2) Mailing Address:

(3) City:

(4) State:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

b. (1) Company:

(2) Mailing Address:

(3) City: (4) State:

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

10. Reason for selection and description of systems:

[1]Applicant must provide this information when available. Should this information not be available, applicant must state the reason(s) why.

SECTION VII - PREVENTION OF SIGNIFICANT DETERIORATION

A. Company Monitored Data

1. _____no. sites _____ TSP _____( ) SO^{2}* _____ Wind spd/dir

Period of Monitoring _____/_____/_____ to _____/_____/_____
month day year month day year

Other data recorded _____

Attach all data or statistical summaries to this application.

*Specify bubbler (B) or continuous (C).

2. Instrumentation, Field and Laboratory

a. Was instrumentation EPA referenced or its equivalent? [ ] Yes [ ] No

b. Was instrumentation calibrated in accordance with Department procedures?

[ ] Yes [ ] No [ ] Unknown

B. Meteorological Data Used for Air Quality Modeling

1. _____ Year(s) of data from _____/_____/_____ to _____/_____/_____
month day year month day year

2. Surface data obtained from (location)_____

3. Upper air (mixing height) data obtained from (location)_____

4. Stability wind rose (STAR) data obtained from (location)_____

C. Computer Models Used

1. _____ Modified? If yes, attach description.

2. _____ Modified? If yes, attach description.

3. _____ Modified? If yes, attach description.

4. _____ Modified? If yes, attach description.

Attach copies of all final model runs showing input data, receptor locations, and principle output tables.

D. Applicants Maximum Allowable Emission Data

Pollutant	Emission Rate	
TSP	_____	grams/sec
SO^2	_____	grams/sec

E. Emission Data Used in Modeling

Attach list of emission sources. Emission data required is source name, description of point source (on NEDS point number), UTM coordinates, stack data, allowable emissions, and normal operating time.

F. Attach all other information supportive to the PSD review.

G. Discuss the social and economic impact of the selected technology versus other applicable technologies (i.e., jobs, payroll, production, taxes, energy, etc.). Include assessment of the environmental impact of the sources.

H. Attach scientific, engineering, and technical material, reports, publications, journals, and other competent relevant information describing the theory and application of the requested best available control technology.

CHARGE Granulation - Solvents DATE 1-19-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 1 of 1 FILE NO. _____

SUBJECT Emission Calculation for Solvent Granulation

Basis:

Machine maximum capacity for solvent granulations - 300 kg

1 Granulation machine

lot cycle is 24 Hrs including drying

Lot Specification

300 kg Solids

75 kg IPA or 3A Alcohol

Maximum thruput 120.7 Tons/year solids
30.2 Tons/year VOC

Emissions

VOC - Emission Potential 30.2 T/y

No emission control

Annual Emissions 30.2 T/y

6.9 lb/Hr

Solids - Emission Potential (½ of 1% of Solids) 0.6 T/y

Dust Collector Design - 99% removal efficiency

Annual Emissions 0.006 T/y

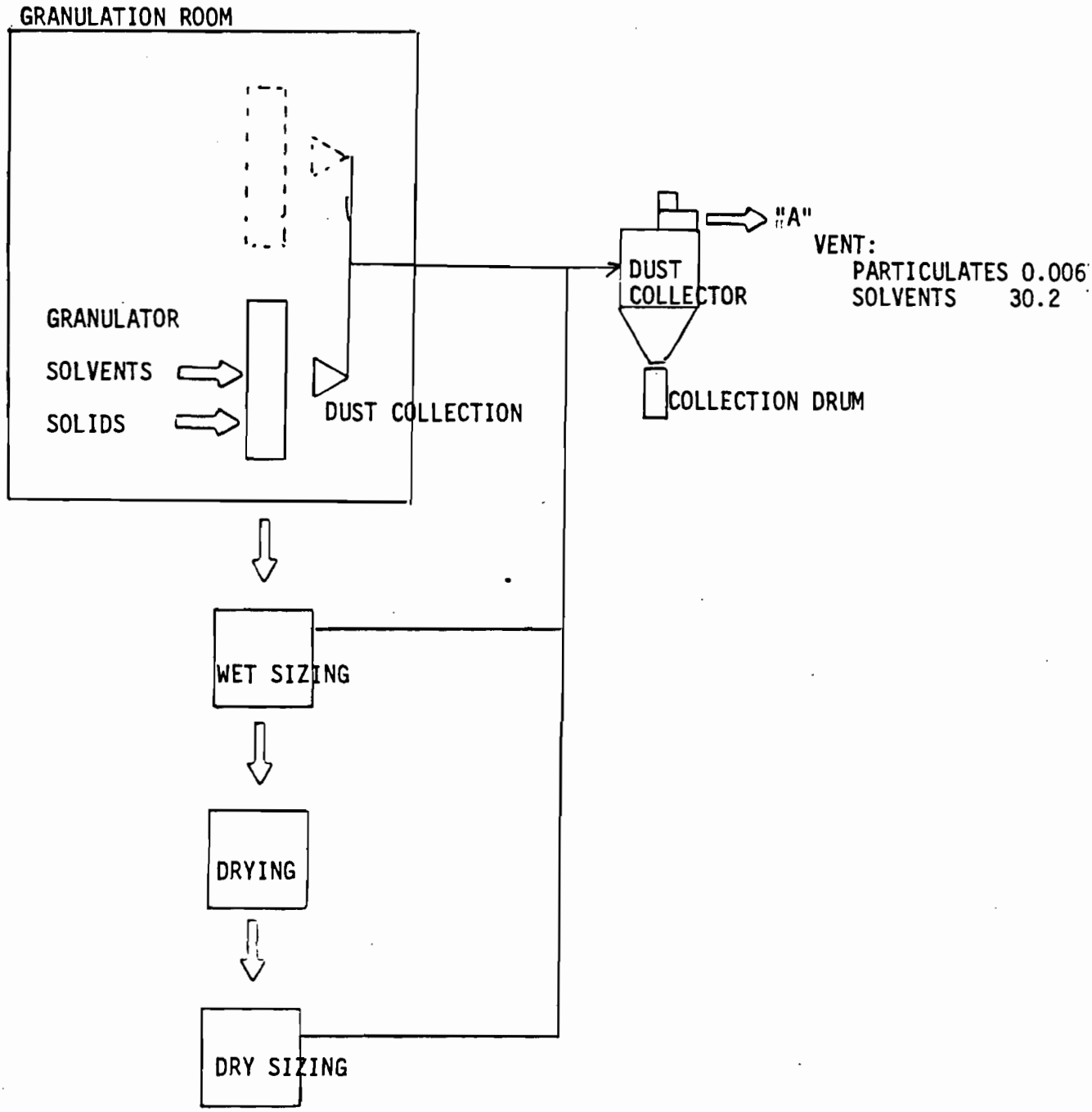
0.001 lb/Hr

C-7209 (10-76)

CHARGE Solvent Granulation DATE 1-18-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 1 of 1 FILE NO. _____

SUBJECT Process Flow - Solvent Granulation



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200
Telex: 808235

C E R T I F I C A T E

To Whom It May Concern:

This is to certify that Robert A. Franke, Director of Engineering of Key Pharmaceuticals, Inc., is duly authorized to represent Key Pharmaceuticals, Inc., along with his designate, Thomas W. Flachmeyer, Manager Environmental Engineering and Waste Management; for the purpose of making Application for Permit to Construct or Operate Pollution Control Facilities for said company.

Key Pharmaceuticals, Inc.

Charles V. Flemming,
Senior Vice President Schering
Technical Operations

CVF/db

STATE OF FLORIDA
COUNTY OF DADE

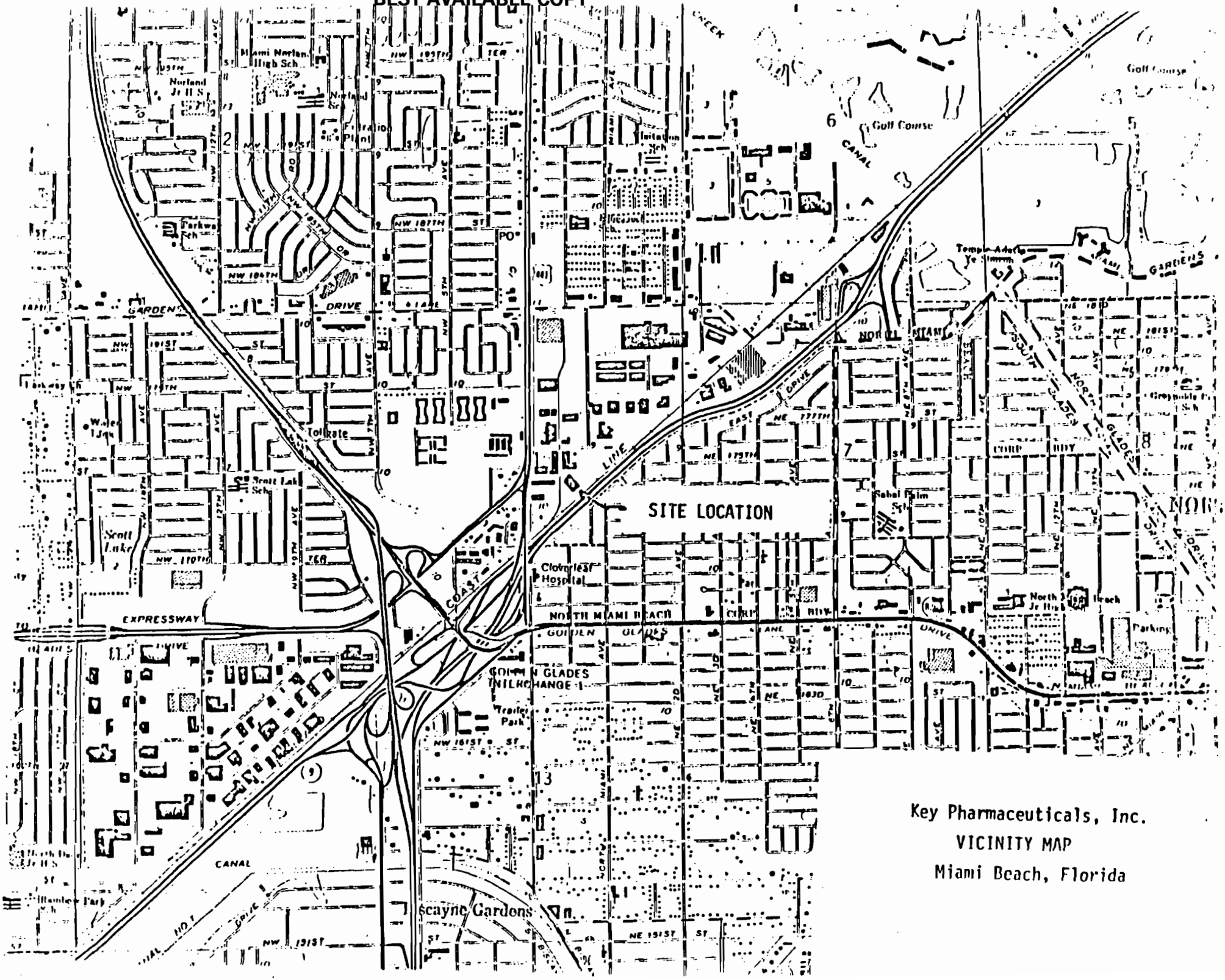
Sworn to and subscribed before me
this 27th day of January A.D. 1988.

NOTARY PUBLIC
STATE OF FLORIDA

My commission expires:

NOTARY PUBLIC STATE OF FLORIDA
MY COMMISSION EXP. APR 17,1988
BONDED THRU GENERAL INS. UND.

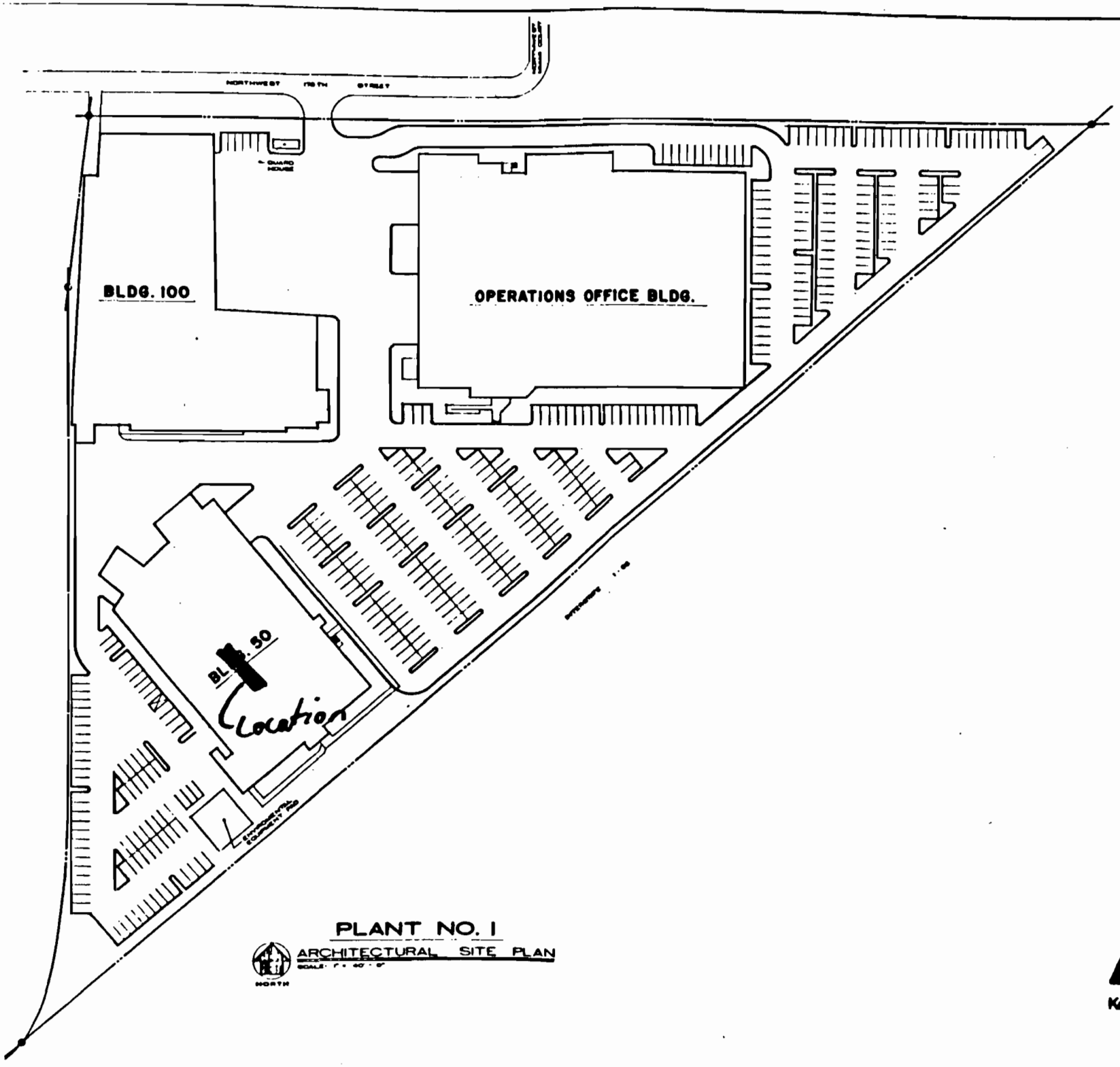
BEST AVAILABLE COPY



Key Pharmaceuticals, Inc.

VICINITY MAP

Miami Beach, Florida

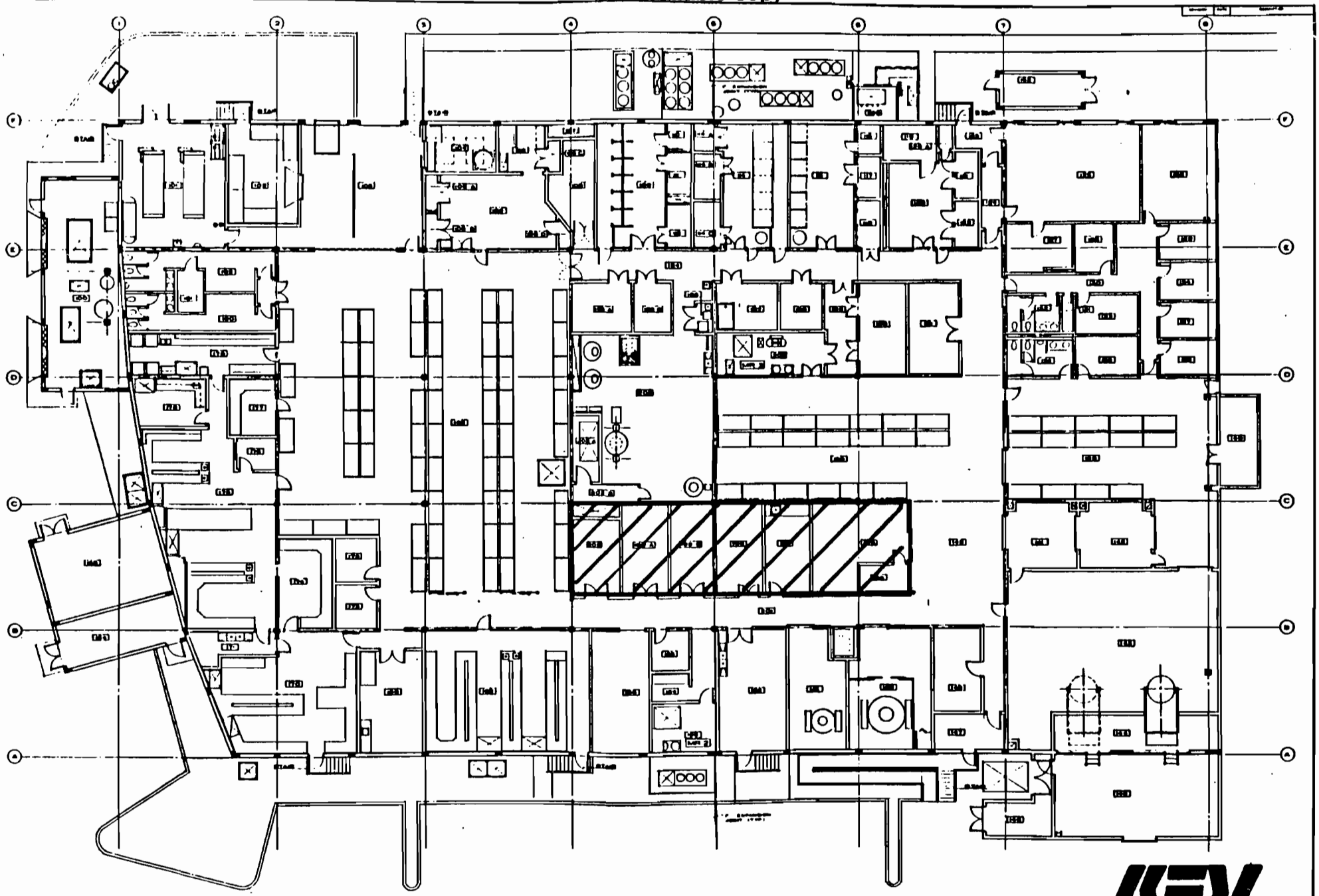


PLANT NO. 1

ARCHITECTURAL SITE PLAN

Key Pharmaceuticals, Inc.

Best Available Copy

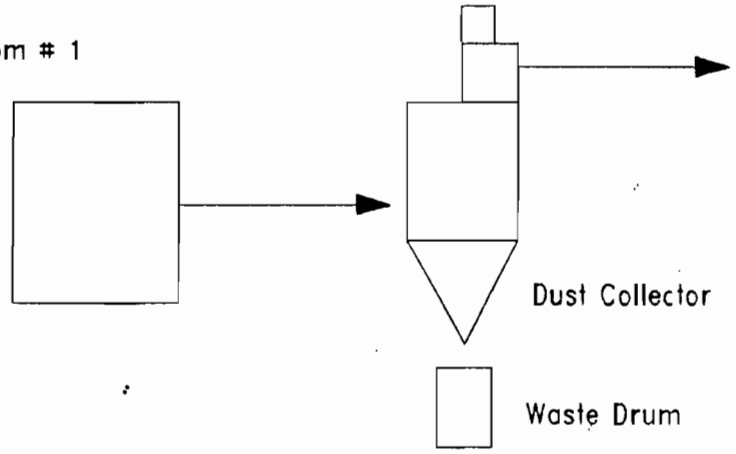


BUILDING 50 FLOOR PLAN

Key Pharmaceuticals, Inc.

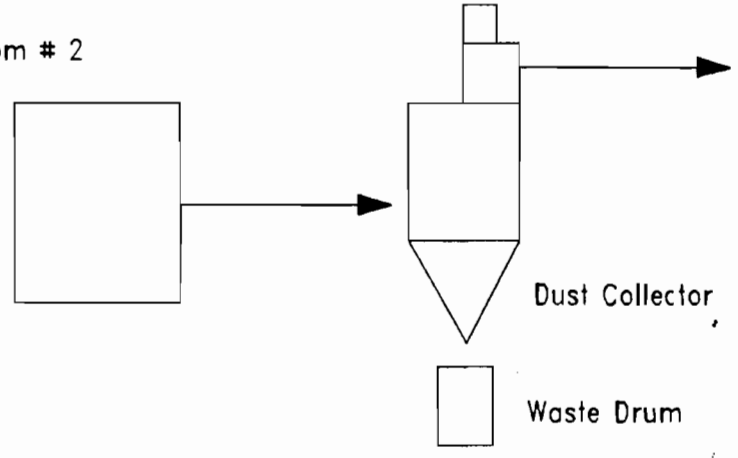
Tablet Press

Room # 1



Tablet Press

Room # 2



Basis:

Press maximum capacity = 1,500 Tablets per minute

Maximum Tablet Weight = 1.2 grams

Machine capacity = 1,500*1.2*0.002205*60

=238 lbs/hrs

Maximum allowable loss is 1/2 of 1% of capacity

Maximum emission potential = 2*238*0.005

=2.38 lbs/hr

Dust collector efficiency is 99%

Annual emissions = 2.38*0.01*8760/2000

= 0.10 T/Y

or

= 2.38*0.01

= 0.024 lbs/hr

ENVIROPACT

March 2, 1988

Mr. Eric Borbe
Schering Laboratories
50 N.W. 176 St.
Miami, FL 33169

RE: Enviropact Number 1173-0011

Dear Mr. Borbe:

Enviropact Services, Inc. is pleased to submit the following report of findings from the February 5, 1988 Visible Emission Test at the Key Pharmaceutical facility located at 50 N.W. 176 Street, Miami, Florida.

BACKGROUND

On February 5, 1988, a Visible Emission Test was conducted by our subcontractor BKJ Services, Inc. at the Key Pharmaceutical facility located at 50 N.W. 176 Street, Miami, Florida on the dust collector serving the Tablet Press Unit (D.E.R. permit number: AC 13-129894). The purpose of our investigation was to determine if any airborne pollutants or contaminants were being generated during the ~~granulation~~ tablet Press process.

ANALYSIS AND RESULTS

The visible emission evaluation was determined following the procedures recommended by the Department of Environmental Regulation State of Florida (E.P.A. Reference Method 9). The maximum and minimum opacity reading during the visible emission evaluation was zero opacity, which is below the limits set in your Department of Environmental Regulation permit.

SUMMARY AND RECOMMENDATION

Based on the data of the Visible Emission Test performed by Enviropact Services, Inc., the evaluation indicates no violations of applicable visible emission standards of testing.

ENVIROPACT SERVICES, INC.
MIAMI DIVISION
4790 N.W. 157th STREET
MIAMI, FL 33014-6421
305-620-1700

If you have any questions, please no not hesitate to contact me at your convenience (305)620-1700.

Sincerely,

Peggie Moore for . . .

Anthony Parrish
Visible Emission Technician
ENVIROPACT SERVICES, INC.

AT/GCA

AT/GCA/LETTER 1

EVP.

VISIBLE EMISSION OBSERVATION FORM

No. 0002

COMPANY NAME: Schering - Plough		
STREET ADDRESS: 50 NW 176 St. Bldg. 50		
CITY: Miami	STATE: Fla.	ZIP: 33169
PHONE (KEY CONTACT): 305-654-2432	SOURCE ID NUMBER: AC13-129894	

PROCESS EQUIPMENT: Tablet Press	OPERATING MODE: 100 %
CONTROL EQUIPMENT: Torit Dust Collector	OPERATING MODE: 100 %

DESCRIBE EMISSION POINT: 12" x 12" Vertical Metal Opening w/ Flapper Valve

HEIGHT ABOVE GROUND LEVEL: 33'	HEIGHT RELATIVE TO OBSERVER: Start 7' End Same
DISTANCE FROM OBSERVER: Start 20' End Same	DIRECTION FROM OBSERVER: Start SSW End SAME

DESCRIBE EMISSIONS: Start None Visible End Same

EMISSION COLOR: Start None End Same	IF WATER DROPLET PLUME: Attached ☐ N/A Detached ☐

POINT IN THE PLUME AT WHICH OPACITY WAS DETERMINED: Start 1' from Opening End Same

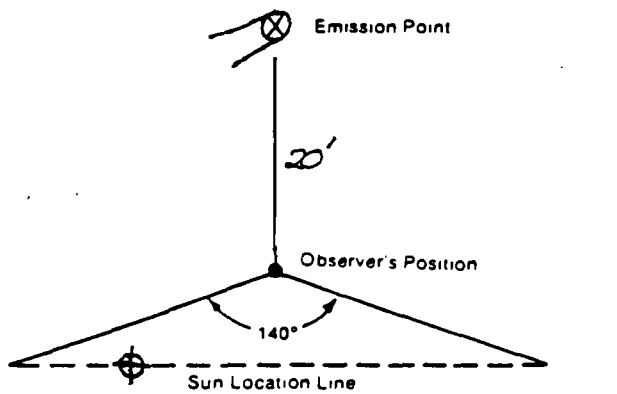
DESCRIBE PLUME BACKGROUND: Start Open Sky End Same

BACKGROUND COLOR: Start Blue End Blue	SKY CONDITIONS: Start 60% Cld End 30% Cld.	
WIND SPEED: Start 3-5 End 3-5	WIND DIRECTION: Start West End S.East ~~S.East~~	
AMBIENT TEMP: Start 75°F End Same	WET BULB TEMP: 60°F	RH, percent: 60%

Stack with Plume ⊂
Sun ⊕
Wind →

SOURCE LAYOUT SKETCH

Draw North Arrow



ADDITIONAL INFORMATION

OBSERVATION DATE	START TIME	END TIME
2/5/88	10:38	11:08

SEC / MIN	0	15	30	45	COMMENTS
1	0	0	0	0	Clear
2	0	0	0	0	
3	0	0	0	0	
4	0	0	0	0	
5	0	0	0	0	
6	0	0	0	0	
7	0	0	0	0	
8	0	0	0	0	
9	0	0	0	0	
10	0	0	0	0	Cloud in Background
11	0	0	0	0	
12	0	0	0	0	
13	0	0	0	0	Clear
14	0	0	0	0	
15	0	0	0	0	
16	0	0	0	0	
17	0	0	0	0	
18	0	0	0	0	
19	0	0	0	0	
20	0	0	0	0	
21	0	0	0	0	
22	0	0	0	0	
23	0	0	0	0	
24	0	0	0	0	
25	0	0	0	0	Cloud
26	0	0	0	0	
27	0	0	0	0	
28	0	0	0	0	Clear
29	0	0	0	0	
30	0	0	0	0	

OBSERVER'S NAME (PRINT): James N. Krakoski	
OBSERVER'S SIGNATURE: James N. Krakoski	DATE: 2/5/88
ORGANIZATION: BKJ Services, Inc.	
CERTIFIED BY: Eastern Technical Associates	DATE: 1/20/88

CONTINUED ON VEO FORM NUMBER

VISIBLE EMISSIONS EVALUATOR

This is to certify that

Anthony Parrish

met the specifications of Federal Reference Method 9 and qualified as a visible emissions evaluator. Maximum deviation on white and black smoke did not exceed 7.5% opacity and no single error exceeding 15% opacity was incurred during the certification test conducted by Eastern Technical Associates of Raleigh, North Carolina. This certificate is valid for six months from date of issue.

Thomas G. Rose	218461
President	Certificate Number
Willie S. Lee	Orlando
Vice President	Location
David Savage	September 8, 1987
Program Manager	Date of Issue

IOEB 445 LITHO. IN U.S.A.

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

March 15, 1988

Ms. S. Brooks
Florida Department of
Environmental Regulation
Southeast Florida District
3301 Gun Club Road
P.O. Box 3858
West Palm Beach, FL 33402

RE: Key Pharmaceuticals 1987 VOC Emissions

Dear Ms. Brooks:

In the past year Key Pharmaceuticals has re-permitted all of the production equipment located at the 50 NW 176th Street facility. This re-permitting was done to reflect actual emission potential of the process equipment rather than permitting each product manufactured.

The data presented in ATTACHMENT I reflects Key Pharmaceuticals understanding of the current permitting situation. As indicated by the table all production equipment is currently covered under construction permits. For your information ATTACHMENT II indicates the actual production and VOC emissions of the equipment that is authorized to utilize solvents. The emissions were calculated from batch records which are required by the Food and Drug Administration for all manufacturing at this site.

Should you have any questions or comments please don't hesitate to call me at 305-654-2240.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

attachments

cc: Mr. W.Hanks (DER)
Mr. P.Wong (DERM)

ATTACHMENT I

Key Pharmaceuticals Inc

Permit status

Expired Permits

Permit #	Permit Status	Equipment	Product
AC 13-129893	Superceded	CA/SolRec 4 Glatts	K-Dur
		2 Accela Cotas	Unk
AC 13-100437	Expired	3 Glatts	K-Dur
AC 13-115383	Superceded AO 13-129420	Granulation	Guanidine & Quinora
AO 13-114316	Ex.3-31-92	Scrubber 3 Glatts	K-Dur
AO 13-129470	Ex.3-31-92	Granulation 1 Granulator	Guanidine
AC 13-128475	Ex.12-31-87	Pan Coating	Guanidine & Quinora
AC 13-129895	Ex.12-31-87	Tablet Presses 3 & 4	unk

1987 Active Permits

Permit #	Permit Status	Equipment	Product	# of Lots	Product Content (lbs) Solids	VOC	Halogenated	% Loading to System	%RE	Allowable Emission Rate (T/Y) Solids	VOC	Halogenated
AC 13-129899	Ex. 1-1-89	CA/SolRec 4 Glatts	K-Dur	461 WSG	665.03			0.50%	99%	0.00766		
						199.99		100.00%	90%		4.61	
							2139.95	100.00%	90%			49.33
				2388 GPGC	665.03			0.50%	99%	0.03970		
						199.99		100.00%	90%		23.88	
							2139.95	100.00%	90%			255.51
		6 Coating Pans	Theo-Dur 100	160	191.09			0.50%	80%	0.01529		
		Ex. 7-1-88				150.69		100.00%	0%		12.06	
								100.00%	0%			
		6 Coating Pans		2190	246.96			0.50%	99%	0.01352		
						88.20		100.00%	90%		9.66	
	Total									0.07617	50.20	304.84
AC 13-129897	Ex. 4-30-88	Granulation 2 Granulators	unk	700	992.25			0.50%	99%	0.01736		
	Ext. req. 6-30-88			(350)		165.38		100.00%	0%		28.94	
	Total									0.01736	28.94	0.00
AC 13-129891	Ex. 10-1-88	Scrubber 3 Glatts	K-Dur	461 WSG	665.03			0.50%	99%	0.00766		
						199.99		100.00%	90%		4.61	
							2139.95	100.00%	0%			493.26
				1592 GPGC	665.03			0.50%	99%	0.02647		
						199.99		100.00%	90%		15.92	
							2139.95	100.00%	0%			1703.40
	Total									0.03413	20.53	2196.66
AC 13-129894	Ex. 4-30-88	Tablet Presses 1 & 2	unk	17520	238.00			0.50%	99%	0.10424		
	Ext. req. 6-30-88											

ATTACHMENT II

Key Pharmaceuticals, Inc.

Annual Operation for 1987

Date Created 26-Feb-1988

Date Printed 15-Mar-88

Production from Glatts (AC 13-129891)

Lots Manufactured

Solvent Ratio	80:20	90:10
Glatt # 1	108	0
Glatt # 2	66	20
Glatt # 3	6	19

Solvent composition of lots in Kgs

	80 : 20		90 : 10	
	MECL2	MEOH	MECL2	MEOH
Glatt # 1	914	183	NA	NA
Glatt # 2	914	183	1003	94
Glatt # 3	914	183	1003	94

Annual Solvent Consumption

Methylene Chloride	449019.59 lbs	224.51 Tons
Methanol	80716.23 lbs	40.36 Tons

VOC Emission For 1987

Methylene Chloride	Average Hourly	51.26 lbs/hr
Methanol (90% control)	Average Hourly	0.92 lbs/hr
Methylene Chloride	Annual	224.51 Tons
Methanol (90% control)	Annual	4.04 Tons

Production from Coating Pans (AC 13-129899)

Lots Manufactured	96	lots
Solvent contend per lot	150.69	lbs
Annual Solvent Consumption	14,466.24	lbs
VOC Emission	1.65	lbs/hr average
	7.23	Tons per Year

Production from Granulation (AC 13-129897)

Product A		
Lots Manufactured	6	lots
Solvent contend per lot	77.00	lbs
Annual Solvent Consumption	462.00	lbs
Product B		
Lots Manufactured	3	lots
Solvent contend per lot	160.00	lbs
Annual Solvent Consumption	480.00	lbs
VOC Emission	0.11	lbs/hr average
	0.47	Tons per Year

P 274 007 429

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED
NOT FOR INTERNATIONAL MAIL
(See Reverse)

Sent to James R. Confroy ~~Key Pharmaceuticals, Inc.~~	
Street and No. 50 Northeast 176th Street	
P.O., State and ZIP Code Miami, FL 33169	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt showing to whom and Date Delivered	
Return Receipt showing to whom, Date, and Address of Delivery	
TOTAL Postage and Fees	$
Postmark or Date Mailed: 12/1/87 Permits: AC 13-129894 13-129897	

PS Form 3800, June 1985 ★ U.S.G.P.O. 1985-480-794

PS Form 3811, July 1983 447-845 DOMESTIC RETURN RECEIPT

SENDER: Complete items 1, 2, 3 and 4.

Put your address in the "RETURN TO" space on the reverse side. Failure to do this will prevent this card from being returned to you. The return receipt fee will provide you the name of the person delivered to and the date of delivery. For additional fees the following services are available. Consult postmaster for fees and check box(es) for service(s) requested.

1. ☒ Show to whom, date and address of delivery.
2. ☐ Restricted Delivery.

3. Article Addressed to: James R. Confroy
Vice President of Operations
Key Pharmaceuticals, Inc.
50 Northeast 176th Street
Miami, FL 33169

4. Type of Service:	Article Number
☐ Registered ☐ Insured ☒ Certified ☐ COD ☐ Express Mail	P 274 007 429

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature – Addressee
X

6. Signature – Agent
X

7. Date of Delivery

8. Addressee's Address *(ONLY if requested and fee paid)*

File

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

November 20, 1987

Certified Mail - Return Receipt Requested

Mr. James R. Confroy
Vice President of Operations
Key Pharmaceuticals, Inc.
50 Northeast 176th Street
Miami, Florida 33169

Dear Mr. Confroy:

Re: Amendment of Permits
AC 13-129894, Tablet Press Rooms Numbers 1 and 2
AC 13-129897, Granulation Process

The Department is in receipt of two letters dated October 26, 1987, from Thomas Flachmeyer, Manager Environmental Engineering and Waste Management, requesting the expiration dates of the two referenced permits be extended to allow additional time to test the emissions, prepare the test reports, and submit the applications for permits to operate the sources.

Permit No. AC 13-129894 expires on December 31, 1987. Permit No. AC 13-129897 expires on January 1, 1988. The requests for extensions are acceptable and the expiration dates of the referenced construction permits are extended to April 30, 1988.

A copy of this letter must be attached to each of the referenced construction permits and shall become a part of each permit.

Attachments to be Incorporated:

Key Pharmaceuticals, Inc. letter dated October 26, 1987;
Re: Permit No. AC 13-129894

Key Pharmaceuticals, Inc. letter dated October 26, 1987;
Re: AC 13-129897

Sincerely,

Dale Twachtmann
Secretary

DT/jp

cc: Isidore Goldman
Pat Wong

State of Florida
DEPARTMENT OF ENVIRONMENTAL REGULATION

Interoffice Memorandum

For Routing To Other Than The Addressee	
To:	Location:
To:	Location:
To:	Location:
From:	Date:

TO: Dale Twachtmann

THROUGH: Howard L. Rhodes

FROM: Clair Fancy

DATE: November 20, 1987

SUBJECT: Amendment of Construction Permits

Attached for your approval and signature is a letter that will extend the expiration dates of two construction permits issued to Key Pharmaceuticals, Inc. The extensions will allow additional time for the applicant to conduct the compliance tests, prepare the test reports, and submit the applications for permits to operate. These extensions are not controversial. The Bureau recommends the extensions be approved.

CF/jp

Attachment

RECEIVED
NOV 24 1987
Office of the Secretary

DER
NOV 30 1987
BAQM

Hand Delivered Full Copy

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

October 26, 1987

Mr. C.H.Fancy, P.E., Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: Permit No. AC 13-129897

Dear Mr. Fancy:

Key Pharmaceuticals, Inc. would like to request an extension to the expiration date of the subject permit. The equipment is operational, but due to low product demand, emission testing (visible emission Method 9) could not be scheduled. Therefore, we request that the permit expiration data be extended to April 30, 1988.

Should you have any questions or comments please don't hesitate to call me at (305) 654-2240.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

I. Goldman - WPB
P. Wong - Dade - DERM
W Hand Hand
B. Thomas ICHP

Copies furnished by company per WH 10/27/87

DER

OCT 27 1987

BAQM

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

October 26, 1987

Mr. C.H.Fancy, P.E., Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: Permit No. AC 13-129894

Dear Mr. Fancy:

Key Pharmaceuticals, Inc. would like to request an extension to the expiration date of the subject permit. The equipment is operational, but due to low product demand, emission testing (visible emission Method 9) could not be scheduled. Therefore, we request that the permit expiration data be extended to April 30, 1988.

Should you have any questions or comments please don't hesitate to call me at (305) 654-2240.

Sincerely,

Thomas W Flachmeyer

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

I. Goldman - WPB
P. Wong - Miami - DERM
Willard Hanks
B. Thomas/CH Fancy

Copies furnished by company pd w H/10/29/87

DER
OCT 27 1987
BAQM

DER
OCT 27 1987
BAQM

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

October 26, 1987

Mr. C.H.Fancy, P.E., Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: Permit No. AC 13-128475 and AC 13-129895

Dear Mr. Fancy:

This letter is to inform your department that Key Pharmaceuticals, Inc. intends to let the above referenced permits expire without requesting an operating permit. This action is due to a lack in production capacity demand.

Should you have any questions or comments please don't hesitate to call me at (305) 654-2240.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

I. Goldman - WPB
P. Wong - Miami - DERM
Willard Hanks
B. Thomas / C.H. Fancy

Copies furnished by company per WH 10/27/87 mg

DER
OCT 27 1987
BAQM

P 408 531 216

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to James R. Confroy	
Street and No. Key Pharmaceuticals, Inc. 50 N.W. 176th Street	
P.O., State and ZIP Code Miami, FL 33169	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt Showing to whom and Date Delivered	
Return Receipt Showing to whom, Date, and Address of Delivery	
TOTAL Postage and Fees	$
Postmark or Date 5/21/87 AC 13-129891, -93, -94, -95, & -97	

PS Form 3800, Feb. 1982

PS Form 3811, July 1983 447-845

SENDER: Complete items 1, 2, 3 and 4.

Put your address in the "RETURN TO" space on the reverse side. Failure to do this will prevent this card from being returned to you. The return receipt fee will provide you the name of the person delivered to and the date of delivery. For additional fees the following services are available. Consult postmaster for fees and check box(es) for service(s) requested.

1. ☒ Show to whom, date and address of delivery.
2. ☐ Restricted Delivery.

3. Article Addressed to:

James R. Confroy
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169

4. Type of Service:	Article Number
☐ Registered ☐ Insured ☒ Certified ☐ COD ☐ Express Mail	P 408 531 216

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature – Addressee
X

6. Signature – Agent
X

7. Date of Delivery

8. Addressee's Address *(ONLY if requested and fee paid)*

DOMESTIC RETURN RECEIPT

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION
NOTICE OF PERMITS

Mr. James R. Confroy
Vice President of Operations
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169

May 21, 1987

Enclosed are construction permits Nos. AC 13-129891, -129893, -129894, -129895, and -129897, to Key Pharmaceuticals, Inc., which authorizes the modification of the operations of 3 Glatts units (91), the construction of a carbon adsorption and solvent recovery system to serve existing, permitted, and new process equipment (93), the construction of 2 tablet press room operations (94 & 95), and the construction of a granulation process (97). These permits are issued pursuant to Section 403, Florida Statutes.

Any Party to these permits have the right to seek judicial review of the permits pursuant to Section 120.68, Florida Statutes, by the filing of a Notice of Appeal pursuant to Rule 9.110, Florida Rules of Appellate Procedure, with the Clerk of the Department in the Office of General Counsel, 2600 Blair Stone Road, Tallahassee, Florida 32399-2400; and, by filing a copy of the Notice of Appeal accompanied by the applicable filing fees with the appropriate District Court of Appeal. The Notice of Appeal must be filed within 30 days from the date these permits are filed with the Clerk of the Department.

Executed in Tallahassee, Florida.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL REGULATION

C. H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality
Management

Copy furnished to:
I. Goldman, SE District
P. Wong, DERM
J. Wells, P.E.

CERTIFICATE OF SERVICE

This is to certify that this NOTICE OF PERMITS and all copies were mailed before the close of business on May 31, 1987 to the listed persons.

FILING AND ACKNOWLEDGEMENT
FILED, on this date, pursuant to §120.52(9), Florida Statutes, with the designated Department Clerk, receipt of which is hereby acknowledged.

R Bruce McPherson
Clerk

5/31/87
Date

Final Determination

Key Pharmaceuticals, Inc.
Dade County
Miami, Florida

Project	Construction Permit Nos.
Modification of Operations of 3 Fluidized Bed Coating Units	AC 13-129891
Construction of a Carbon Adsorption and Solvent Recovery System	AC 13-129893
Tablet Press Rooms Nos. 1 and 2 with Dust Collector	AC 13-129894
Tablet Press Rooms Nos. 3 and 4 with Dust Collector	AC 13-129895
Granulation Process	AC 13-129897

Florida Department of Environmental Regulation
Bureau of Air Quality Management
Central Air Permitting

May 18, 1987

Final Determination

Key Pharmaceuticals, Inc. submitted a series of applications for permits to construct for existing and proposed process equipment at their Miami, Dade County, Florida facility on January 26, 1987.

These applications were reviewed by the Bureau and the Technical Evaluation and Preliminary Determinations were distributed on the dates noted below.

Number	Project	Distribution Date
AC 13-129891	3 Fluidized Bed Coating Units	March 18, 1987
AC 13-129893	Carbon Adsorption and Solvent Recovery System	March 26, 1987
AC 13-129894	Tablet Press Rooms Nos. 1 & 2	March 27, 1987
AC 13-129895	Tablet Press Rooms Nos. 3 & 4	March 27, 1987
AC 13-129897	Granulation Process	April 2, 1987

One application of the original package submitted by the applicant (File No. AC 13-129899 - 6 coating pans, 3 drying rooms) is still being reviewed by the Bureau.

Public Notices of the Department's intent to issue the permits were published in the Miami News on April 6, 1987, (AC 13-129891, -129893, -129894, -129895) and April 18, 1987, (AC 13-129897). Copies of the Technical Evaluation and Preliminary Determinations were available for public inspection at Dade County's Department of Environmental Resources Management in Miami and the Department of Environmental Regulation's offices in West Palm Beach and Tallahassee.

Comments were submitted by the SE District and the applicant.

In a interoffice memorandum dated April 8, 1987, the District questioned whether the expiration date of October 1, 1987, for the two permits for the tablet press rooms with dust collectors (AC 13-129894 and -129895) allowed adequate time for the applicant to prepare and submit the applications for permits to operate. To allow adequate time for the applicant to submit the application for permits to operate, the Bureau has extended the expiration date of these two construction permits to December 31, 1987.

The District noted that the particulate matter emissions calculation for the 3 Glatt Units (AC 13-129891) was in error.

The Bureau agrees with the District and has lowered the particulate matter standard from 0.5 to 0.05 lb/hr.

The District also noted that the construction permit expired 6 months prior to the installation of the air pollution control equipment that these units are required to discharge to. To clarify this situation, the Bureau has extended the expiration date of this permit to October 1, 1988 and modified Specific Conditions Nos. 3 and 5 to be consistent with the new expiration date. The District also commented that the emissions table in the determination needed more explanation. The table lists the maximum and annual emissions of pollutants from this process. As the Glatt units operate as batch processes with nonliniear emissions, the calculations attached to the application need to be consulted to see how the standards were obtain. The emission standards in the permit (Specific Condition No. 3) are more descriptive. No changes were made for this comment.

The District also felt that a particulate matter (Method 5) and visible emissions (Method 9) tests should be required initially and on renewable of the permits to operate for the sources addressed in this Final Determination. The Bureau chose to regulate particulate matter emissions by allowing the use of an alternate visible emissions standard as allowed by the regulations (17-2.700(3)(d)). We have reservations about the Method 5 test procedure being able to measure particulate matter emissions of the quantity estimated by the applicant with any precision and accuracy. If the District has good reasons to believe the regulations on particulate matter are being violated, the permittee can be required to make a compliance test on his source (Rule 17-2.700(2)(b), FAC). The particulate matter testing requirements remain as proposed.

The District believes the carbon adsorption system should be tested initially and each time the permit to operate is renewed (every 5 years). The Bureau agrees with the District on the VOC testing frequency for the carbon adsorption system and has reworded Specific Condition No. 5 of permit No. AC 13-129893 to address this comment.

In a letter dated April 16, 1987, the applicant requested that the manufacturer's term "Accela-Cota" be replaced with the technical description of "perforated pan coating unit" for that process equipment. The Bureau has no objection to the substitution of equivalent process equipment for the Accela-Cota and has made the requested changes to construction permit No. AC 13-129893.

The applicant also requested that Specific Condition No. 4 of this permit, which specified the VOC removal efficiency for the carbon adsorption system, be modified to reflect that the 90% VOC removal is over a cycle (batch). The applicant said that the

instantaneous removal efficiency when the VOC concentration to the adsorber is low, such as at the end of a cycle, may be less than 90 percent. The Bureau based its review on 90% of the VOC being removed during each cycle batch which is consistent with the applicant's request and has changed Specific Condition No. 4 of this permit to reflect this.

The applicant also requested that the carbon adsorber/solvent recovery construction permit be modified to include the pan coating equipment. As the applicant has submitted a separate application (AC 13-129899) for the pan coating equipment and the change will increase emissions from the adsorber, the Bureau has decided to process the pan coating application separtely.

The final action of the Department will be to issue the permits to construct as proposed in the Technical Evaluation and Preliminary Determinations except for the changes noted above.

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

PERMITTEE:
Key Pharmaceuticals, Inc.
50 NW 176th Street
Miami, Florida 33169-1307

Permit Number: AC 13-129891
Expiration Date: October 1, 1988
County: Dade
Latitude/Longitude: 25° 56' 04" N
80° 12' 11" W
Project: 3 Fluidized Bed
Processors with Scrubber

This permit is issued under the provisions of Chapter 403, Florida Statutes, and Florida Administrative Code Rule(s) 17-2 and 17-4. The above named permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents attached hereto or on file with the Department and made a part hereof and specifically described as follows:

Modification of the operations of Nos. 1, 2, and 3 fluidized bed coating units (Glatts) by increasing the allowable hours of operation and changing the ratio of methylene chloride to methanol to 90:10 Glatt Nos. 1, 2, and 3 can manufacture up to 2,053 lots of drugs per year. Each lot uses approximately 3,000 lbs of solvent and excipients. Emissions are controlled by a Torit 3DF60 dust collector and a packed bed scrubber designed by Koch Engineering Company and equipped with a 50 foot high, 2.5 foot diameter stack that discharges approximately 18,000 scfm of air.

The facility location is bounded on the west by S.R. 441, on the east and south by Interstate Highway 95, and on the north by NW 176th Street in Miami, Dade County, Florida. The UTM coordinates of this site are zone 17, 579.9 km E and 2868.4 km N.

The operation of Glatt Nos. 1, 2, and 3 shall be in accordance with the application for permit to construct 3 fluidized bed processors with scrubber that was delivered to the department on January 26, 1987.

Attachments:

1. Application for 3 Fluidized Bed Processors with Scrubber received by BAQM on January 26, 1987.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129891
Expiration Date: October 1, 1988

GENERAL CONDITIONS:

1. The terms, conditions, requirements, limitations, and restrictions set forth herein are "Permit Conditions" and as such are binding upon the permittee and enforceable pursuant to the authority of Sections 403.161, 403.727, or 403.859 through 403.861, Florida Statutes. The permittee is hereby placed on notice that the Department will review this permit periodically and may initiate enforcement action for any violation of the "Permit Conditions" by the permittee, its agents, employees, servants or representatives.

2. This permit is valid only for the specific processes and operations applied for and indicated in the approved drawings or exhibits. Any unauthorized deviation from the approved drawings, exhibits, specifications, or conditions of this permit may constitute grounds for revocation and enforcement action by the Department.

3. As provided in Subsections 403.087(6) and 403.722(5), Florida Statutes, the issuance of this permit does not convey any vested rights or any exclusive privileges. Nor does it authorize any injury to public or private property or any invasion of personal rights, nor any infringement of federal, state or local laws or regulations. This permit does not constitute a waiver of or approval of any other Department permit that may be required for other aspects of the total project which are not addressed in the permit.

4. This permit conveys no title to land or water, does not constitute state recognition or acknowledgement of title, and does not constitute authority for the use of submerged lands unless herein provided and the necessary title or leasehold interests have been obtained from the state. Only the Trustees of the Internal Improvement Trust Fund may express state opinion as to title.

5. This permit does not relieve the permittee from liability for harm or injury to human health or welfare, animal, plant or aquatic life or property and penalties therefore caused by the construction or operation of this permitted source, nor does it allow the permittee to cause pollution in contravention of Florida Statutes and Department rules, unless specifically authorized by an order from the Department.

GENERAL CONDITIONS:

6. The permittee shall at all times properly operate and maintain the facility and systems of treatment and control (and related appurtenances) that are installed or used by the permittee to achieve compliance with the conditions of this permit, as required by Department rules. This provision includes the operation of backup or auxiliary facilities or similar systems when necessary to achieve compliance with the conditions of the permit and when required by Department rules.

7. The permittee, by accepting this permit, specifically agrees to allow authorized Department personnel, upon presentation of credentials or other documents as may be required by law, access to the premises, at reasonable times, where the permitted activity is located or conducted for the purpose of:

a. Having access to and copying any records that must be kept under the conditions of the permit;

b. Inspecting the facility, equipment, practices, or operations regulated or required under this permit; and

c. Sampling or monitoring any substances or parameters at any location reasonably necessary to assure compliance with this permit or Department rules.

Reasonable time may depend on the nature of the concern being investigated.

8. If, for any reason, the permittee does not comply with or will be unable to comply with any condition or limitation specified in this permit, the permittee shall immediately notify and provide the Department with the following information:

a. a description of and cause of non-compliance; and

b. the period of noncompliance, including exact dates and times; or, if not corrected, the anticipated time the noncompliance is expected to continue, and steps being taken to reduce, eliminate, and prevent recurrence of the noncompliance.

GENERAL CONDITIONS:

The permittee shall be responsible for any and all damages which may result and may be subject to enforcement action by the Department for penalties or revocation of this permit.

9. In accepting this permit, the permittee understands and agrees that all records, notes, monitoring data and other information relating to the construction or operation of this permitted source, which are submitted to the Department, may be used by the Department as evidence in any enforcement case arising under the Florida Statutes or Department rules, except where such use is proscribed by Sections 403.73 and 403.111, Florida Statutes.

10. The permittee agrees to comply with changes in Department rules and Florida Statutes after a reasonable time for compliance, provided however, the permittee does not waive any other rights granted by Florida Statutes or Department rules.

11. This permit is transferable only upon Department approval in accordance with Florida Administrative Code Rules 17-4.12 and 17-30.30, as applicable. The permittee shall be liable for any non-compliance of the permitted activity until the transfer is approved by the Department.

12. This permit is required to be kept at the work site of the permitted activity during the entire period of construction or operation.

13. This permit also constitutes:

( ) Determination of Best Available Control Technology (BACT)
( ) Determination of Prevention of Significant Deterioration (PSD)
( ) Compliance with New Source Performance Standards.

14. The permittee shall comply with the following monitoring and record keeping requirements:

a. Upon request, the permittee shall furnish all records and plans required under Department rules. The retention period for all records will be extended automatically, unless otherwise stipulated by the Department, during the course of any unresolved enforcement action.

GENERAL CONDITIONS:

b. The permittee shall retain at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation), copies of all reports required by this permit, and records of all data used to complete the application for this permit. The time period of retention shall be at least three years from the date of the sample, measurement, report or application unless otherwise specified by Department rule.

c. Records of monitoring information shall include:

- the date, exact place, and time of sampling or measurements;
- the person responsible for performing the sampling or measurements;
- the date(s) analyses were performed;
- the person responsible for performing the analyses;
- the analytical techniques or methods used; and
- the results of such analyses.

15. When requested by the Department, the permittee shall within a reasonable time furnish any information required by law which is needed to determine compliance with the permit. If the permittee becomes aware that relevant facts were not submitted or were incorrect in the permit application or in any report to the Department, such facts or information shall be submitted or corrected promptly.

SPECIFIC CONDITIONS:

1. The Nos. 1, 2, and 3 fluidized bed processor (Glatts) may operate continuously, 8760 hours per year, provided the air pollution control system serving these units is operating properly.

2. The maximum production of each Glatt unit shall not exceed the following without prior approval of the department (BAQM):

Glatt Unit No. 1 - 461 lots/year
Glatt Unit No. 2 - 796 lots/year
Glatt Unit No. 3 - 796 lots/year

The approximate composition of each lot is 2,139 lbs of methylene chloride, 198 lbs methanol, and 665 lbs of excipients.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129891
Expiration Date: October 1, 1988

SPECIFIC CONDITIONS:

The permittee shall maintain records of the number of lots manufactured by each Glatt unit and the composition of each lot for a minumum of 2 years for Department inspection.

3. The maximum emissions (with 3 Glatt units in operation) from the air pollution control system scrubber shall not exceed:

Methanol-(VOC) 6.9 lbs/hr (max) and 4.64 lbs/hr (avg), and 20.3 TPY (VOC)

Particulate Matter - 0.05 lbs/hr and 0.14 TPY or 5% opacity

Methylene Chloride (exempt VOC) - 743 lbs/hr (max), 501 lbs/hr (avg), and 2195 TPY

Compliance with the standards listed above shall be determined as follows:

Methanol (VOC) - The efficiency and maximum emissions of the scrubber shall be determined by a Method 25, 25A, or 18 test as described in 40 CFR 60, Appendix A, prior to the expiration of this permit and each time a permit to operate is applied for (every five years). Compliance with the particulate matter standard shall be determined by Method 5, described in 40 CFR 60, Appendix A, or (at the option of the permitee) an alternate standard of no visible emissions (5 percent opacity maximum) as determined by Method 9, 40 CFR 60, Appendix A, may be substituted for the particulate matter standard.

Compliance with the methylene chloride standard (exempt VOC) shall be calculated from inventory records and logs for the Glatt units.

The allowable organic emissions are lower (prorated based on design calculations in the application) when any of the Glatt units is not in operation.

4. The permittee shall install a carbon absorption system to reduce methylene chloride emissions (after department (BAQM) approval) before July 1, 1988.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129891
Expiration Date: October 1, 1988

SPECIFIC CONDITIONS:

5. The permittee shall prove compliance with all conditions of this permit and submit a complete application for permit to operate to the Department (SE District) 90 days prior to the expiration of this construction permit. The application for the permit to operate shall include a status report and schedule for the installation of the carbon absorption system. The permittee may continue to operate in compliance with all terms of this construction permit until its expiration date.

6. Upon obtaining a permit to operate, the permittee will be required to submit annual reports on the actual operation of the facility. These reports shall include, as a minimum, a recent Method 9 test on the scrubber, the number of lots manufactured by the 3 Glatt units, and the calculated emissions of methylene chloride and methanol based on plant records.

Issued this 19 day of May 1987

STATE OF FLORIDA DEPARTMENT OF
ENVIRONMENTAL REGULATION

Dale Twachtmann

Dale Twachtmann, Secretary

____ pages attached

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

PERMITTEE:
Key Pharmaceuticals, Inc.
50 NW 176th Street
Miami, Florida 33169-1307

Permit Number: AC 13-129893
Expiration Date: January 1, 1989
County: Dade
Latitude/Longitude: 25° 56' 03" N
80° 11' 42" W
Project: Construction of Carbon Adsorption & Solvent Recovery System to Serve Existng, Permitted, & New Process Equipment

This permit is issued under the provisions of Chapter 403, Florida Statutes, and Florida Administrative Code Rule(s) 17-2 and 17-4. The above named permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents attached hereto or on file with the Department and made a part hereof and specifically described as follows:

Authorization to replace the existing methanol scrubber/activated sludge treatment system with a 90% efficient carbon adsorption/solvent recovery system to control the emissions from four fluid bed processors (Glatt) and two Perforated Pan Coating Units (PPCU). Two of the Glatt units are existing equipment and a construction permit has been issued for the third Glatt (AC 13-100437). This permit authorizes the construction of the fourth Glatt, two Perforated Pan Coating Units (PPCU), and the carbon adsorption/solvent recovery system. This equipment will be located at the pharmaceutical plant at 50 N.W. 176th Street, Miami, Dade County, Florida. The UTM coordinates of this plant are zone 17, 579.9 km E and 2868.4 km N.

The construction and operation shall be in accordance with the attached permit applications, plans, documents, and drawings except as noted in the Specific Conditions of this permit.

Attachments:

1. Key's Application No. 2 - 4 Fluid Bed Processors; 2 Pan Coaters; and Carbon Adsorption Unit, received by BAQM on January 26, 1987.
2. Key's Application No. 3 - 1 Fluid Bed Processor with Carbon Adsorption/Solvent Recovery, received by BAQM on January 26, 1987.
3. Key's Application No. 4 - 2 Pan Coating Units, received by BAQM on January 26, 1987.
4. Interoffice memorandum dated April 8, 1987.
5. Key's letter dated April 16, 1987.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129893
Expiration Date: January 1, 1989

GENERAL CONDITIONS:

1. The terms, conditions, requirements, limitations, and restrictions set forth herein are "Permit Conditions" and as such are binding upon the permittee and enforceable pursuant to the authority of Sections 403.161, 403.727, or 403.859 through 403.861, Florida Statutes. The permittee is hereby placed on notice that the Department will review this permit periodically and may initiate enforcement action for any violation of the "Permit Conditions" by the permittee, its agents, employees, servants or representatives.

2. This permit is valid only for the specific processes and operations applied for and indicated in the approved drawings or exhibits. Any unauthorized deviation from the approved drawings, exhibits, specifications, or conditions of this permit may constitute grounds for revocation and enforcement action by the Department.

3. As provided in Subsections 403.087(6) and 403.722(5), Florida Statutes, the issuance of this permit does not convey any vested rights or any exclusive privileges. Nor does it authorize any injury to public or private property or any invasion of personal rights, nor any infringement of federal, state or local laws or regulations. This permit does not constitute a waiver of or approval of any other Department permit that may be required for other aspects of the total project which are not addressed in the permit.

4. This permit conveys no title to land or water, does not constitute state recognition or acknowledgement of title, and does not constitute authority for the use of submerged lands unless herein provided and the necessary title or leasehold interests have been obtained from the state. Only the Trustees of the Internal Improvement Trust Fund may express state opinion as to title.

5. This permit does not relieve the permittee from liability for harm or injury to human health or welfare, animal, plant or aquatic life or property and penalties therefore caused by the construction or operation of this permitted source, nor does it allow the permittee to cause pollution in contravention of Florida Statutes and Department rules, unless specifically authorized by an order from the Department.

GENERAL CONDITIONS:

6. The permittee shall at all times properly operate and maintain the facility and systems of treatment and control (and related appurtenances) that are installed or used by the permittee to achieve compliance with the conditions of this permit, as required by Department rules. This provision includes the operation of backup or auxiliary facilities or similar systems when necessary to achieve compliance with the conditions of the permit and when required by Department rules.

7. The permittee, by accepting this permit, specifically agrees to allow authorized Department personnel, upon presentation of credentials or other documents as may be required by law, access to the premises, at reasonable times, where the permitted activity is located or conducted for the purpose of:

a. Having access to and copying any records that must be kept under the conditions of the permit;

b. Inspecting the facility, equipment, practices, or operations regulated or required under this permit; and

c. Sampling or monitoring any substances or parameters at any location reasonably necessary to assure compliance with this permit or Department rules.

Reasonable time may depend on the nature of the concern being investigated.

8. If, for any reason, the permittee does not comply with or will be unable to comply with any condition or limitation specified in this permit, the permittee shall immediately notify and provide the Department with the following information:

a. a description of and cause of non-compliance; and

b. the period of noncompliance, including exact dates and times; or, if not corrected, the anticipated time the noncompliance is expected to continue, and steps being taken to reduce, eliminate, and prevent recurrence of the noncompliance.

GENERAL CONDITIONS:

The permittee shall be responsible for any and all damages which may result and may be subject to enforcement action by the Department for penalties or revocation of this permit.

9. In accepting this permit, the permittee understands and agrees that all records, notes, monitoring data and other information relating to the construction or operation of this permitted source, which are submitted to the Department, may be used by the Department as evidence in any enforcement case arising under the Florida Statutes or Department rules, except where such use is proscribed by Sections 403.73 and 403.111, Florida Statutes.

10. The permittee agrees to comply with changes in Department rules and Florida Statutes after a reasonable time for compliance, provided however, the permittee does not waive any other rights granted by Florida Statutes or Department rules.

11. This permit is transferable only upon Department approval in accordance with Florida Administrative Code Rules 17-4.12 and 17-30.30, as applicable. The permittee shall be liable for any non-compliance of the permitted activity until the transfer is approved by the Department.

12. This permit is required to be kept at the work site of the permitted activity during the entire period of construction or operation.

13. This permit also constitutes:

( ) Determination of Best Available Control Technology (BACT)
( ) Determination of Prevention of Significant Deterioration (PSD)
( ) Compliance with New Source Performance Standards.

14. The permittee shall comply with the following monitoring and record keeping requirements:

a. Upon request, the permittee shall furnish all records and plans required under Department rules. The retention period for all records will be extended automatically, unless otherwise stipulated by the department, during the course of any unresolved enforcement action.

GENERAL CONDITIONS:

b. The permittee shall retain at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation), copies of all reports required by this permit, and records of all data used to complete the application for this permit. The time period of retention shall be at least three years from the date of the sample, measurement, report or application unless otherwise specified by Department rule.

c. Records of monitoring information shall include:

- the date, exact place, and time of sampling or measurements;
- the person responsible for performing the sampling or measurements;
- the date(s) analyses were performed;
- the person responsible for performing the analyses;
- the analytical techniques or methods used; and
- the results of such analyses.

15. When requested by the Department, the permittee shall within a reasonable time furnish any information required by law which is needed to determine compliance with the permit. If the permittee becomes aware that relevant facts were not submitted or were incorrect in the permit application or in any report to the Department, such facts or information shall be submitted or corrected promptly.

SPECIFIC CONDITIONS:

1. The fluid bed unit (Glatt No. 4) and two perforated pan coating units Nos. 1 and 2 shall not be placed in service before the dust collector and carbon adsorption/solvent recovery system are able to control their air pollutant emissions.

2. Production shall not exceed the following without prior approval of the Department (BAQM):

Glatt Unit No. 1 - 461 lots/year
Glatt Unit No. 2 - 796 lots/year
Glatt Unit No. 3 - 796 lots/year
Glatt Unit No. 4 - 796 lots/year

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129893
Expiration Date: January 1, 1989

SPECIFIC CONDITIONS:

Each Glatt lot uses approximately 2,140 lbs methylene chloride, 200 lbs methanol, and 665 lbs solids (excipients).

Perforated Pan Coating Unit (PPCU) #1 - 1095 lots per year
Perforated Pan coating Unit (PPCU) #2 - 1095 lots per year

Each perforated pan coating unit lot uses approximately 600 lbs methylene chloride, 90 lbs methanol, and 400 lbs solids (excipients).

Other solvents shall not be used in by this process equipment without prior approval of the Department (BAQM).

The permittee shall keep logs on the process equipment that shows the number of lots produced by each unit. These records shall be available for Department inspection for two years.

3. The process equipment may operate continuously (8760 hr/yr) if the carbon adsorption/solvent recovery system is operating properly.

4. The carbon adsorption/solvent recovery system shall remove a minimum of 90% of the methylene chloride and methanol emitted by the process equipment (Glatts and Perforated Pan Coating Units) during the process cycle. Compliance with this standard shall be determined using the data from the continuous monitors on the inlet and discharge of the carbon adsorbers.

5. Allowable emissions from the air pollution control system are a function of the number of units in operation and shall not exceed the following:

Unit	Methylene Chloride			Methanol			PM	
	lb/hr	lb/day	TPY	lb/hr	lb/day	TPY	lb/hr	TPY
Glatt No. 1	20.9	271.2	49.5	1.9	25.0	4.6		
Glatt No. 2	26.7	465.6	85.0	2.5	43.2	7.9		
Glatt No. 3	26.7	465.6	85.0	2.5	43.2	7.9	Trace	
Glatt No. 4	26.7	465.6	85.0	2.5	43.2	7.9		
PPCU No. 1	20.0	180.0	32.8	3.0	27.1	4.9		
PPCU No. 2	20.0	180.0	32.8	3.0	27.1	4.9		
Total	141.0	2028.0	370.1	15.4	208.8	38.1	0.1	0.23

The maximum TPY emissions listed above are based on continuous operation of all units. If any unit is not operated continuously (producing the number of lots listed in Specific Condition No. 2), the allowable emissions are reduced accordingly.

SPECIFIC CONDITIONS:

Compliance with hourly standards (for the solvent) shall be determined initially and on renewal of any permit to operate issued for the carbon adsorption/solvent recovery system by reference methods 25, 25A, or 18 as described in 40 CFR 60, Appendix A, or other methods as approved by the Department. Compliance with the annual standards shall be based on production records and the measured efficiency of the carbon adsorption unit.

An alternate standard of no visible emissions from the stacks and equipment as determined by Method 9 described in 40 CFR 60, Appendix A, is substituted for the particulate matter standard.

VOC emission tests, based on production records and the carbon absorption unit monitoring data, are required as each additional unit is placed in service.

The Department (SE District) shall be notified 15 days prior to any compliance test. Test results shall be submitted to the Department (SE District) within 45 days of any test.

6. This operation (Glatts, Perforated Pan Coating Units, Carbon Adsorption/Solvent Recovery) shall not cause, suffer, allow, or permit the discharge of air pollutants which cause or contribute to an objectionable odor.

7. The construction shall reasonably conform to the plans and schedule submitted in the application. If the permittee is unable to complete construction on schedule, he must notify the Department in writing 60 days prior to the expiration of the construction permit and submit a new schedule and request for an extension of the construction permit. (FAC Rule 17-4.09)

8. To obtain a permit to operate, the permittee must demonstrate compliance with the conditions of the construction permit and submit a complete application for an operating permit, including the application fee, along with test results and Certificate of Completion, to the Department's district office 90 days prior to the expiration date of the construction permit. The permittee may continue to operate in compliance with all terms of the construction permit until its expiration date. Operation beyond the construction permit expiration date requires a valid permit to operate. (FAC Rule 17-4.22 and 17-4.23)

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129893
Expiration Date: January 1, 1989

SPECIFIC CONDITIONS:

9. If the construction permit expires prior to the permittee requesting an extension or obtaining a permit to operate, then all activities at the project must cease and the permittee must apply for a new permit to construct which can take up to 90 days to process a complete application. (FAC Rule 17-4.10)

Issued this 19 day of May, 19 87

STATE OF FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATION

Dale Twachtmann

Dale Twachtmann, Secretary

____ pages attached

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

PERMITTEE:
Key Pharmaceuticals, Inc.
50 NW 176th Street
Miami, Florida 33169-1307

Permit Number: AC 13-129894
Expiration Date: December 31, 1987
County: Dade
Latitude/Longitude: 25° 56' 03" N
80° 11' 42" W
Project: Tablet Press Rooms Nos. 1 and 2

This permit is issued under the provisions of Chapter 403, Florida Statutes, and Florida Administrative Code Rule(s) 17-2 and 17-4. The above named permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents attached hereto or on file with the Department and made a part hereof and specifically described as follows:

Authorization to operate two existing tablet press rooms containing tablet presses with air from the rooms and process equipment exhausted through a Torit dust collector. The Torit dust collector will discharge 4,000 ACFM of air at 70 °F from the process at roof level (11 feet) through a 12" x 12" duct. This equipment is located at the pharmaceutical plant at 50 N.W. 176th Street in Miami, Dade County, Florida. The UTM coordinates of this plant are zone 17, 579.9 km E and 2868.4 km N.

The operation shall be in accordance with the attached permit application, plans, documents, and drawings except as noted in the Specific Conditions of this permit.

Attachment:

1. Application for Permit to Construct 4 Tablet Presses received by BAQM on January 26, 1987.

2. Interoffice memorandum dated April 8, 1987.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129894
Expiration Date: December 31, 1987

GENERAL CONDITIONS:

1. The terms, conditions, requirements, limitations, and restrictions set forth herein are "Permit Conditions" and as such are binding upon the permittee and enforceable pursuant to the authority of Sections 403.161, 403.727, or 403.859 through 403.861, Florida Statutes. The permittee is hereby placed on notice that the Department will review this permit periodically and may initiate enforcement action for any violation of the "Permit Conditions" by the permittee, its agents, employees, servants or representatives.

2. This permit is valid only for the specific processes and operations applied for and indicated in the approved drawings or exhibits. Any unauthorized deviation from the approved drawings, exhibits, specifications, or conditions of this permit may constitute grounds for revocation and enforcement action by the Department.

3. As provided in Subsections 403.087(6) and 403.722(5), Florida Statutes, the issuance of this permit does not convey any vested rights or any exclusive privileges. Nor does it authorize any injury to public or private property or any invasion of personal rights, nor any infringement of federal, state or local laws or regulations. This permit does not constitute a waiver of or approval of any other Department permit that may be required for other aspects of the total project which are not addressed in the permit.

4. This permit conveys no title to land or water, does not constitute state recognition or acknowledgement of title, and does not constitute authority for the use of submerged lands unless herein provided and the necessary title or leasehold interests have been obtained from the state. Only the Trustees of the Internal Improvement Trust Fund may express state opinion as to title.

5. This permit does not relieve the permittee from liability for harm or injury to human health or welfare, animal, plant or aquatic life or property and penalties therefore caused by the construction or operation of this permitted source, nor does it allow the permittee to cause pollution in contravention of Florida Statutes and Department rules, unless specifically authorized by an order from the Department.

GENERAL CONDITIONS:

6. The permittee shall at all times properly operate and maintain the facility and systems of treatment and control (and related appurtenances) that are installed or used by the permittee to achieve compliance with the conditions of this permit, as required by Department rules. This provision includes the operation of backup or auxiliary facilities or similar systems when necessary to achieve compliance with the conditions of the permit and when required by Department rules.

7. The permittee, by accepting this permit, specifically agrees to allow authorized Department personnel, upon presentation of credentials or other documents as may be required by law, access to the premises, at reasonable times, where the permitted activity is located or conducted for the purpose of:

a. Having access to and copying any records that must be kept under the conditions of the permit;

b. Inspecting the facility, equipment, practices, or operations regulated or required under this permit; and

c. Sampling or monitoring any substances or parameters at any location reasonably necessary to assure compliance with this permit or Department rules.

Reasonable time may depend on the nature of the concern being investigated.

8. If, for any reason, the permittee does not comply with or will be unable to comply with any condition or limitation specified in this permit, the permittee shall immediately notify and provide the Department with the following information:

a. a description of and cause of non-compliance; and

b. the period of noncompliance, including exact dates and times; or, if not corrected, the anticipated time the noncompliance is expected to continue, and steps being taken to reduce, eliminate, and prevent recurrence of the noncompliance.

GENERAL CONDITIONS:

The permittee shall be responsible for any and all damages which may result and may be subject to enforcement action by the Department for penalties or revocation of this permit.

9. In accepting this permit, the permittee understands and agrees that all records, notes, monitoring data and other information relating to the construction or operation of this permitted source, which are submitted to the Department, may be used by the Department as evidence in any enforcement case arising under the Florida Statutes or Department rules, except where such use is proscribed by Sections 403.73 and 403.111, Florida Statutes.

10. The permittee agrees to comply with changes in Department rules and Florida Statutes after a reasonable time for compliance, provided however, the permittee does not waive any other rights granted by Florida Statutes or Department rules.

11. This permit is transferable only upon Department approval in accordance with Florida Administrative Code Rules 17-4.12 and 17-30.30, as applicable. The permittee shall be liable for any non-compliance of the permitted activity until the transfer is approved by the Department.

12. This permit is required to be kept at the work site of the permitted activity during the entire period of construction or operation.

13. This permit also constitutes:

( ) Determination of Best Available Control Technology (BACT)
( ) Determination of Prevention of Significant Deterioration (PSD)
( ) Compliance with New Source Performance Standards.

14. The permittee shall comply with the following monitoring and record keeping requirements:

a. Upon request, the permittee shall furnish all records and plans required under Department rules. The retention period for all records will be extended automatically, unless otherwise stipulated by the Department, during the course of any unresolved enforcement action.

GENERAL CONDITIONS:

b. The permittee shall retain at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation), copies of all reports required by this permit, and records of all data used to complete the application for this permit. The time period of retention shall be at least three years from the date of the sample, measurement, report or application unless otherwise specified by Department rule.

c. Records of monitoring information shall include:

- the date, exact place, and time of sampling or measurements;
- the person responsible for performing the sampling or measurements;
- the date(s) analyses were performed;
- the person responsible for performing the analyses;
- the analytical techniques or methods used; and
- the results of such analyses.

15. When requested by the Department, the permittee shall within a reasonable time furnish any information required by law which is needed to determine compliance with the permit. If the permittee becomes aware that relevant facts were not submitted or were incorrect in the permit application or in any report to the Department, such facts or information shall be submitted or corrected promptly.

SPECIFIC CONDITIONS:

1. The dust collector system must be operating properly when the tablet presses are in use. Any malfunction of the air pollution control system shall be repaired promptly.

2. The tablet press process may operate continously, 8760 hrs/year.

3. Particulate matter (PM) emissions shall not exceed 0.024 lb/hr (0.1 TPY) as determined by Method 5 described in 40 CFR 60, Appendix A. Visible emissions from the rooms and dust collector for this process shall not exceed 5% opacity as determined by Method 9 which is described in 40 CFR 60, Appendix A. The Department (SE District) must be notified 15 days prior to any compliance test. The PM test will be waived if visible emissions do not exceed 5% opacity.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129894
Expiration Date: December 31, 1987

SPECIFIC CONDITIONS:
(continued)

4. The process shall not cause, suffer, allow, or permit the discharge of air pollutants which cause or contribute to an objectionable odor.

5. Use of VOC solvents in the tablet press process is prohibited.

6. The permittee shall submit a complete application for a permit to operate this equipment, which must include an emissions test report, to the SE District office at least 90 days prior to the expiration date of this construction permit. The permittee may continue to operate this source, if it is in compliance with all conditions of this construction permit, until its expiration date.

7. Upon obtaining a permit to operate, the permittee will be required to submit annual operation reports to the DER SE District office which shall include as a minimum a recent visible emissions test report as specified in Specific Condition No. 3.

Issued this 19 day of May, 1987

STATE OF FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATION

Dale Twachtmann

Dale Twachtmann, Secretary

____ pages attached

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

PERMITTEE:
Key Pharmaceuticals, Inc.
50 NW 176th Street
Miami, Florida 33169-1307

Permit Number: AC 13-129895
Expiration Date: December 31, 1987
County: Dade
Latitude/Longitude: 25° 56' 03" N
80° 11' 42" W
Project: Tablet Press Rooms Nos. 3 and 4

This permit is issued under the provisions of Chapter 403, Florida Statutes, and Florida Administrative Code Rule(s) 17-2 and 17-4. The above named permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents attached hereto or on file with the Department and made a part hereof and specifically described as follows:

Authorization to operate two existing tablet press rooms containing tablet presses with air from the rooms and process equipment exhausted through a Torit dust collector. The Torit dust collector will discharge 4,000 ACFM of air at 70 °F from the process at roof level (11 feet) through a 12" x 12" duct. This equipment is located at the pharmaceutical plant at 50 N.W. 176th Street in Miami, Dade County, Florida. The UTM coordinates of this plant are zone 17, 579.9 km E and 2868.4 km N.

The operation shall be in accordance with the attached permit application, plans, documents, and drawings except as noted in the Specific Conditions of this permit.

Attachment:

1. Application for Permit to Construct 4 Tablet Presses received by BAQM on January 26, 1987.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129895
Expiration Date: December 31, 1987

GENERAL CONDITIONS:

1. The terms, conditions, requirements, limitations, and restrictions set forth herein are "Permit Conditions" and as such are binding upon the permittee and enforceable pursuant to the authority of Sections 403.161, 403.727, or 403.859 through 403.861, Florida Statutes. The permittee is hereby placed on notice that the Department will review this permit periodically and may initiate enforcement action for any violation of the "Permit Conditions" by the permittee, its agents, employees, servants or representatives.

2. This permit is valid only for the specific processes and operations applied for and indicated in the approved drawings or exhibits. Any unauthorized deviation from the approved drawings, exhibits, specifications, or conditions of this permit may constitute grounds for revocation and enforcement action by the Department.

3. As provided in Subsections 403.087(6) and 403.722(5), Florida Statutes, the issuance of this permit does not convey any vested rights or any exclusive privileges. Nor does it authorize any injury to public or private property or any invasion of personal rights, nor any infringement of federal, state or local laws or regulations. This permit does not constitute a waiver of or approval of any other Department permit that may be required for other aspects of the total project which are not addressed in the permit.

4. This permit conveys no title to land or water, does not constitute state recognition or acknowledgement of title, and does not constitute authority for the use of submerged lands unless herein provided and the necessary title or leasehold interests have been obtained from the state. Only the Trustees of the Internal Improvement Trust Fund may express state opinion as to title.

5. This permit does not relieve the permittee from liability for harm or injury to human health or welfare, animal, plant or aquatic life or property and penalties therefore caused by the construction or operation of this permitted source, nor does it allow the permittee to cause pollution in contravention of Florida Statutes and Department rules, unless specifically authorized by an order from the Department.

GENERAL CONDITIONS:

6. The permittee shall at all times properly operate and maintain the facility and systems of treatment and control (and related appurtenances) that are installed or used by the permittee to achieve compliance with the conditions of this permit, as required by Department rules. This provision includes the operation of backup or auxiliary facilities or similar systems when necessary to achieve compliance with the conditions of the permit and when required by Department rules.

7. The permittee, by accepting this permit, specifically agrees to allow authorized Department personnel, upon presentation of credentials or other documents as may be required by law, access to the premises, at reasonable times, where the permitted activity is located or conducted for the purpose of:

a. Having access to and copying any records that must be kept under the conditions of the permit;

b. Inspecting the facility, equipment, practices, or operations regulated or required under this permit; and

c. Sampling or monitoring any substances or parameters at any location reasonably necessary to assure compliance with this permit or Department rules.

Reasonable time may depend on the nature of the concern being investigated.

8. If, for any reason, the permittee does not comply with or will be unable to comply with any condition or limitation specified in this permit, the permittee shall immediately notify and provide the Department with the following information:

a. a description of and cause of non-compliance; and

b. the period of noncompliance, including exact dates and times; or, if not corrected, the anticipated time the noncompliance is expected to continue, and steps being taken to reduce, eliminate, and prevent recurrence of the noncompliance.

GENERAL CONDITIONS:

The permittee shall be responsible for any and all damages which may result and may be subject to enforcement action by the Department for penalties or revocation of this permit.

9. In accepting this permit, the permittee understands and agrees that all records, notes, monitoring data and other information relating to the construction or operation of this permitted source, which are submitted to the Department, may be used by the Department as evidence in any enforcement case arising under the Florida Statutes or Department rules, except where such use is proscribed by Sections 403.73 and 403.111, Florida Statutes.

10. The permittee agrees to comply with changes in Department rules and Florida Statutes after a reasonable time for compliance, provided however, the permittee does not waive any other rights granted by Florida Statutes or Department rules.

11. This permit is transferable only upon Department approval in accordance with Florida Administrative Code Rules 17-4.12 and 17-30.30, as applicable. The permittee shall be liable for any non-compliance of the permitted activity until the transfer is approved by the Department.

12. This permit is required to be kept at the work site of the permitted activity during the entire period of construction or operation.

13. This permit also constitutes:

( ) Determination of Best Available Control Technology (BACT)
( ) Determination of Prevention of Significant Deterioration (PSD)
( ) Compliance with New Source Performance Standards.

14. The permittee shall comply with the following monitoring and record keeping requirements:

a. Upon request, the permittee shall furnish all records and plans required under department rules. The retention period for all records will be extended automatically, unless otherwise stipulated by the Department, during the course of any unresolved enforcement action.

GENERAL CONDITIONS:

b. The permittee shall retain at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation), copies of all reports required by this permit, and records of all data used to complete the application for this permit. The time period of retention shall be at least three years from the date of the sample, measurement, report or application unless otherwise specified by Department rule.

c. Records of monitoring information shall include:

- the date, exact place, and time of sampling or measurements;
- the person responsible for performing the sampling or measurements;
- the date(s) analyses were performed;
- the person responsible for performing the analyses;
- the analytical techniques or methods used; and
- the results of such analyses.

15. When requested by the Department, the permittee shall within a reasonable time furnish any information required by law which is needed to determine compliance with the permit. If the permittee becomes aware that relevant facts were not submitted or were incorrect in the permit application or in any report to the Department, such facts or information shall be submitted or corrected promptly.

SPECIFIC CONDITIONS:

1. The dust collector system must be operating properly when the tablet presses are in use. Any malfunction of the air pollution control system shall be repaired promptly.

2. The tablet press process may operate continously, 8760 hrs/year.

3. Particulate matter (PM) emissions shall not exceed 0.024 lb/hr (0.1 TPY) as determined by Method 5 described in 40 CFR 60, Appendix A. Visible emissions from the rooms and dust collector for this process shall not exceed 5% opacity as determined by Method 9 which is described in 40 CFR 60, Appendix A. The Department (SE District) must be notified 15 days prior to any compliance test. The PM test will be waived if visible emissions do not exceed 5% opacity.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129895
Expiration Date: December 31, 1987

SPECIFIC CONDITIONS:
(continued)

4. The process shall not cause, suffer, allow, or permit the discharge of air pollutants which cause or contribute to an objectionable odor.

5. Use of VOC solvents in the tablet press process is prohibited.

6. The permittee shall submit a complete application for a permit to operate this equipment, which must include an emissions test report, to the SE District office at least 90 days prior to the expiration date of this construction permit. The permittee may continue to operate this source, if it is in compliance with all conditions of this construction permit, until its expiration date.

7. Upon obtaining a permit to operate, the permittee will be required to submit annual operation reports to the DER SE District office which shall include as a minimum, a recent emission test for visible emissions test report as specified in Specific Condition No. 3.

Issued this 19 day of Nov, 1987

STATE OF FLORIDA DEPARTMENT OF
ENVIRONMENTAL REGULATION

Dale Twachtmann

Dale Twachtmann, Secretary

____ pages attached

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

PERMITTEE:
Key Pharmaceuticals, Inc.
50 NW 176th Street
Miami, Florida 33169-1307

Permit Number: AC 13-129897
Expiration Date: January 1, 1988
County: Dade
Latitude/Longitude: 25° 56' 03" N
80° 11' 42" W
Project: Granulation Process

This permit is issued under the provisions of Chapter 403, Florida Statutes, and Florida Administrative Code Rule(s) 17-2 and 17-4. The above named permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents attached hereto or on file with the department and made a part hereof and specifically described as follows:

Authorization to operate the existing granulation process continuously. This process contains: 2 granulators; wet sizing, drying, and dry sizing equipment; 4,000 ACFM dust collector with a 12" x 12" stack; and associated ducts, hoods, and collection drums. It is located at the pharmaceutical plant at 50 N.W. 176th Street in Miami, Dade County, Florida. The UTM coordinates of this plant are zone 17, 579.9 km E and 2868.4 km N.

The operation shall be in accordance with two attached permit applications, plans, documents, and drawings except as noted in the Specific Conditions of this permit.

Attachments:

1. Application for Permit to Construct 2 Granulators received by BAQM on January 26, 1987.

2. Application for Permit to Construct 1 Granulator and Dryer received by BAQM on January 26, 1987.

GENERAL CONDITIONS:

1. The terms, conditions, requirements, limitations, and restrictions set forth herein are "Permit Conditions" and as such are binding upon the permittee and enforceable pursuant to the authority of Sections 403.161, 403.727, or 403.859 through 403.861, Florida Statutes. The permittee is hereby placed on notice that the department will review this permit periodically and may initiate enforcement action for any violation of the "Permit Conditions" by the permittee, its agents, employees, servants or representatives.

2. This permit is valid only for the specific processes and operations applied for and indicated in the approved drawings or exhibits. Any unauthorized deviation from the approved drawings, exhibits, specifications, or conditions of this permit may constitute grounds for revocation and enforcement action by the department.

3. As provided in Subsections 403.087(6) and 403.722(5), Florida Statutes, the issuance of this permit does not convey any vested rights or any exclusive privileges. Nor does it authorize any injury to public or private property or any invasion of personal rights, nor any infringement of federal, state or local laws or regulations. This permit does not constitute a waiver of or approval of any other department permit that may be required for other aspects of the total project which are not addressed in the permit.

4. This permit conveys no title to land or water, does not constitute state recognition or acknowledgement of title, and does not constitute authority for the use of submerged lands unless herein provided and the necessary title or leasehold interests have been obtained from the state. Only the Trustees of the Internal Improvement Trust Fund may express state opinion as to title.

5. This permit does not relieve the permittee from liability for harm or injury to human health or welfare, animal, plant or aquatic life or property and penalties therefore caused by the construction or operation of this permitted source, nor does it allow the permittee to cause pollution in contravention of Florida Statutes and department rules, unless specifically authorized by an order from the department.

GENERAL CONDITIONS:

6. The permittee shall at all times properly operate and maintain the facility and systems of treatment and control (and related appurtenances) that are installed or used by the permittee to achieve compliance with the conditions of this permit, as required by department rules. This provision includes the operation of backup or auxiliary facilities or similar systems when necessary to achieve compliance with the conditions of the permit and when required by department rules.

7. The permittee, by accepting this permit, specifically agrees to allow authorized department personnel, upon presentation of credentials or other documents as may be required by law, access to the premises, at reasonable times, where the permitted activity is located or conducted for the purpose of:

a. Having access to and copying any records that must be kept under the conditions of the permit;

b. Inspecting the facility, equipment, practices, or operations regulated or required under this permit; and

c. Sampling or monitoring any substances or parameters at any location reasonably necessary to assure compliance with this permit or department rules.

Reasonable time may depend on the nature of the concern being investigated.

8. If, for any reason, the permittee does not comply with or will be unable to comply with any condition or limitation specified in this permit, the permittee shall immediately notify and provide the department with the following information:

a. a description of and cause of non-compliance; and

b. the period of noncompliance, including exact dates and times; or, if not corrected, the anticipated time the noncompliance is expected to continue, and steps being taken to reduce, eliminate, and prevent recurrence of the noncompliance.

GENERAL CONDITIONS:

The permittee shall be responsible for any and all damages which may result and may be subject to enforcement action by the department for penalties or revocation of this permit.

9. In accepting this permit, the permittee understands and agrees that all records, notes, monitoring data and other information relating to the construction or operation of this permitted source, which are submitted to the department, may be used by the department as evidence in any enforcement case arising under the Florida Statutes or department rules, except where such use is proscribed by Sections 403.73 and 403.111, Florida Statutes.

10. The permittee agrees to comply with changes in department rules and Florida Statutes after a reasonable time for compliance, provided however, the permittee does not waive any other rights granted by Florida Statutes or department rules.

11. This permit is transferable only upon department approval in accordance with Florida Administrative Code Rules 17-4.12 and 17-30.30, as applicable. The permittee shall be liable for any non-compliance of the permitted activity until the transfer is approved by the department.

12. This permit is required to be kept at the work site of the permitted activity during the entire period of construction or operation.

13. This permit also constitutes:

( ) Determination of Best Available Control Technology (BACT)
( ) Determination of Prevention of Significant Deterioration (PSD)
( ) Compliance with New Source Performance Standards.

14. The permittee shall comply with the following monitoring and record keeping requirements:

a. Upon request, the permittee shall furnish all records and plans required under department rules. The retention period for all records will be extended automatically, unless otherwise stipulated by the department, during the course of any unresolved enforcement action.

GENERAL CONDITIONS:

b. The permittee shall retain at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation), copies of all reports required by this permit, and records of all data used to complete the application for this permit. The time period of retention shall be at least three years from the date of the sample, measurement, report or application unless otherwise specified by department rule.

c. Records of monitoring information shall include:

- the date, exact place, and time of sampling or measurements;
- the person responsible for performing the sampling or measurements;
- the date(s) analyses were performed;
- the person responsible for performing the analyses;
- the analytical techniques or methods used; and
- the results of such analyses.

15. When requested by the department, the permittee shall within a reasonable time furnish any information required by law which is needed to determine compliance with the permit. If the permittee becomes aware that relevant facts were not submitted or were incorrect in the permit application or in any report to the department, such facts or information shall be submitted or corrected promptly.

SPECIFIC CONDITIONS:

1. The dust collection system must be operating properly when any of the process equipment (granulators, wet sizing, drying, dry sizing unit) is in operation. Any malfunction of the air pollution control system shall be repaired promptly.

2. Use of isopropanol or 3-A alcohol for the solvent is limited to one granulator at any given time.

3. The granulation process may operate continuously, 8760 hrs/yr.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129897
Expiration Date: January 1, 1988

SPECIFIC CONDITIONS:

4. Each granulator is limited to 1 lot per 24 hours. Not more than 75 kg of isopropanol or 3-A alcohol will be used in any one lot. The permittee shall maintain records of the number of lots and the quantity of alcohol used in each granulator for 2 years for department inspection.

5. Emissions from the dust collector serving the granulation process shall not exceed the following:

Particulate matter - 0.004 lb/hr and 0.02 TPY or 5% opacity
VOC - 20.7 lb/hr, 165.2 lbs/day, and 30.2 TPY (for continuous operation)

Compliance with the particulate matter standard by Method 5 described in 40 CFR 60, Appendix A, shall be waived if visible emissions determined by Method 9 described in 40 CFR 60, Appendix A, does not exceed 5% opacity during any consecutive 6 minute period.

Compliance with the VOC standard shall be based on records of the quantity of alcohol used in the process. These records shall be retained for a minimum of two years for department review.

6. The process shall not cause, suffer, allow, or permit the discharge of air pollutants which cause or contribute to an objectionable odor.

7. The permittee shall submit a complete application for a permit to operate this equipment, which must include an emissions test report, to the SE District office at least 90 days prior to the expiration date of this construction permit. The permittee may continue to operate this source, if it is in compliance with all conditions of this construction permit, until its expiration date.

8. Upon obtaining a permit to operate, the permittee will be required to submit annual operation reports to the DER SE District office and the Dade County Department of Environmental Resources Management which shall include as a minimum: total quantity of solvent input; and a recent emissions test report for visible emissions as specified in Specific Condition No. 5.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129897
Expiration Date: January 1, 1988

SPECIFIC CONDITIONS:

Issued this 19 day of May, 1987

STATE OF FLORIDA DEPARTMENT OF
ENVIRONMENTAL REGULATION

Dale Twachtmann

Dale Twachtmann, Secretary

____ pages attached

State of Florida
DEPARTMENT OF ENVIRONMENTAL REGULATION

Interoffice Memorandum

FOR ROUTING TO OTHER THAN THE ADDRESSEE

To: _____ Locin: _____

To: _____ Locin: _____

To: _____ Locin: _____

From: _____ Date: _____

RECEIVED

MAY 18 1987

Office of the Secretary

TO: Dale Twachtmann

THRU: Howard L. Rhodes

FROM: C. H. Fancy

DATE: May 18, 1987

SUBJ: Approval of Air Construction Permits

Attached for your approval and signature are five air construction permits to Key Pharmaceuticals, Inc. to authorize the manufacture of drugs at the applicant's facility in Miami, Dade County, Florida. There have been no controversies regarding these permits.

Day 90, after which the permits would begin being issued by default, is May 27, 1987.

The Bureau recommends your approval and signature.

CHF/WH/s

attachment

PM
4-27-87
Miami, FL

CM-P-083-539-534

File Copy

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

DER
APR 29 1987
BAQM

April 24, 1987

Mr. C.H. Fancy, P.E., Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: PERMIT NO. AC 13-129897

Dear Mr. Fancy:

Key Pharmaceuticals, Inc. is in receipt of the Technical Evaluation and Preliminary Determination for the above referenced DER permits. The Public Notice for these permits was published in the legal section of the Miami News on April 18, 1987. Documentation concerning this publication is attached.

Key Pharmaceuticals, Inc. personnel have reviewed the documentation provided by BAQM in detail, and find the Technical Evaluation and Preliminary Determination complete and accurate. The specifications and conditions set forth in the draft permit are acceptable to Key Pharmaceuticals, Inc..

Should you have any questions or comments, please do not hesitate to call me (305-654-2240).

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

copied:
Willard Hanks
Isidore Goldman } 4-29-87 BAR
Patrick Wong

BEST AVAILABLE COPY

THE MIAMI NEWS
A COX NEWSPAPER

PUBLISHED DAILY
MIAMI — DADE — FLORIDA

STATE OF FLORIDA
COUNTY OF DADE:

Before the undersigned authority personally appeared

Ann Martula

who on oath says that he/she is

Custodian of Records

of The Miami News, a daily newspaper published at Miami in Dade County, Florida; that the attached copy of advertisement was published in said newspaper in the issues of ...

April 18, 1987

Affiant further says that the said The Miami News is a newspaper published at Miami, in the said Dade County, Florida, and that the said newspaper has heretofore been continuously published in said Dade County, Florida, each day and has been entered as second class mail matter at the post office in Miami, in said Dade County, Florida, for a period of one year next preceding the first publication of the attached copy of advertisement; and affiant further says that he has neither paid nor promised any person, firm or corporation any discount, rebate, commission or refund for the purpose of securing this advertisement for publication in the said newspaper.

Ann Martula

Sworn to and subscribed before me this 20 day of April A.D. 19 87

My commission expires Lynette M Beard

NOTARY PUBLIC STATE OF FLORIDA
MY COMMISSION EXP JULY 17,1989
BONDED THRU GENERAL INS. UND.

STATE OF FLORIDA
Department of Environmental Regulation
Notice of Proposed Agency Action on Permit Application

The Department of Environmental Regulation gives notice of its intent to issue a permit to Key Pharmaceuticals, Inc. to modify the granulation process at their existing pharmaceutical plant located at 50 N.W. 176th Street, Miami, Dade County, Florida. The granulation process will emit less than 1 TPY particulate matter and 30.2 TPY volatile organic compounds. A determination of best available control technology (BACT) was not required.

Persons whose substantial interests are affected by the department's proposed permitting decision may petition for an administrative proceeding (hearing) in accordance with Section 120.57, Florida Statutes. The petition must conform to the requirements of Chapters 17-103 and 28-5, Florida Administrative Code, and must be filed (received) in the Office of General Counsel of the Department at 2600 Blair Stone Road, Twin Towers Office Building, Tallahassee, Florida 32301, within fourteen (14) days of publication of this notice. Failure to file a request for hearing within this time period shall constitute a waiver of any right such person may have to request an administrative determination (hearing) under Section 120.57, Florida Statutes.

If a petition is filed, the administrative hearing process is designed to formulate agency action. Accordingly, the Department's final action may be different from the position taken by it in this preliminary statement. Therefore, persons who may wish to intervene in the processing. A petition for intervention must be filed pursuant to Model Rule 28-5.207 at least five (5) days before the final hearing and be filed with the hearing officer if one has been assigned at the Division of Administrative Hearings, Department of Administration, 2009 Apalachee Parkway, Tallahassee, Florida 32301. If no hearing officer has been assigned, the petition is to be filed with the Department's Office of General Counsel, 2600 Blair Stone Road, Tallahassee, Florida 32301. Failure to petition to intervene within the allowed time frame constitutes a waiver of any right such person has to request a hearing under Section 120.57, Florida Statutes.

The application is availabe for public inspection during normal business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays, at:

Dept. of Environmental Regulation, Southeast District, 3301 Gun Club Road, West Palm Beach, Florida 33402

Dept. of Environmental Regulation, Bureau of Air Quality Management, 2600Blair Stone Road, Tallahassee, Florida 32301

Dade County Department of Environmental, Resources Management, Metro Dade Governmental Center, Suite 310, 111 N.W. 1st Street, Miami, Florida 33128

Any person may send written comments on the proposed action to Mr. Bill Thomas at the department's Tallahassee address. All comments mailed within 14 days of the publication of this notice will be considered in the departmnet's final determination.

April 19, 1987
Ad No 917-695N

PM
4-30-87
Miami, FL

File Copy

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

DER

APR 22 1987

BAQM

April 14, 1987

Mr. C.H. Fancy, P.E., Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: PERMIT NO. AC 13-129891

Dear Mr. Fancy:

Key Pharmaceuticals, Inc. is in receipt of the Technical Evaluation and Preliminary Determination for the above referenced DER permit. The Public Notice for this permit was published in the legal section of the Miami News on April 6, 1987. Documentation concerning this publication has been forwarded to your department under separate cover.

The conditions set forth in the draft permit are acceptable to Key Pharmaceuticals, Inc.. Key Pharmaceuticals, Inc. is committed to installing additional emission controls, therefore, a July, 1988 completion for these controls is currently attainable.

Should you have any questions or comments please do not hesitate to call me at 305-654-2240.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

PM
4-20-87
Miami, FL

File Co 17

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

April 14, 1987

DER
APR 22 1987
BAQM

Mr. C.H. Fancy, P.E., Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: PERMIT NO. AC 13-129894, AC 13-129895

Dear Mr. Fancy:

Key Pharmaceuticals, Inc. is in receipt of the Technical Evaluation and Preliminary Determination for the above referenced DER permits. The Public Notice for these permits was published in the legal section of the Miami News on April 6, 1987. Documentation concerning this publication has been forwarded to your department under separate cover.

Key Pharmaceuticals, Inc. personnel have reviewed the documentation provided by BAQM in detail, and find the Technical Evaluation and Preliminary Determination complete and accurate. The specifications and conditions set forth in the draft permit are acceptable to Key Pharmaceuticals, Inc..

Should you have any questions or comments, please do not hesitate to call me (305-654-2240).

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

Willard Hanks 4-22-87 Fax

Airborne Letter Express
MIA 390 119321

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

DER
APR 20 1987
BAQM

April 17, 1987

Mr. C.H. Fancy, P.E., Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: PUBLIC NOTICE FOR PERMITS

Dear Mr. Fancy:

As requested, enclosed please find original Public Notices which were published in the April 6, 1987 Miami News, Legal Section:

AC 13-129891

AC 13-129894

AC 13-129895

AC 13-129893

Key Pharmaceuticals will issue its comments concerning these permits to your office by April 17, 1987.

Sincerely.

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

enclosures

THE MIAMI NEWS
A COX NEWSPAPER

PUBLISHED DAILY
MIAMI — DADE — FLORIDA

STATE OF FLORIDA
COUNTY OF DADE:

Before the undersigned authority personally appeared

Ann Martula

who on oath says that he/she is

Custodian of Records

of The Miami News, a daily newspaper published at Miami in Dade County, Florida; that the attached copy of advertisement was published in said newspaper in the issues of ...

April 6, 1987

Affiant further says that the said The Miami News is a newspaper published at Miami, in the said Dade County, Florida, and that the said newspaper has heretofore been continuously published in said Dade County, Florida, each day and has been entered as second class mail matter at the post office in Miami, in said Dade County, Florida, for a period of one year next preceding the first publication of the attached copy of advertisement; and affiant further says that he has neither paid nor promised any person, firm or corporation any discount, rebate, commission or refund for the purpose of securing this advertisement for publication in the said newspaper.

Ann Martula

Sworn to and subscribed before me this 6 day of April A.D. 19 87

My commission expires Linette M Beard

NOTARY PUBLIC STATE OF FLORIDA
MY COMMISSION EXP JULY 17,1989
BONDED THRU GENERAL INS. UND.

NOTARY PUBLIC STATE OF FLORIDA

State of Florida
Department of Environmental Regulation Notice of Proposed Agency Action on Permit Application

The Department of Environmental Regulation gives notice of its intent of issue a permit to Key Pharmaceuticals, Inc. for the modification of the operation of 3 fluidized bed coating units (Glatts) at their existing pharmaceutical plant located at 50 N.W. 176th Street, Miami, Dade County, Florida. The modification will increase methylene chloride emissions by 1,217 TPY. A determination of best available control technology (BACT) was not required.
Persons whose substantial interests are affected by the department's proposed permitting decision may petition for an administrative proceeding (hearing) in accordance with Section 120.57, Florida Statutes. The petition must conform to the requirements of Chapters 17-103 and 28-5, Florida Administrative Code, and must be filed (received) in the Office of General Counsel of the Department at 2600 Blair Stone Road, Twin Towers Office Building, Tallahassee, Florida 32301 within fourteen (14) days of publication of this notice. Failure to file a request for hearing within this time period shall constitute a waiver of any right such person may have to request an administrative determination (hearing) under Section 120.57, Florida Statutes.
If a petition is filed, the administrative hearing process is designed to formulate agency action. Accordingly the Departmnet's final action may be different from the position taken by it in this preliminary statement. Therefore, persons who may not object to the proposed agency action may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Model Rule 28-5.207 at least five (5) days before the final hearing and be filed with the hearing office if one has been assigned at the Division of Administrative Hearings, Department of Administration, 2009 Apalachee Parkway, Tallahassee, Florida 32301. If no hearing officer has been assigned, the petition is to be filed with the Department's Office of General Counsel, 2600 Blair Stone Road, Tallahassee, Florida 32301. Failure to petition to intervene within the allowed time frame constitutes a waiver of any right such person has to request a hearing under Section 120.57 Florida Statutes.
The applications are available for public inspection during normal business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays:

Dept. of Environmental Regulation
Southeast District
3301 Gun Club Road
West Palm Beach, Florida 32301

Dept of Environmental Regulation Bureau of Air Quality Management
2600 Blair Stone Road
Tallahassee, Florida 32301

Dade County Department of Environmental Resources Management
Metro Dade Governmental Center
Suite 310
111 N.W. 1st Street
Miami, Florida 33128

Any Person may send written comments on the proposed action to Mr. Bill Thomas at the department's Tallahassee address. All comments mailed within 30 days of the publication of this notice will be considered in the department's final determination.
April 6, 1987
Ad No: 888-150N

DER
APR 20 1987
BAQM

THE MIAMI NEWS
A COX NEWSPAPER

PUBLISHED DAILY
MIAMI — DADE — FLORIDA

STATE OF FLORIDA
COUNTY OF DADE:

Before the undersigned authority personally appeared

Ann Martula

who on oath says that he/she is

Custodian of Records

of The Miami News, a daily newspaper published at Miami in Dade County, Florida; that the attached copy of advertisement was published in said newspaper in the issues of ...

April 6, 1987

Affiant further says that the said The Miami News is a newspaper published at Miami, in the said Dade County, Florida, and that the said newspaper has heretofore been continuously published in said Dade County, Florida, each day and has been entered as second class mail matter at the post office in Miami, in said Dade County, Florida, for a period of one year next preceding the first publication of the attached copy of advertisement; and affiant further says that he has neither paid nor promised any person, firm or corporation any discount, rebate, commission or refund for the purpose of securing this advertisement for publication in the said newspaper.

Ann Martula

Sworn to and subscribed before me this 16 day of April A.D. 19 87

My commission expires Lynette N Beard

NOTARY PUBLIC STATE OF FLORIDA
MY COMMISSION EXP JULY 17,1989
BONDED THRU GENERAL INS. UND.

State of Florida

Department of Environmental Regulation Notice of Proposed Agency Action on Permit Application.

The Department of Environmental Regulation gives notice of its intent of issue a permit to Key Pharmaceuticals, Inc. for the construction of a carbon adsorption and solvent recovery system to serve existing, permitted,and new process equipment at their existing pharmaceutical plant located at 50 N.W. 176th Street, Miami, Dade County, Florida. Annual emissions from the carbon adsorption system will not exceed 370.1 TPY methylene chloride, 38.1 TPY methanol, and 0.23 TPY particulate matter. The modification will increase methylene chloride emission by 1,217 TPY. A determination of best available control technology (BACT) was not required.

Persons whose substantial interests are affected by the department's proposed permitting decision may petition for an administrative proceeding (hearing) in accordance with Section 120.57, Florida Statutes. The petition must conform to the requirements of Chapters 17-103 and 28-5, Florida Administrative Code, and must be filed (received) in the Office of General Counsel of the Department at 2600 Blair Stone Road, Twin Towers Office Building Tallahassee, Florida 32301, within fourteen (14) days of publication of this notice. Failure to file a request for hearing within this time period shall constitute a waiver of any right such person may have to request an administrative determination (hearing) under Section 120.57, Florida Statutes.

If a petition is filed, the administrative hearing process is designed to formulate agency action. Accordingly, the Department's final action may be different from the position taken by it in this preliminary statement. Therefore, persons who may not object to the proposed agency action may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Model Rule 28-5.207 at least five (5) days before the final hearing and be filed with the hearing officer if one has been assigned at the Division of Administrative Hearings, Department of Administration, 2009 Apalachee Parkway, Tallahassee, Florida 32301. If no hearing officer has been assigned at the Division of Administrative Hearings, Department Office of General Counsel, 2600 Blair Stone Road, Tallahassee, Florida 32301. Failure to petition to intervene within the allowed time frame constitutes a waiver of any right such person has to request a hearing under Section 120.57, Florida Statutes.

The applications are available for public inspection during normal business hours 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays at:

Dept. of Environmental Regulation
Southeast District
3301 Gun Club Road
West Palm Beach, Florida 33402

Dept. of Environmental Regulation
Bureau of Air Quality Management
2600 Blair Stone Road
Tallahassee, Florida 32301

Dade County Department of Environmental Resources Management
Metro Dade Governmental Center
Suite 310
111 N.W. 1st Street
Miami, Florida 33128

Any person may send written comments on the proposed action to Mr. Bill Thomas at the department's Tallahassee address. All comments mailed within 30 days of the publication of this notice will be considered in the department's final determination.

April 6, 1987
Ad NO: 888619N

DER
APR 20 1987
BAQM

Airborne Letter Express
MIA 590 119321

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

DER

APR 20 1987

BAQM

April 16, 1987

Mr. C.H. Fancy, P.E., Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: PERMIT NO. AC 13-129893

Dear Mr. Fancy:

Key Pharmaceuticals, Inc. is in receipt of the Technical Evaluation and Preliminary Determination for the above referenced DER permit. The Public Notice for this permit was published in the legal section of the Miami News on April 6, 1987. Documentation concerning this publication has been forwarded to your department under separate cover.

Key Pharmaceuticals, Inc. personnel have reviewed the documentation provided by BAQM in detail, and find the Technical Evaluation and Preliminary Determination complete and accurate. Key Pharmaceuticals, Inc. would like to submit the following comments for consideration:

1. Replace the manufacturer specific term "Accela-Cota" with the following: "Perforated Pan Coating Unit".

2. Replace specific condition number 4 as follows: "The carbon adsorption/solvent recovery system shall remove a minimum of 90% of the methylene chloride and methanol emitted by the process equipment (Glatt and perforated pan coaters) during the equipment process cycle. Compliance with this standard shall be determined using the concentration data from continuous monitors on the inlet and discharge of the carbon adsorbers".

In addition to these comments, Key would like at this time to reply to the letter dated January 28, 1987 from C.H. Fancy to T. Flachmeyer titled "8 permit applications for construction of various manufacturing equipment" (letter is enclosed as Attachment I).

In the above referenced letter BAQM has requested pollution control, specifically VOC emission control, be added to the pan coating equipment in application number 8. At this time Key Pharmaceuticals, Inc. would like to request that the equipment in permit application number 8 be included in the permit number AC 13-129893. The carbon adsorber/solvent recovery system has been sized to accommodate this additional loading. This will facilitate a 90% reduction in VOC emissions from this equipment. Attachment II includes a revision of Pages 4, 5 and 6 of the permit application and a worksheet reflecting the revised calculations. Due to the higher air flow capabilities of the adsorber the emission potential of the equipment was doubled. This was accomplished by reducing the lot cycle from 24 hours to 12 hours.

These changes are reflected in Attachment II.

The carbon adsorption system will not be operational until June, 1988. Therefore, as part of application number 8, Key Pharmaceuticals, Inc. would like to be permitted to manufacture 128 lots of Drug 0420 in 1987 and 128 lots of Drug 0420 in the first half of 1988. The VOC emissions from this product are 10.6 tons per 128 lots. The calculations for this are included in Attachment III. The facilities VOC emissions in tons per year are tabulated in Attachment IV. At no time will the facilities regulated VOC (methylene chloride not included) emissions exceed 100 tons per year.

Your prompt review of these comments will be appreciated.

Should you have any questions or comments, please do not hesitate to call me (305-654-2240).

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

attachments

ATTACHMENT I

letter from C.H. Fancy to T. Flachmeyer (dated 1/28/87)

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

January 28, 1987

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Mr. Thomas W. Flachmeyer, Manager
Environmental Engineering and Waste Management
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307

Dear Mr. Flachmeyer:

Re: 8 Permit Applications for Construction of Various Manufacturing Equipment

The bureau has made a preliminary review of the 8 applications for construction of various manufacturing equipment at Key Pharmaceutical's Miami facility. Based on our general policy, your applications will be processed as follows:

Application No. 1 (AC 13-129891): Increase production and emissions of 2 existing plus 1 permitted Glatt units.

Application Nos. 2, 3, & 4 (AC 13-129893): Carbon absorption unit to replace the existing scrubber system and control emissions from 3 Glatt units (above), one new Glatt unit (4th unit), and 2 pan coating process units.

Application No. 5 (AC 13-129894): 4 table presses - Tablet press room No. 1 and 2 with dust collector.

Application No. 5 (AC 13-129895): 4 table presses - Tablet press room No. 3 and 4 with dust collector.

Application Nos. 6 and 7 (AC 13-129897): Granulator and dryer with dust collector.

Application No. 8 (AC 13-129899): 6 coating pans and 3 drying rooms.

As a result of processing your applications as listed above, the fees for applications Nos. 3 and 4 are not required. Schering Corporation's checks for these fees (Midlantic No. 7032 for

$1,000 and Midlantic NO. 7072 for $750) are being returned to you in this letter.

We note in application No. 8, 6 Coating Pans and 3 Drying Rooms, that Key Pharmaceuticals proposes to discharge up to 66.75 lbs/hr and 97.5 TPY of volatile organic compounds (VOC) into an ozone nonattainment area without any controls to remove VOC. The bureau believes that some control is necessary for this quantity of emissions. We request you investigate the use of some type of VOC controls to reduce emissions prior to the department reviewing this application. Air pollution control equipment that should be considered for this source are use of the existing methyl alcohol scrubber system, use of the proposed carbon absorption system, a condenser, use of a combustion unit (flare, catalytic combustion, etc.) or any other form of control to reduce VOC emissions that your company feels is feasible. Include the reduction in VOC emissions and the cost of the control (capitol and operations) to the company in you reply.

The bureau will begin processing your application Nos. 1 through 7. We will begin processing application No. 8 after you reply on the use of air pollution controls for VOC for this process. If you have any questions, please call Willard Hanks at (904)488-1344 or write to me at the letterhead address.

Sincerely,

C. H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality
Management

CHF/WH/s

cc: S. Brooks
P. Wong

enclosure

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

No 76143

RECEIPT FOR APPLICATION FEES AND MISCELLANEOUS REVENUE

Received from Schering Corporation Date Jan. 26, 1987

Address 50 N.W. 176th Street, Miami, FL 33169 Dollars $ 3200.00

Applicant Name & Address Key Pharmaceuticals, Inc.

Source of Revenue

Revenue Code 001031 Application Number AC13-129491, -129893, 129894, -129895, -129897, -129899

By Patricia G. Adams

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7072

[redacted]

JANUARY 20 1987

PAY TO THE ORDER OF FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATIONS $ 750.00

SEVEN HUNDRED FIFTY AND 00/100----------DOLLARS

MIDLANTIC
Midlantic National Bank
Metro Park Office, Edison, N.J. 08818

FOR PERMIT FEE

[redacted]

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7032

[redacted]

DECEMBER 12 1986

PAY TO THE ORDER OF FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATION $ 1,000.00

ONE THOUSAND AND 00/100----------DOLLARS

MIDLANTIC
Midlantic National Bank
Metro Park Office, Edison, N.J. 08818

FOR PERMIT (GLATT 4)

[redacted]

ATTACHMENT II

Revisions to Application No. 8

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

No 76143

RECEIPT FOR APPLICATION FEES AND MISCELLANEOUS REVENUE

Received from Schering Corporation Date Jan. 26, 1987

Address 50 N.W. 176th Street, Miami, FL 33169 Dollars $ 3200.00

Applicant Name & Address Key Pharmaceuticals, Inc.

Source of Revenue

Revenue Code 001031 Application Number AC 13-129891, -129893, 129894 -129895, -129897, -129899

By Patricia G. Adams

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7072

[redacted]

JANUARY 20 1987

PAY TO THE ORDER OF FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATIONS $ 750.00

SEVEN HUNDRED FIFTY AND 00/100----------DOLLARS

MIDLANTIC
Midlantic National Bank
Metro Park Office, Edison, N.J. 08818

FOR PERMIT FEE

[redacted]

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7032

[redacted]

DECEMBER 12 1986

PAY TO THE ORDER OF FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATION $ 1,000.00

ONE THOUSAND AND 00/100----------DOLLARS

MIDLANTIC
Midlantic National Bank
Metro Park Office, Edison, N.J. 08818

FOR PERMIT (GLATT 4)

[redacted]

SECTION III: AIR POLLUTION SOURCES & CONTROL DEVICES (Other than Incinerators)

A. Raw Materials and Chemicals Used in your Process, if applicable:

Description	Contaminants		Utilization * Rate - lbs/hr	Relate to Flow Diagram
	Type	% Wt		
SOLVENTS	VOC	100%	22.25	"A"

* based on solvents used in 24 hours.

B. Process Rate, if applicable: (See Section V, Item 1)

1. Total Process Input Rate (lbs/hr): 84.75

2. Product Weight (lbs/hr): 62.2

C. Airborne Contaminants Emitted: (Information in this table must be submitted for each emission point, use additional sheets as necessary)

Name of Contaminant	Emission[1]		Allowed[2] Emission Rate per Rule 17-2	Allowable[3] Emission lbs/hr	Potential[4] Emission		Relate to Flow Diagram
	Maximum lbs/hr	Actual T/yr			lbs/yr	T/yr	
PARTICULATE	0.50	1.00				4.97	"A"
VOC	66.81 **	18.13				181.32	"A"

** based on all solvents used in 8 hours.

[1]See Section V, Item 2.

[2]Reference applicable emission standards and units (e.g. Rule 17-2.600(5)(b)2. Table II, E. (1) - 0.1 pounds per million BTU heat input)

[3]Calculated from operating rate and applicable standard.

[4]Emission, if source operated without control (See Section V, Item 3).

D. Control Devices: (See Section V, Item 4)

Name and Type (Model & Serial No.)	Contaminant	Efficiency	Range of Particles Size Collected (in microns) (If applicable)	Basis for Efficiency (Section V Item 5)
Depth filter	Particulate	80%	2 micron or larger	Supplier's design
Carbon filter	VOC	90%	N / A	Supplier's design

E. Fuels

Type (Be Specific)	Consumption*		Maximum Heat Input (MMBTU/hr)
	avg/hr	max./hr	

*Units: Natural Gas--MMCF/hr; Fuel Oils--gallons/hr; Coal, wood, refuse, other--lbs/hr.

Fuel Analysis:

Percent Sulfur: _____ Percent Ash: _____

Density: _____ lbs/gal Typical Percent Nitrogen: _____

Heat Capacity: _____ BTU/lb _____ BTU/gal

Other Fuel Contaminants (which may cause air pollution): _____

F. If applicable, indicate the percent of fuel used for space heating.

Annual Average _____ Maximum _____

G. Indicate liquid or solid wastes generated and method of disposal.

Filters are removed every two weeks and replaced. Filters are disposed of off-site at an approved facility.

H. Emission Stack Geometry and Flow Characteristics (Provide data for each stack):

Stack Height: 35 ft. Stack Diameter: 3.5 ft.

Gas Flow Rate: 32,000 ACFM _____ DSCFM Gas Exit Temperature: 80° to 90° °F.

Water Vapor Content: 25 % Velocity: 55.4 FPS

SECTION IV: INCINERATOR INFORMATION

Type of Waste	Type 0 (Plastics)	Type I (Rubbish)	Type II (Refuse)	Type III (Garbage)	Type IV (Pathological)	Type V (Liq.& Gas By-prod.)	Type VI (Solid By-prod.)
Actual lb/hr Incinerated							
Uncontrolled (lbs/hr)							

Description of Waste _____

Total Weight Incinerated (lbs/hr) _____ Design Capacity (lbs/hr) _____

Approximate Number of Hours of Operation per day _____ day/wk _____ wks/yr. _____

Manufacturer _____

Date Constructed _____ Model No. _____

	Volume $(ft)^3$	Heat Release (BTU/hr)	Fuel		Temperature (°F)
			Type	BTU/hr	
Primary Chamber					
Secondary Chamber					

Stack Height: _____ ft. Stack Diamter: _____ Stack Temp. _____

Gas Flow Rate: _____ ACFM _____ DSCFM* Velocity: _____ FPS

*If 50 or more tons per day design capacity, submit the emissions rate in grains per standard cubic foot dry gas corrected to 50% excess air.

Type of pollution control device: [ ] Cyclone [ ] Wet Scrubber [ ] Afterburner

[ ] Other (specify) _____

KEY PHARMACEUTICALS
EMISSION CALCULATIONS
PAN COATING AT MAXIMUM PRODUCTION CAPACITY

PREPARED BY: V.K. Technologies
CHECKED BY: _____

BASIS :

#1 NUMBER OF ACTIVE PAN LOTS : 2190 LOTS

ACTIVE LOT CYCLE TIME : 12 HOURS

ANNUAL OPERATING HOURS : 26280 HOURS

LOT SPECIFICATIONS :

EXCIPIENTS : 247 LBS

VOC : 89 LBS

A. PARTICULATE EMISSIONS

(i) EMISSION POTENTIAL

1/2 OF 1% OF LOT

0.005 * 2190 * 246.96 / 2000 = 1.35 TONS/YEAR

(ii) MAXIMUM INSTANTANEOUS EMISSION POTENTIAL

ASSUMING A PAN ROTATION CYCLE OF 8 HOURS
WITH ALL 6 PANS SIMULTANEOUSLY

246.96 * 6 * 0.005 / 8 = 0.93 LBS/HOUR

(iii) MAXIMUM INSTANTANEOUS EMISSIONS

DEPTH FILTER DESIGN - 80% REMOVAL EFFICIENCY

0.9261 * 0.2 = 0.19 LBS/HOUR

(iv) AVERAGE ANNUAL EMISSIONS

1.352106 * 0.2 = 0.27 TONS/YEAR
==========
0.02 LBS/HOUR
==========

B. VOC EMISSIONS

(i) MAXIMUM INSTANTANEOUS EMISSIONS POTENTIAL

ASSUMING A PAN ROTATION OF 8 HOURS WITH
ALL 6 PAN OPERATING IN THE SOLVENTS MODE SIMULTANEOUSLY

89 * 6 / 8 = 66.81 LBS/HOUR

(ii) MAXIMUM INSTANTANEOUS EMISSIONS

CONTROL SYSTEM DESIGN 90 %REMOVAL EFFICIENCY

0.1 *66.80653 = 6.68 LBS/HOUR

(iii) AVERAGE ANNUAL EMISSIONS POTENTIAL

89 * 2190 / 2000 = 97.54 TONS/YEAR

(iv) AVERAGE ANNUAL EMISSIONS

CONTROL SYSTEM DESIGN 90 %REMOVAL EFFICIENCY

0.1 *97.53754 = 9.75 TONS/YEAR
==========
0.74 LBS/HOUR
==========

BASIS :

#2 NUMBER OF WAX PAN LOTS : 2190 LOTS

WAX LOT CYCLE TIME : 12 HOURS

ANNUAL OPERATING HOURS : 26280 HOURS

LOT SPECIFICATIONS :

EXCIPIENTS : 662 LBS

VOC : 77 LBS

A. PARTICULATE EMISSIONS

(i) EMISSION POTENTIAL

1/2 OF 1% OF LOT

0.005 * 2190 * 661.5 / 2000 = 3.62 TONS/YEAR

(ii) MAXIMUM INSTANTANEOUS EMISSION POTENTIAL

ASSUMING A PAN ROTATION CYCLE OF 8 HOURS
WITH ALL 6 PANS SIMULTANEOUSLY

661.5 * 6 * 0.005 / 8 = 2.48 LBS/HOUR

(iii) MAXIMUM INSTANTANEOUS EMISSIONS

DEPTH FILTER DESIGN - 80% REMOVAL EFFICIENCY

2.480625 * 0.2 = 0.50 LBS/HOUR

(iv) AVERAGE ANNUAL EMISSIONS

3.621712 * 0.2 = 0.72 TONS/YEAR
==========
0.06 LBS/HOUR
==========

B. VOC EMISSIONS

(i) MAXIMUM INSTANTANEOUS EMISSIONS POTENTIAL

ASSUMING A PAN ROTATION OF 8 HOURS WITH
ALL 6 PAN OPERATING IN THE SOLVENTS MODE SIMULTANEOUSLY

77 * 6 / 8 = 57.39 LBS/HOUR

(ii) MAXIMUM INSTANTANEOUS EMISSIONS

CONTROL SYSTEM DESIGN 90 %REMOVAL EFFICIENCY

0.1 *57.38512 = 5.74 LBS/HOUR

(iii) AVERAGE ANNUAL EMISSIONS POTENTIAL

77 * 2190 / 2000 = 83.78 TONS/YEAR

(iv) AVERAGE ANNUAL EMISSIONS

CONTROL SYSTEM DESIGN 90 %REMOVAL EFFICIENCY

0.1 *83.78228 = 8.38 TONS/YEAR
==========
0.64 LBS/HOUR
==========

TOTAL EMISSIOMS

(i) PARTICULATE

EMISSION POTENTIAL	1.352106 +3.621712 =	4.97 TONS/YEAR
MAX. INST. POTENTIAL	0.9261 !2.480625 =	2.48 LBS/HOUR
MAX. INST. EMISSIONS	0.18522 !0.496125 =	0.50 LBS/HOUR
AVG. ANNUAL EMISSIONS	0.270421 +0.724342 =	0.99 TONS/YEAR
		==========
		0.08 LBS/HOUR
		==========

(ii) VOC

EMISSION POTENTIAL	97.53754 +83.78228 =	181.32 TONS/YEAR
MAX. INST. POTENTIAL	66.80653 !57.38512 =	66.81 LBS/HOUR
MAX. INST. EMISSIONS	6.680653 !5.738512 =	6.68 LBS/HOUR
AVG. ANNUAL EMISSIONS	9.753754 +8.378228 =	18.13 TONS/YEAR
		==========
		4.14 LBS/HOUR
		==========

ATTACHMENT III

VOC Emission Calculations for Drug 0420

KEY PHARMACEUTICALS
EMISSION CALCULATIONS
PAN COATING OF DRUG 0420

PREPARED BY: _____
CHECKED BY: _____

BASIS :

#1 NUMBER OF ACTIVE PAN LOTS : 128 LOTS

ACTIVE LOT CYCLE TIME : 24 HOURS

ANNUAL OPERATING HOURS : 3072 HOURS

LOT SPECIFICATIONS :

EXCIPIENTS : 247 LBS

VOC : 89 LBS

A. PARTICULATE EMISSIONS

(i) EMISSION POTENTIAL

1/2 OF 1% OF LOT

0.005 * 128 * 246.96 / 2000 = 0.08 TONS/YEAR

(ii) MAXIMUM INSTANTANEOUS EMISSION POTENTIAL

ASSUMING A PAN ROTATION CYCLE OF 8 HOURS
WITH ALL 6 PANS SIMULTANEOUSLY

246.96 * 6 * 0.005 / 8 = 0.93 LBS/HOUR

(iii) MAXIMUM INSTANTANEOUS EMISSIONS

DEPTH FILTER DESIGN - 80% REMOVAL EFFICIENCY

0.9261 * 0.2 = 0.19 LBS/HOUR

(iv) AVERAGE ANNUAL EMISSIONS

0.079027 * 0.2 = 0.02 TONS/YEAR
==========
0.01 LBS/HOUR
==========

B. VOC EMISSIONS

(i) MAXIMUM INSTANTANEOUS EMISSIONS

ASSUMING A PAN ROTATION OF 8 HOURS WITH
ALL 6 PAN OPERATING IN THE SOLVENTS MODE SIMULTANEOUSLY

89 * 6 / 8 = 66.81 LBS/HOUR

(ii) AVERAGE ANNUAL EMISSIONS

89 * 128 / 2000 = 5.70 TONS/YEAR
==========
3.71 LBS/HOUR
==========

BASIS :

#2 NUMBER OF WAX PAN LOTS : 128 LOTS

WAX LOT CYCLE TIME : 24 HOURS

ANNUAL OPERATING HOURS : 3072 HOURS

LOT SPECIFICATIONS :

EXCIPIENTS : 662 LBS

VOC : 77 LBS

A. PARTICULATE EMISSIONS

(i) EMISSION POTENTIAL

1/2 OF 1% OF LOT

0.005 * 128 * 661.5 / 2000 = 0.21 TONS/YEAR

(ii) MAXIMUM INSTANTANEOUS EMISSION POTENTIAL

ASSUMING A PAN ROTATION CYCLE OF 8 HOURS
WITH ALL 6 PANS SIMULTANEOUSLY

661.5 * 6 * 0.005 / 8 = 2.48 LBS/HOUR

(iii) MAXIMUM INSTANTANEOUS EMISSIONS

DEPTH FILTER DESIGN - 80% REMOVAL EFFICIENCY

2.480625 * 0.2 = 0.50 LBS/HOUR

(iv) AVERAGE ANNUAL EMISSIONS

0.21168 * 0.2 = 0.04 TONS/YEAR
==========
0.03 LBS/HOUR
==========

B. VOC EMISSIONS

(i) MAXIMUM INSTANTANEOUS EMISSIONS

ASSUMING A PAN ROTATION OF 8 HOURS WITH
ALL 6 PAN OPERATING IN THE SOLVENTS MODE SIMULTANEOUSLY

77 * 6 / 8 = 57.39 LBS/HOUR

(ii) AVERAGE ANNUAL EMISSIONS

77 * 128 / 2000 = 4.90 TONS/YEAR
==========
3.19 LBS/HOUR
==========

TOTAL EMISSIONS

(i) PARTICULATE

EMISSION POTENTIAL	0.079027 + 0.21168 =	0.29	TONS/YEAR
MAX. INST. POTENTIAL	0.9261 !2.480625 =	2.48	LBS/HOUR
MAX. INST. EMISSIONS	0.18522 !0.496125 =	0.50	LBS/HOUR
AVG. ANNUAL EMISSIONS	0.015805 +0.042336 =	0.06	TONS/YEAR
		0.04	LBS/HOUR

(ii) VOC

MAX. INST. EMISSIONS	66.80653 !57.38512 =	66.81	LBS/HOUR
AVG. ANNUAL EMISSIONS	5.700824 +4.896864 =	10.60	TONS/YEAR
		6.90	LBS/HOUR

ATTACHMENT IV

Key Pharmaceuticals, Inc.

50 N.W. 176th Street Facility

VOC Emission Tabulations

KEY PHARMACEUTICALS, INC.
50 N.W.176TH STREET
MIAMI FACILITY

REGULATED VOC EMISSIONS
(EXCEPT METHYLENE CHLORIDE)

PROPOSED EMISSIONS POTENTIAL
(tons/year)

		1987		1988		1989
		JAN-JUNE	JULY-DEC	JAN-JUNE	JULY-DEC	
AO 13-129470	QUINORA & GUANIDINE	0.475	0.475	0.475	0*	0*
AC 13-128475	DRUG 0420	0.450	0**	0**	0**	0**
AC 13-129891	GLATT 1-3	10.150	10.150	10.150	0***	0***
AC 13-129897	GRANULATION	-	15.100	15.100	15.100	30.200
AC 13-129893	CARBON ADSORBER	-	10.600	10.600	28.115	56.230
		11.075	36.325	36.325	43.215	86.430
TOTAL PER YEAR			47.400		79.540	86.430

NOTE: * EMISSIONS INCLUDED IN PERMIT AC 13-129897
** PERMIT AC 13-128475 REPLACED BY PERMIT FOR PAN COATING
*** EMISSIONS INCLUDED IN PERMIT AC 13-129893

KEY PHARMACEUTICALS, INC.
50 N.W.176TH STREET
MIAMI FACILITY

NON REGULATED VOC EMISSIONS
(METHYLENE CHLORIDE)

PROPOSED EMISSIONS POTENTIAL
(tons/year)

		1987		1988		1989
		JAN-JUNE	JULY-DEC	JAN-JUNE	JULY-DEC	
AC 13-129891	GLATT 1-3	1097.190	1097.190	1097.190	-	-
AC 13-129893	CARBON ADSORBER					
	GLATT 1	-	-	-	24.750	49.940
	GLATT 2	-	-	-	42.490	85.000
	GLATT 3	-	-	-	42.490	85.000
	GLATT 4	-	-	-	42.490	85.000
	ACCELA COTA 1	-	-	-	16.425	32.850
	ACCELA COTA 2	-	-	-	16.425	32.850
	PAN COATING 1-6	-	-	-	0.000	0.000
AC 13-129893	TOTAL	0.000	0.000	0.000	185.070	370.640
		1097.190	1097.190	1097.190	185.070	370.640
TOTAL PER YEAR			2194.380		1282.260	370.640

KEY PHARMACEUTICALS, INC.
50 N.W.176TH STREET
MIAMI FACILITY

REGULATED VOC EMISSIONS
(EXCEPT METHYLENE CHLORIDE)

PROPOSED EMISSIONS POTENTIAL
(tons/year)

		1987		1988		1989
		JAN-JUNE	JULY-DEC	JAN-JUNE	JULY-DEC	
AC 13-129893	CARBON ADSORBER					
	GLATT 1 *	2.280	2.280	2.280	2.280	4.560
	GLATT 2 *	3.940	3.940	3.940	3.940	7.880
	GLATT 3 *	3.940	3.940	3.940	3.940	7.880
	GLATT 4	-	-	-	3.940	7.880
	ACCELA COTA 1	-	-	-	2.475	4.950
	ACCELA COTA 2	-	-	-	2.475	4.950
	PAN COATING 1-6 **	-	10.600	10.600	9.065	18.130
AC 13-129893	TOTAL	0.000	10.600	10.600	28.115	56.230

* EMISSION FROM THIS EQUIPMENT IS INCLUDED IN AC 13-129891 IN 1987 AND JAN-JUNE IN 1988

** EMISSIONS ARE UNCONTROLLED FOR PRODUCT 0420 FROM JULY 1987 TO THE START-UP OF THE CARBON ADSORPTION/SOLVENT RECOVERY SYSTEM

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

April 13, 1987

Mr. C. H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, Florida 32301-8241

DER
APR 14 1987
BAQM

RE: PUBLIC NOTICE FOR PERMITS

Dear Mr. Fancy:

The following permit public notices were published on April 6, 1987 in the legal section of the Miami News.

AC 13 - 129891

AC 13 - 129894

AC 13 - 129895

AC 13 - 129893

Key Pharmaceuticals will issue its comments concerning these permits to your department by April 17, 1987.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/dt

Attachment

AIRBORNE EXPRESS

ORIGIN AIRBILL NO. MIA390119391

FROM (COMPANY NAME)
Key Pharmaceuticals Inc.
ADDRESS
50 N.W. 176th Street
CITY STATE ZIP CODE (REQUIRED)
Miami FL 33169
SENT BY (NAME/DEPT.) PHONE
Thomas Flachmeyer (305) 654-2240
BILLING REFERENCE INFORMATION TO APPEAR ON INVOICE

TO (COMPANY NAME)
Bureau of Air Quality Management
ADDRESS
Twin Towers Office Bldg.
2600 Blair Stone Road
CITY STATE ZIP CODE (REQUIRED)
Tallahassee FL 32301-8241
ATTN. (NAME/DEPT.) PHONE
MR. C. H. FANCY, DEPUTY CHIEF
RECEIVER'S AIRBORNE EXPRESS ACCOUNT NO.

TYPE OF PACKAGING
- [ ] EXPRESS/AD PACK ENVELOPE
- [X] LETTER EXPRESS (UP TO 8 OZ.)
- [ ] EXPRESS PACK BOX/TUBE
- [ ] MAG TAPE PACK

DESCRIPTION OF CONTENTS: DOCUMENTS

NO. OF PACKAGES	WEIGHT (LBS.)
1	2 X

ROUTING
TLH
3-B

BILL CHARGES TO (ASSUMED SENDER UNLESS OTHERWISE SPECIFIED)
- [X] SENDER
- [ ] RECEIVER
- [ ] 3RD PARTY _____ AIRBORNE EXPRESS ACCOUNT NO.
- [ ] PAID IN ADVANCE $ _____
- CHECK NUMBER _____

TYPE OF SPECIAL SERVICE (EXTRA CHARGES MAY APPLY)
- [ ] SPECIAL PICKUP
- [ ] SATURDAY DELIVERY
- [ ] SPECIAL DELIVERY _____ : TIME
- [ ] HOLD AT AIRBORNE FOR PICKUP (NO CHARGE)
- [ ]

RECEIVER'S COPY 202 (1/86)

390119391

DER
APR 14 1987
BAQM

THE MIAMI NEWS
A COX NEWSPAPER

PUBLISHED DAILY
MIAMI — DADE — FLORIDA

STATE OF FLORIDA
COUNTY OF DADE:

Before the undersigned authority personally appeared

Ann Martula

who on oath says that he/she is

Custodian of Records

of The Miami News, a daily newspaper published at Miami in Dade County, Florida; that the attached copy of advertisement was published in said newspaper in the issues of ...

April 6, 1987

Affiant further says that the said The Miami News is a newspaper published at Miami, in the said Dade County, Florida, and that the said newspaper has heretofore been continuously published in said Dade County, Florida, each day and has been entered as second class mail matter at the post office in Miami, in said Dade County, Florida, for a period of one year next preceding the first publication of the attached copy of advertisement; and affiant further says that he has neither paid nor promised any person, firm or corporation any discount, rebate, commission or refund for the purpose of securing this advertisement for publication in the said newspaper.

Ann Martula

Sworn to and subscribed before me this 16 **day of** April **A.D. 19**87

My commission expires

NOTARY PUBLIC STATE OF FLORIDA
MY COMMISSION EXP JULY 17,1989
BONDED THRU GENERAL INS. UND.

NOTARY PUBLIC STATE OF FLORIDA

116 Legal Notices

State of Florida
Department of Environmental Regulation Notice of Proposed Agency Action on Permit Application

The Department of Environmental Regulation gives notice of its intent of issue two permits to Key Pharmaceuticals, Inc. for the tablet press room operations at their existing pharmaceutical plant located at 50 N.W. 176th Street, Miami, Dade County, Florida. The tablet press room operations will result in emission of less than 1 TPY particulate matter. A determination of best control tehcnology (BACT) was not required.

Persons whose substantial interests are affected by the department's proposed permitting decision may petition for an administrative proceeding (hearing) in accordance with Section 120.57, Florida Statutes. The petition must conform to the requirements of Chapters 17-103 and 28-5, Florida Administrative Code, and must be filed (received) in the Office of General Counsel of the Department at 2600 Blair Stone Road, Twin Towers Office Building, Tallahassee, Florida 32301m within fourteen (14) days of publication of this notice. Failure to file a request for hearing within this time period shall constitute a waiver of any right such person may have to request an administrative determination (hearing) under Section 120.57, Florida Statutes.

If a petition is filed, the administrative hearing process is designed to formulate agency action. Accordingly, the Department's final action may be differnet from the position taken by it in this preliminary statement. Therefore, persons who may not object to the prosed agency action may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Model Rule 28-5.207 at least five (5) days before the final hearing and be filed with the hearing officer if one has been assigned at the Division of Administrative Hearings, Department of Administration, 2009 Apalachee Parkway, Tallahassee, Florida 32301. If no hearing officer has been assigned, the petition is to be filed with the Department's Office of General Counsel, 2600 Blair Stone Road, Tallahassee 32301. Failure to petition to intervene within the allowed time frame constitutes a waiver of any right such person has to request a hearing under Section 120.57, Florida Statutes.

The applications are available for public inspection during normal business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays, at:
Dept. of Environmental Regulation
Southeast District
3301 Gun Club Road
West Palm Beach, Florida, 33402

Dept. of Environmental Regulation
Bureau of Air Quality Management
2600 Blair Stone Road
Tallahassee, Florida 32301

Dade County Department of Environmental Resources Management
Metro Dade Governmental Center
Suite 310
111 N.W. 1st Street
Miami, Florida 33128

Any person may send written comments on the proposed action to Mr. Bill Thomas at the department's Tallahassee address. All comments mailed within 30 days of the publication of this notice will be considered in the department's final determination.
April 6, 1987
Ad No: 888-930N

DER

APR 20 1987

BAQM

DER

APR 17 1987

BAQM

File Copy

State of Florida
DEPARTMENT OF ENVIRONMENTAL REGULATION

Interoffice Memorandum

FOR ROUTING TO OTHER THAN THE ADDRESSEE

To: _____ Loctn: _____
To: _____ Loctn: _____
To: _____ Loctn: _____
From: _____ Date: _____

TO: Bill Thomas

FROM: Stephanie S. Brooks Stephanie S Brooks

DATE: April 8, 1987

RE: Key Pharmaceuticals - Permit Numbers: AC13-129894 AC13-129895, AC13-129897, AC13-129891 & AC13-129893

I have several comments on Key Pharmaceuticals' Construction Permits:

AC13-129894 & AC13-129895

1.) Is an expiration date of October 1, 1987 going to be enough time for them to submit an operation permit application including a Compliance Test 90 days before 10/1/87?
2.) The Air Section feels that a Method 5 and Method 9 are required initially with 5% VE in lieu of a Stack Test for every year except renewal when both would be required to be reasonable.

AC13-129897

1.) The Air Section feels that a Method 5 and Method 9 are required initially and that a Method 9 could be done in lieu of a Stack Test every year except for renewal.

AC13-129891

1.) Specific Condition No. 3
Particulate Matter Emission rate should be 0.047 lb./hr. not 0.5 lb./hr. unless the baghouse is 90% efficient rather than 99% efficient.
2.) Methanol Testing frequency is ok. Particulate Matter Testing Method 5 and Method 9 should be required initially and at renewal with a VE in lieu of Stack Test during the rest of the permit's time.
3.) Also, the permit expires 6 months prior to the installation deadline for the carbon absorption system.
4.) General comments on the preliminary determination - if the applicant's calculations are going to be used then they should be checked more carefully and a better explanation of the Emissions Table should be included. The Table is misleading and if just glanced at, confusing. If the lb./hr. were labeled mas lb./hr. and TPY as Potential TPY, it would serve its function much better.

AC13-129893

1.) Test methods should require an initial Compliance Test for VOC & Particulate (Methods 5 & 9) and prior to renewal with the production records used to verify VOC Emissions and a VE for Particulate in the interim.

DEPARTMENT OF ENVIRONMENTAL REGULATION

ROUTING AND TRANSMITTAL SLIP

ACTION NO

ACTION DUE DATE

	Initial	Date
1. TO: (NAME, OFFICE, LOCATION) ~~Bill Thomas, BAQM~~		
2. ~~Clair Fancy~~		
3. DER		
4. APR 17 1987 BAQM		

REMARKS:

Comments of Key Pharmaceuticals permits

~~Clair~~
Bill,
I have copied Willard.

Bruce

INFORMATION

- Review & Return
- Review & File
- Initial & Forward

DISPOSITION

- Review & Respond
- Prepare Response
- For My Signature
- For Your Signature
- Let's Discuss
- Set Up Meeting
- Investigate & Report
- Initial & Forward
- Distribute
- Concurrence
- For Processing
- Initial & Return

FROM: S. Brooks

DATE 4-8-87

PHONE 221-5005

FI

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7

```
MPTPLU
    - MODEL FOR SCREENING MAXIMUM CONCENTRATIONS FOR MULTIPLE SOURCES
      MODIFIED FROM PTPLU


*** TITLE OF SOURCE #  1 ***

*** TEST OF MPTPLU ***

)))INPUT PARAMETERS(((

***OPTIONS***
IF = 1, USE OPTION
IF = 0, IGNORE OPTION
IOPT(1) = 0  (GRAD PLUME RISE)
IOPT(2) = 0  (STACK DOWNWASH)
IOPT(3) = 0  (BLDY. INDUCED DISP.)
IOPT(4) = 1  (EXTRAPOLATED WIND)

***METEOROLOGY***
AMBIENT AIR TEMPERATURE =    293.00 (K)
MIXING HEIGHT            =   2000.00 (M)
ANEMOMETER HEIGHT        =     10.00 (M)
WIND EXTRAPOLATION EXPONENTS  = A: .10, B: .15, C: .20
                                D: .25, E: .30, F: .30

***RECEPTOR HEIGHT***   =      .00 (M)

***SOURCE***
EMISSION RATE =  2.61E+00 (G/SEC)
STACK HEIGHT  =      3.35 (M)
EXIT TEMP.    =    294.11 (K)
EXIT VELOCITY =     25.87 (M/SEC)
STACK DIAM.   =       .30 (M)
VOLUME FLOW   =  1.89E+00 (M**3/SEC)

)))CALCULATED PARAMETERS(((

VOLUMETRIC FLOW =  1.89E+00 (M**3/SEC)
BUOYANCY FLUX PARAMETER =       .02 (M**4/SEC**3)


        *** MAXIMUM CONCENTRATION FOR SOURCE #  1 ***

   **** STACK TOP WINDS EXTRAPOLATED FROM 10.0 METERS ****

    *** WIND SPEED AT 10.0 METER HEIGHT IS GIVEN HERE ***
STABILITY   WIND SPEED   MAX CONC    DIST OF MAX    PLUME HT
             (M/SEC)     (UG/CU M)      (KM)          (M)
   6           1.00     1.4375E+03      .700          13.2

        **** CORRESPONDING SPATIAL DISTRIBUTION ****
         DISTANCE (KM)       CONCENTRATION (UG/M**3)
              .1                 3.5451E-06
              .2                 1.4461E+01
              .3                 2.8842E+02
              .5                 1.1877E+03
              .7                 1.4375E+03
```

Key Pharmaceuticals, Inc.
Granulation Process
VOC emission

20.7 lb/hr VOC
11'
70°F
17 FPS ← apple Roo 67 FPS
1'
4000 ACFM ← 1' D, model actually run @ 84 FPS
Predicted impact should be slightly higher

4000 FT³/MIN / 60 SEC ÷ 1 FT² = 67 FPS

← Max Impact

TLV Isopropyl Alcohol
400 PPM
980 mg/m³ = 980,000 ug/m³
moderate Toxicity Air Contaminant
1% TLV = 9,800 ug/m³
2% TLV = 19,600 ug/m³

Max 1 hr impact = 1,438 ug/m³
= (1438)(0.7) = 1007 ug

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AMBIENT AIR TEMPERATURE = 293.00 (K)
MIXING HEIGHT = 2000.00 (M)
ANEMOMETER HEIGHT = 10.00 (M)
WIND EXTRAPOLATION EXPONENTS = A: .10, B: .15, C: .20
D: .25, E: .30, F: .30

RECEPTOR HEIGHT = .00 (M)

SOURCE
EMISSION RATE = 2.61E+00 (G/SEC) 20.7 lb/hr VOC
STACK HEIGHT = 3.35 (M) 11'
EXIT TEMP. = 294.11 (K) 70°F
EXIT VELOCITY = 25.87 (M/SEC) 17 FPS ← Apple Rec 67 FPS
STACK DIAM. = .30 (M) 1'
VOLUME FLOW = 1.89E+00 (M**3/SEC) 4000 ACFM ← 1'D, model actually run @ 84 FPS
Preferred input should be slightly higher

)))CALCULATED PARAMETERS(((

VOLUMETRIC FLOW = 1.89E+00 (M**3/SEC)
BUOYANCY FLUX PARAMETER = .02 (M***4/SEC**3)

*** MAXIMUM CONCENTRATION FOR SOURCE # 1 ***

**** STACK TOP WINDS EXTRAPOLATED FROM 10.0 METERS ****

*** WIND SPEED AT 10.0 METER HEIGHT IS GIVEN HERE ***

STABILITY	WIND SPEED (M/SEC)	MAX CONC (UG/CU M)	DIST OF MAX (KM)	PLUME HT (M)
6	1.00	1.4375E+03	.700	16.2

**** CORRESPONDING SPATIAL DISTRIBUTION ****

DISTANCE (KM)	CONCENTRATION (UG/M**3)
.1	3.5451E-06
.2	1.4461E+01
.3	2.8842E+02
.5	1.1877E+03
.7	1.4375E+03 ← Max Impact 1 hr
1.0	1.2423E+03
1.5	8.7063E+02
2.0	6.3209E+02
3.0	3.8803E+02
5.0	2.0672E+02
7.0	1.3472E+02
10.0	8.6279E+01
15.0	5.1749E+01
20.0	3.6798E+01
30.0	2.2754E+01
50.0	1.2752E+01

*** SPATIAL DISTRIBUTION OF WORST CONDITIONS ***
(CUMULATED FOR THE LAST 1 SOURCE(S))

DISTANCE (KM)	MAX CONC (UG/M**3)	STABILITY	WIND (M/SEC)
.1	1.0896E+03	4	10.00
.2	8.9753E+02	5	5.00
.3	9.6852E+02	5	2.00
.5	1.1877E+03	6	1.00
.7	1.4375E+03	6	1.00
1.0	1.2423E+03	6	1.00
1.5	8.7063E+02	6	1.00
2.0	6.3209E+02	6	1.00
3.0	3.8803E+02	6	1.00
5.0	2.0672E+02	6	1.00
7.0	1.3472E+02	6	1.00
10.0	8.6279E+01	6	1.00
15.0	5.1749E+01	6	1.00

TLV Isopropyl Alcohol
400 PPM
980 mg/m³ = 980,000 ug/m³ Air Contaminant
moderate Toxicity
1% TLV = 9,800 ug/m³
2% TLV = 19,600 ug/m³

Max 1 hr impact = 1,438 ug/m³
Max 8 hr impact = (1438)(0.7) = 1007 ug/m³

Avg 8 hr emission = 20.7 lb/hr
Max impact is 1% TLV For 8 hrs

Avg 24 hr impact = 1438 ug/m³ × 6.9 lb/hr / 20.7 lb/hr × 0.4 ≈ 480 ug/m³

480 × 100 / 980,000 ≈ 0.05 % of TLV for 24 hrs

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Key Pharmaceuticals, Inc. - Combined Impact 3 sources - 2/10/87

```
 MPTPLU
 MODEL FOR SCREENING MAXIMUM CONCENTRATIONS FOR MULTIPLE SOURCES
      MODIFIED FROM PTPLU

 *** TITLE OF SOURCE #  1 ***

 dray 0420

 >>>INPUT PARAMETERS<<<

 ***OPTIONS***
 IF = 1, USE OPTION
 IF = 0, IGNORE OPTION
 IOPT(1) = 0  (GRAD PLUME RISE)
 IOPT(2) = 0  (STACK DOWNWASH)
 IOPT(3) = 0  (BUOY. INDUCED DISP.)
 IOPT(4) = 1  (EXTRAPOLATED WIND)

 ***METEOROLOGY***
 AMBIENT AIR TEMPERATURE =   293.00 (K)
 MIXING HEIGHT           =  2000.00 (M)
 ANEMOMETER HEIGHT       =    10.00 (M)
 WIND EXTRAPOLATION EXPONENTS = A: .10, B: .15, C: .20
                                D: .25, E: .30, F: .30
 ***RECEPTOR HEIGHT*** =      .00 (M)

 ***SOURCE***
 EMISSION RATE =  1.17E+00 (G/SEC)  — 9.3 lb/hr (total VOC)
 STACK HEIGHT  =     3.35 (M)       — 11'
 EXIT TEMP.    =   294.11 (K)       — 70°F
 EXIT VELOCITY =    20.26 (M/SEC)   — 67 FPS
 STACK DIAM.   =      .34 (M)       — 1.13' (equivalent for 12"x12" duct)
 VOLUME FLOW   =  1.89E+00 (M**3/SEC)  4000 SCFM

 >>>CALCULATED PARAMETERS<<<
 VOLUMETRIC FLOW =  1.89E+00 (M**3/SEC)
 BUOYANCY FLUX PARAMETER =      .02 (M**4/SEC**3)

      *** MAXIMUM CONCENTRATION FOR SOURCE #  1 ***

   **** STACK TOP WINDS EXTRAPOLATED FROM 10.0 METERS ****

   *** WIND SPEED AT 10.0 METER HEIGHT IS GIVEN HERE ***
 STABILITY   WIND SPEED   MAX CONC.   DIST OF MAX   PLUME RISE
               (M/SEC)   (UG/CU-M)       (KM)         (M)
    5            1.00   7.4212E+02        .650        15.2

      **** CORRESPONDING SPATIAL DISTRIBUTION ****
        DISTANCE (KM)      CONCENTRATION (UG/M**3)
                .1          2.9451E-05
                .2          1.6661E+01
                .3          2.1336E+02
                .5          6.6744E+02
                .7          7.3700E+02
```

7421.2 µg/m³ MAX IMPACT FOR 0420

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1.0	6.0526E+02
	4.1060E+02
2.0	2.9372E+02
3.0	1.7815E+02
5.0	9.4136E+01
7.0	6.1127E+01
10.0	3.9048E+01
15.0	2.3371E+01
20.0	1.6604E+01
30.0	1.0257E+01
50.0	5.7437E+00

*** SPATIAL DISTRIBUTION OF WORST CONDITIONS ***
(CUMULATED FOR THE LAST 1 SOURCE(S))

DISTANCE (KM)	MAX CONC (UG/M**3)	STABILITY	WIND (M/S)
.1	5.4313E+02	4	10.00
.2	4.2530E+02	5	5.00
.3	5.1233E+02	5	2.00
.5	6.6744E+02	6	1.00
.7	7.3700E+02	6	1.00
1.0	6.0526E+02	6	1.00
1.5	4.1060E+02	6	1.00
2.0	2.9372E+02	6	1.00
3.0	1.7815E+02	6	1.00
5.0	9.4136E+01	6	1.00
7.0	6.1127E+01	6	1.00
10.0	3.9048E+01	6	1.00
15.0	2.3371E+01	6	1.00
20.0	1.6604E+01	6	1.00
30.0	1.0257E+01	6	1.00
50.0	5.7437E+00	6	1.00

ENTER POLLUTANT FLAG FOR THE NEXT SOURCE
0 NEW POLLUTANT
1 SAME POLLUTANT

?

*** TITLE OF SOURCE # 2 ***

carbon adsorption — GLATTS + OTHER EQUIP CONTROLLED BY CARBON ADSORPTION

)))INPUT PARAMETERS(((

OPTIONS
IF = 1, USE OPTION
IF = 0, IGNORE OPTION
IOPT(1) = 0 (GRAD PLUME RISE)
IOPT(2) = 0 (STACK DOWNWASH)
IOPT(3) = 0 (BUOY. INDUCED D.SP.)
IOPT(4) = 1 (EXTRAPOLATED WIND)

METEOROLOGY
AMBIENT AIR TEMPERATURE = 293.00 (K)
MIXING HEIGHT = 2000.00 (M)
MEASURE.. HEIGHT = 10.00 (M)
WIND EXTRAPOLATION EXPONENTS = A: .10, B: .15, C: .20
D: .25, E: .30, F: .30

RECEPTOR HEIGHT = .00 (M)

SOURCE
EMISSION RATE = 1.94E+00 (G/SEC) — 15.4 lb/hr alcohol
STACK HEIGHT = 10.67 (M) — 35'

BEST AVAILABLE COPY

EXIT TEMP. = ... — 90°F
EXIT VELOCITY = 16.90 (M/SEC) — 55.4 FPS
STACK DIAM. = 1.07 (M) — 3.5'
VOLUME FLOW = 1.51E+01 (M**3/SEC) — 32,000 ACFM

>>> CALCULATED PARAMETERS <<<

VOLUMETRIC FLOW = 1.51E+01 (M**3/SEC)
BUOYANCY FLUX PARAMETER = 1.05 (M**4/SEC**3)

*** MAXIMUM CONCENTRATION FOR SOURCE # 2 ***

**** STACK TOP WINDS EXTRAPOLATED FROM 10.0 METERS ****

*** WIND SPEED AT 10.0 METER HEIGHT IS GIVEN HERE ***

STABILITY	WIND SPEED (M/SEC)	MAX CONC (UG/CU-M)	DIST OF MAX (KM)	PLUME HT (M)
3	5.00	1.1692E+02	1.215	213.0

116.92 ug/m³ Max impact

**** CORRESPONDING SPATIAL DISTRIBUTION ****

DISTANCE (KM)	CONCENTRATION (UG/M**3)
.1	2.1609E+01
.2	1.1566E+02
.3	1.0080E+02
.5	5.5280E+01
.7	3.3005E+01
1.0	1.8199E+01
1.5	8.9703E+00
2.0	5.3763E+00
3.0	2.5958E+00
5.0	1.0329E+00
7.0	5.6269E-01
10.0	2.9573E-01
15.0	1.4252E-01
20.0	8.5026E-02
30.0	4.2278E-02
50.0	2.2777E-02

*** SPATIAL DISTRIBUTION OF WORST CONDITIONS ***
(CUMULATED FOR THE LAST 2 SOURCE(S)) — Sum of 2 sources

DISTANCE (KM)	MAX CONC (UG/M**3)	STABILITY	WIND (M/S)
.1	5.4746E+02	4	10.00
.2	4.8536E+02	5	5.00
.3	5.1313E+02	5	2.00
.5	6.6795E+02	6	1.00
.7	7.4838E+02	6	1.00
1.0	6.5502E+02	6	1.00
1.5	5.0855E+02	6	1.00
2.0	4.0752E+02	6	1.00
3.0	2.8060E+02	6	1.00
5.0	1.6495E+02	6	1.00
7.0	1.1290E+02	6	1.00
10.0	7.4980E+01	6	1.00
15.0	4.6406E+01	6	1.00
20.0	3.3458E+01	6	1.00
30.0	2.1019E+01	6	1.00
50.0	1.1933E+01	6	1.00

748 ug/m³ Max impact (748 ug/m³) of 0.46 + Carbon absorption

ENTER POLLUTANT FLAG FOR THE NEXT SOURCE
0 NEW POLLUTANT
1 SAME POLLUTANT

7

BEST AVAILABLE COPY

*** TITLE OF SOURCE # 3 ***

granulation ← Granulation Process (on VOC solvent)

)))INPUT PARAMETERS(((

OPTIONS
IF = 1, USE OPTION
IF = 0, IGNORE OPTION
IOPT(1) = 0 (GRAD PLUME RISE)
IOPT(2) = 0 (STACK DOWNWASH)
IOPT(3) = 0 (BUOY. INDUCED DISP.)
IOPT(4) = 1 (EXTRAPOLATED WIND)

METEOROLOGY
AMBIENT AIR TEMPERATURE = 293.00 (K)
MIXING HEIGHT = 2000.00 (M)
ANEMOMETER HEIGHT = 10.00 (M)
WIND EXTRAPOLATION EXPONENTS = A: .10, B: .15, C: .20
D: .25, E: .30, F: .30

RECEPTOR HEIGHT = .00 (M)

SOURCE
EMISSION RATE = 2.61E+00 (G/SEC) - 20.716/hr
STACK HEIGHT = 3.35 (M) - 11'
EXIT TEMP. = 294.11 (K) - 70°F
EXIT VELOCITY = 20.26 (M/SEC) - 67 FPS
STACK DIAM. = .34 (M) - 1.13' (equivalent)
VOLUME FLOW = 1.89E+00 (M**3/SEC) - 4000 ACFM

)))CALCULATED PARAMETERS(((

VOLUMETRIC FLOW = 1.89E+00 (M**3/SEC)
BUOYANCY FLUX PARAMETER = .02 (M**4/SEC**3)

*** MAXIMUM CONCENTRATION FOR SOURCE # 3 ***

**** STACK TOP WINDS EXTRAPOLATED FROM 10.0 METERS ****

*** WIND SPEED AT 10.0 METER HEIGHT IS GIVEN HERE ***

STABILITY	WIND SPEED (M/SEC)	MAX CONC (UG/CU M)	DIST OF MAX (KM)	PLUME HT (M)
6	1.00	1.6518E+03	.650	15.2

1,652 ug/m³ max impact of Granulation
1 hr max

**** CORRESPONDING SPATIAL DISTRIBUTION ****

DISTANCE (KM)	CONCENTRATION (UG/M**3)
.1	6.5553E-05
.2	3.7085E+01
.3	4.7489E+02
.5	1.4856E+03
.7	1.6404E+03 ←
1.0	1.3472E+03
1.5	9.1392E+02
2.0	6.5377E+02
3.0	3.9654E+02
5.0	2.0953E+02
7.0	1.3606E+02
10.0	8.6914E+01
15.0	5.2020E+01
20.0	3.6958E+01
30.0	2.2830E+01
50.0	1.2784E+01

50.0

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** OVERALL MAXIMUM CONCENTRATION IS FOUND IN SOURCE # 3 ***

*** WIND SPEED AT 10.0 METER HEIGHT IS GIVEN HERE ***

STABILITY	WIND SPEED (M/SEC)	MAX CONC (UG/CU M)	DIST OF MAX (KM)	PLUME HT (M)
6	1.00	1.6518E+03	1.650	15.2

(1) THE DISTANCE TO THE POINT OF MAXIMUM CONCENTRATION IS SO GREAT THAT THE SAME STABILITY IS NOT LIKELY TO PERSIST LONG ENOUGH FOR THE PLUME TO TRAVEL THIS FAR.

(2) THE PLUME IS CALCULATED TO BE AT A HEIGHT WHERE CARE SHOULD BE USED IN INTERPRETING THE COMPUTATION.

(3) NO COMPUTATION WAS ATTEMPTED FOR THIS HEIGHT AS THE POINT OF MAXIMUM CONCENTRATION IS GREATER THAN 50 KILOMETERS FROM THE SOURCE.

*** SPATIAL DISTRIBUTION OF WORST CONDITIONS *** MAX COMBINED IMPACT (3 sources)

(CUMULATED FOR THE LAST 3 SOURCE(S)) 2,389 ug/m³

DISTANCE (KM)	MAX CONC (UG/M**3)	STABILITY	WIND (M/S)
.1	1.7564E+03	4	10.00
.2	1.5655E+03	5	5.00
.3	1.6535E+03	5	2.00
.5	2.1535E+03	6	1.00
.7	2.3888E+03 ←	6	1.00
1.0	2.0022E+03	6	1.00
1.5	1.4225E+03	6	1.00
2.0	1.0613E+03	6	1.00
3.0	6.7713E+02	6	1.00
5.0	3.7447E+02	6	1.00
7.0	2.4896E+02	6	1.00
10.0	1.6189E+02	6	1.00
15.0	9.8426E+01	6	1.00
20.0	7.0416E+01	6	1.00
30.0	4.3849E+01	6	1.00
50.0	2.4717E+01	6	1.00

Stop - Program terminated.

Isopropyl Alcohol TLV = 980,000 ug/m³

1% TLV 9800 ug/m³ 8hr avg

ul 24hr/10 discharge

$\frac{1}{210}(980{,}000) = 4667$ ug/m³

∴ Combined alcohol impact of all 3 sources less than 1% TLV

P 408 531 578

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to James R. Confroy	
Key Pharmaceuticals, Inc. 50 N.W. 176th Street	
P.O., State and ZIP Code Miami, FL 33169	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt Showing to whom and Date Delivered	
Return Receipt Showing to whom, Date, and Address of Delivery	
TOTAL Postage and Fees	$
Postmark or Date 4/2/87 AC 13-129897	

PS Form 3800, Feb. 1982

PS Form 3811, July 1983 447-845

SENDER: Complete items 1, 2, 3 and 4.

Put your address in the "RETURN TO" space on the reverse side. Failure to do this will prevent this card from being returned to you. The return receipt fee will provide you the name of the person delivered to and the date of delivery. For additional fees the following services are available. Consult postmaster for fees and check box(es) for service(s) requested.

1. ☒ Show to whom, date and address of delivery.
2. ☐ Restricted Delivery.

3. Article Addressed to:
James R. Confroy
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169

4. Type of Service:	Article Number
☐ Registered ☐ Insured ☒ Certified ☐ COD ☐ Express Mail	P 408 531 578

Always obtain signature of addressee or agent and **DATE DELIVERED.**

5. Signature – Addressee
X Robert Rose

6. Signature – Agent
X

7. Date of Delivery APR 7 1987

8. Addressee's Address *(ONLY if requested and fee paid)*

DOMESTIC RETURN RECEIPT

File Copy

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

March 31, 1987

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Mr. James R. Confroy
Vice President of Operations
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169

Dear Mr. Confroy:

Attached is one copy of the Technical Evaluation and Preliminary Determination, and proposed permit to construct the granulation process at your pharmaceutical plant in Miami, Dade County, Florida.

Please submit, in writing, any comments which you wish to have considered concerning the department's proposed action to Mr. Bill Thomas of the Bureau of Air Quality Management.

Sincerely,

C. H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality
Management

CHF/pa

Attachments

cc: Isidore Goldman
Patrick Wong
John N. Wells, P.E.

BEFORE THE STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

In the Matter of
Application for Permit by:

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307

DER File No. AC 13-129897

INTENT TO ISSUE

The Department of Environmental Regulation hereby gives notice of its intent to issue a permit (copy attached) for the proposed project as detailed in the application specified above. The Department is issuing this Intent to Issue for the reasons stated in the attached Technical Evaluation and Preliminary Determination.

The applicant, Key Pharmaceuticals, Inc, applied on January 26, 1987, to the Department of Environmental Regulation for a permit to modify the granulation process at their existing pharmaceutical plant in Miami, Dade County, Florida.

The Department has permitting jurisdiction under Chapter 403, Florida Statutes and Florida Administrative Code Rules 17-2 and 17-4. The project is not exempt from permitting procedures. The Department has determined that an air construction permit was needed for the proposed work.

Pursuant to Section 403.815, F.S. and DER Rule 17-103.150, FAC, you (the applicant) are required to publish at your own expense the enclosed Notice of Proposed Agency Action on permit application. The notice must be published one time only in a section of a major local newspaper of general circulation in the county in which the project is located and within thirty (30) days from receipt of this intent. Proof of publication must be provided to the Department within seven days of publication of

the notice. Failure to publish the notice and provide proof of publication within the allotted time may result in the denial of the permit.

The Department will issue the permit with the attached conditions unless petition for an administrative proceeding (hearing) is filed pursuant to the provisions of Section 120.57, F.S. A person whose substantial interests are affected by the Department's proposed permitting decision may petition for an administrative proceeding (hearing) in accordance with Section 120.57, Florida Statutes. Petitions must comply with the requirement of Florida Administrative Code Rules 17-103.155 and 28-5.201 (copies enclosed) and be filed with (received by) the Office of General Counsel of the Department at 2600 Blair Stone Road, Tallahassee, Florida 32399-2400. Petitions filed by the permit applicant must be filed within fourteen (14) days of receipt of this intent. Petitions filed by other persons must be filed within fourteen (14) days of publication of the public notice or within fourteen (14) days of receipt of this intent, whichever first occurs. Failure to file a petition within this time period shall constitute a waiver of any right such person may have to request an administrative determination (hearing) under Section 120.57, Florida Statutes, concerning the subject permit application. Petitions which are not filed in accordance with the above provisions will be dismissed.

Executed in Tallahassee, Florida.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL REGULATION

C. H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality
Management

Copies furnished to:

James R. Confroy
Isidore Goldman
Patrick Wong

CERTIFICATE OF SERVICE

The undersigned duly designated deputy clerk hereby certifies that this NOTICE OF INTENT TO ISSUE and all copies were mailed before the close of business on April 2, 1987.

FILING AND ACKNOWLEDGEMENT
FILED, on this date, pursuant to §120.52(9), Florida Statutes, with the designated Department Clerk, receipt of which is hereby acknowledged.

R Bruce Mitchell
Clerk

4/2/87
Date

State of Florida
Department of Environmental Regulation
Notice of Proposed Agency Action
on Permit Application

The Department of Environmental Regulation gives notice of its intent to issue a permit to Key Pharmaceuticals, Inc. to modify the granulation process at their existing pharmaceutical plant located at 50 N.W. 176th Street, Miami, Dade County, Florida. The granulation process will emit less than 1 TPY particulate matter and 30.2 TPY volatile organic compounds. A determination of best available control technology (BACT) was not required.

Persons whose substantial interests are affected by the department's proposed permitting decision may petition for an administrative proceeding (hearing) in accordance with Section 120.57, Florida Statutes. The petition must conform to the requirements of Chapters 17-103 and 28-5, Florida Administrative Code, and must be filed (received) in the Office of General Counsel of the Department at 2600 Blair Stone Road, Twin Towers Office Building, Tallahassee, Florida 32301, within fourteen (14) days of publication of this notice. Failure to file a request for hearing within this time period shall constitute a waiver of any right such person may have to request an administrative determination (hearing) under Section 120.57, Florida Statutes.

If a petition is filed, the administrative hearing process is designed to formulate agency action. Accordingly, the Department's final action may be different from the position taken by it in this preliminary statement. Therefore, persons who may not object to the proposed agency action may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Model Rule 28-5.207 at least five (5) days before the final hearing and be filed with the hearing officer if one has been assigned at the Division of Administrative Hearings, Department of Administration, 2009 Apalachee Parkway, Tallahassee, Florida 32301. If no hearing officer has been assigned, the petition is to be filed with the Department's Office of General Counsel, 2600 Blair Stone Road, Tallahassee, Florida 32301. Failure to petition to intervene within the allowed time frame constitutes a waiver of any right such person has to request a hearing under Section 120.57, Florida Statutes.

The application is available for public inspection during normal business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays, at:

Dept. of Environmental Regulation
Southeast District
3301 Gun Club Road
West Palm Beach, Florida 33402

Dept. of Environmental Regulation
Bureau of Air Quality Management
2600 Blair Stone Road
Tallahassee, Florida 32301

Dade County Department of Environmental
Resources Management
Metro Dade Governmental Center
Suite 310
111 N.W. 1st Street
Miami, Florida 33128

Any person may send written comments on the proposed action to Mr. Bill Thomas at the department's Tallahassee address. All comments mailed within 14 days of the publication of this notice will be considered in the department's final determination.

RULES OF THE ADMINISTRATIVE COMMISSION
MODEL RULES OF PROCEDURE
CHAPTER 28-5
DECISIONS DETERMINING SUBSTANTIAL INTERESTS

28-5.15 Requests for Formal and Informal Proceedings

(1) Requests for proceedings shall be made by petition to the agency involved. Each petition shall be printed, typewritten or otherwise duplicated in legible form on white paper of standard legal size. Unless printed, the impression shall be on one side of the paper only and lines shall be double spaced and indented.

(2) All petitions filed under these rules should contain:

(a) The name and address of each agency affected and each agency's file or identification number, if known;

(b) The name and address of the petitioner or petitioners;

(c) All disputed issues of material fact. If there are none, the petition must so indicate;

(d) A concise statement of the ultimate facts alleged, and the rules, regulations and constitutional provisions which entitle the petitioner to relief;

(e) A statement summarizing any informal action taken to resolve the issues, and the results of that action;

(f) A demand for the relief to which the petitioner deems himself entitled; and

(g) Such other information which the petitioner contends is material.

Technical Evaluation
and
Preliminary Determination

Key Pharmaceuticals, Inc.
Miami, Florida
Dade County

Granulation Process
File No. AC 13-129897

Florida Department of Environmental Regulation
Bureau of Air Quality Management
Central Air Permitting

April 1, 1987

I. General Information

A. Applicant

Key Pharmaceuticals, Inc
50 N.W. 176th Street
Miami, Florida 33169-1307

B. Request

Mr. Thomas Flachmeyer, Manager of Environmental Engineering and Waste Management for Key Pharmaceuticals, Inc., delivered two applications for permits to construct two granulators on January 26, 1987. The applications were considered complete on receipt (January 26, 1987).

C. Project and Location

Key Pharmaceuticals, Inc. operates a granulation process at their pharmaceutical plant (SIC 2834) located at 50 N.W. 176th Street, in Miami, Dade County, Florida. The UTM coordinates of this facility are zone 17, 579.9 km E and 2868.4 km N. This existing process is currently permitted and in operation. The department requested the applicant reapply for permits for this process equipment, operating at its full potential, for any drug they may manufacture. The applications submitted by the applicant are for the administrative changes for the existing granulation proces equipment requested by the department. No construction or new source is included in this request.

The granulation process uses two granulators in an enclosed room to mix solids and solvents (water or VOC). The slurry from the granuators flows to other process equipment where wet sizing, drying, and dry sizing unit operations occur. A duct system collects the emissions from these operations and passes it through a dust collector before it is discharged to the atmosphere. The dust collector is designed to remove 99% of the particulate matter. All of the solvents pass through the dust collector and are discharged to the atmosphere.

D. Emissions

When using water for the solvent, each granulator can make one 450 kg (991 lbs) lot in 24 hours. Particulate matter emissions are expected to average 0.002 lb/hr for the lot. Both granulators will be allowed to operate with water as the solvent concurrently. Thus the maximum emission from the granulator process, with both granulators in operation, could be 0.004 lb/hr (0.02 TPY).

When using VOC (isopropanol or 3A alcohol) as the solvent, a granulator can make one 300 kg (661 lbs) lot in 24 hours. Each

lot will use 75 kg (165 lbs) of solvents (VOC). At maximum production (120.7 TPY of drugs), this is equivalent to 30.2 TPY VOC. Only one granulation at a time will be authorized to use alcohol as the solvent. Maximum emissions from the granulator using the VOC solvent are estimated to be 0.001 lb/hr (0.006 TPY) particulate matter and 30.2 TPY VOC.

Thus, the maximum emissions from the granulation process are as follows:

	lb/hr	lb/day	TPY
Particulate Matter	0.004	--	0.02
VOC	20.7*	165	30.2

* The applicant estimates that the solvent could be evaporated in 8 hours from this batch operation and hourly emissions during this period would be higher than the average emissions (6.9 lbs VOC/hr).

II. Rule Applicability

A. State Regulations

The proposed project is subject to preconstruction review under the provisions of Chapter 403, Florida Statutes, and Chapter 17-2, Florida Administrative Code.

The pharmaceutical plant (SIC 2834) is located in an area designated nonattainment for ozone (Rule 17-2.410, FAC), and attainment for the other criteria pollutants.

Pharmaceutical plants are classified as chemical process plants which are listed on Table 500-1, Major Facility Categories (list of 28). The plant is a major facility (17-2.100) because the potential emissions of VOC exempt from New Source Review for Nonattainment Areas (17-2.510) exceed 100 TPY. It is a minor source for the regulated VOC because these emissions are less than 100 TPY. The increase in emissions resulting from the proposed project is less than the significant emission rate listed in Table 500-2, Regulated Air Pollutants Significant Emission Rates.

The project is not subject to the prevention of significant deterioration regulation (17-2.500) and new source review for nonattainment areas (17-2.510) because the modification does not result in a significant net emissions increase of any criteria pollutant (17-2.500(2)(d)4.a.(ii) and 17-2.510(2)(d)4.a.).

The project will be reviewed under Rule 17-2.520, Sources Not Subject to Prevention of Significant Deterioration or Nonattainment Requirements. Allowable VOC emissions will be based on the requirement for reasonable controls, Rule 17-2.620, FAC, and Consent Order No. 84-0644. Allowable particulate matter

emissions shall be based on 17-2.610(1), the process weight table. An alternate standard of no visible emissions can be substituted for the particulate matter standard (17-2.700(3)(d)).

Higher emissions would subject this operation to review under other regulations.

B. Federal Regulations

The proposed project, a minor modification to a major facility, is not subject to review under federal regulations because the modification will not result in a significant net emissions increase of any criteria pollutant.

IV. Air Quality Impact

Regulations do not require an ambient air quality impact analysis for this source. However, a screening model (MPTPLU) for the isopropyl alcohol emission predicts the maximum ambient air impact to be less than 2 percent of the TLV for an 8 hour period and less than 1 percent of the TLV for a 24-hour period. These impacts will not endanger health.

V. Conclusion

Based on the data submitted by the applicant, the department has concluded that the emissions from the granulation process will comply with the state regulations. The department proposes to issue a construction permit that will authorize continuous operation of this existing source. The General and Specific Conditions in the proposed permit (draft attached) will assure compliance of this source with the state's air pollution control regulations.

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

PERMITTEE:
Key Pharmaceuticals, Inc.
50 NW 176th Street
Miami, Florida 33169-1307

Permit Number: AC 13-129897
Expiration Date: January 1, 1988
County: Dade
Latitude/Longitude: 25° 56' 03" N
80° 11' 42" W
Project: Granulation Process

This permit is issued under the provisions of Chapter 403, Florida Statutes, and Florida Administrative Code Rule(s) 17-2 and 17-4. The above named permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents attached hereto or on file with the department and made a part hereof and specifically described as follows:

Authorization to operate the existing granulation process continuously. This process contains: 2 granulators; wet sizing, drying, and dry sizing equipment; 4,000 ACFM dust collector with a 12" x 12" stack; and associated ducts, hoods, and collection drums. It is located at the pharmaceutical plant at 50 N.W. 176th Street in Miami, Dade County, Florida. The UTM coordinates of this plant are zone 17, 579.9 km E and 2868.4 km N.

The operation shall be in accordance with two attached permit applications, plans, documents, and drawings except as noted in the Specific Conditions of this permit.

Attachments:

1. Application for Permit to Construct 2 Granulators received by BAQM on January 26, 1987.

2. Application for Permit to Construct 1 Granulator and Dryer received by BAQM on January 26, 1987.

GENERAL CONDITIONS:

1. The terms, conditions, requirements, limitations, and restrictions set forth herein are "Permit Conditions" and as such are binding upon the permittee and enforceable pursuant to the authority of Sections 403.161, 403.727, or 403.859 through 403.861, Florida Statutes. The permittee is hereby placed on notice that the department will review this permit periodically and may initiate enforcement action for any violation of the "Permit Conditions" by the permittee, its agents, employees, servants or representatives.

2. This permit is valid only for the specific processes and operations applied for and indicated in the approved drawings or exhibits. Any unauthorized deviation from the approved drawings, exhibits, specifications, or conditions of this permit may constitute grounds for revocation and enforcement action by the department.

3. As provided in Subsections 403.087(6) and 403.722(5), Florida Statutes, the issuance of this permit does not convey any vested rights or any exclusive privileges. Nor does it authorize any injury to public or private property or any invasion of personal rights, nor any infringement of federal, state or local laws or regulations. This permit does not constitute a waiver of or approval of any other department permit that may be required for other aspects of the total project which are not addressed in the permit.

4. This permit conveys no title to land or water, does not constitute state recognition or acknowledgement of title, and does not constitute authority for the use of submerged lands unless herein provided and the necessary title or leasehold interests have been obtained from the state. Only the Trustees of the Internal Improvement Trust Fund may express state opinion as to title.

5. This permit does not relieve the permittee from liability for harm or injury to human health or welfare, animal, plant or aquatic life or property and penalties therefore caused by the construction or operation of this permitted source, nor does it allow the permittee to cause pollution in contravention of Florida Statutes and department rules, unless specifically authorized by an order from the department.

GENERAL CONDITIONS:

6. The permittee shall at all times properly operate and maintain the facility and systems of treatment and control (and related appurtenances) that are installed or used by the permittee to achieve compliance with the conditions of this permit, as required by department rules. This provision includes the operation of backup or auxiliary facilities or similar systems when necessary to achieve compliance with the conditions of the permit and when required by department rules.

7. The permittee, by accepting this permit, specifically agrees to allow authorized department personnel, upon presentation of credentials or other documents as may be required by law, access to the premises, at reasonable times, where the permitted activity is located or conducted for the purpose of:

a. Having access to and copying any records that must be kept under the conditions of the permit;

b. Inspecting the facility, equipment, practices, or operations regulated or required under this permit; and

c. Sampling or monitoring any substances or parameters at any location reasonably necessary to assure compliance with this permit or department rules.

Reasonable time may depend on the nature of the concern being investigated.

8. If, for any reason, the permittee does not comply with or will be unable to comply with any condition or limitation specified in this permit, the permittee shall immediately notify and provide the department with the following information:

a. a description of and cause of non-compliance; and

b. the period of noncompliance, including exact dates and times; or, if not corrected, the anticipated time the noncompliance is expected to continue, and steps being taken to reduce, eliminate, and prevent recurrence of the noncompliance.

GENERAL CONDITIONS:

The permittee shall be responsible for any and all damages which may result and may be subject to enforcement action by the department for penalties or revocation of this permit.

9. In accepting this permit, the permittee understands and agrees that all records, notes, monitoring data and other information relating to the construction or operation of this permitted source, which are submitted to the department, may be used by the department as evidence in any enforcement case arising under the Florida Statutes or department rules, except where such use is proscribed by Sections 403.73 and 403.111, Florida Statutes.

10. The permittee agrees to comply with changes in department rules and Florida Statutes after a reasonable time for compliance, provided however, the permittee does not waive any other rights granted by Florida Statutes or department rules.

11. This permit is transferable only upon department approval in accordance with Florida Administrative Code Rules 17-4.12 and 17-30.30, as applicable. The permittee shall be liable for any non-compliance of the permitted activity until the transfer is approved by the department.

12. This permit is required to be kept at the work site of the permitted activity during the entire period of construction or operation.

13. This permit also constitutes:

( ) Determination of Best Available Control Technology (BACT)
( ) Determination of Prevention of Significant Deterioration (PSD)
( ) Compliance with New Source Performance Standards.

14. The permittee shall comply with the following monitoring and record keeping requirements:

a. Upon request, the permittee shall furnish all records and plans required under department rules. The retention period for all records will be extended automatically, unless otherwise stipulated by the department, during the course of any unresolved enforcement action.

GENERAL CONDITIONS:

b. The permittee shall retain at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation), copies of all reports required by this permit, and records of all data used to complete the application for this permit. The time period of retention shall be at least three years from the date of the sample, measurement, report or application unless otherwise specified by department rule.

c. Records of monitoring information shall include:

- the date, exact place, and time of sampling or measurements;
- the person responsible for performing the sampling or measurements;
- the date(s) analyses were performed;
- the person responsible for performing the analyses;
- the analytical techniques or methods used; and
- the results of such analyses.

15. When requested by the department, the permittee shall within a reasonable time furnish any information required by law which is needed to determine compliance with the permit. If the permittee becomes aware that relevant facts were not submitted or were incorrect in the permit application or in any report to the department, such facts or information shall be submitted or corrected promptly.

SPECIFIC CONDITIONS:

1. The dust collection system must be operating properly when any of the process equipment (granulators, wet sizing, drying, dry sizing unit) is in operation. Any malfunction of the air pollution control system shall be repaired promptly.

2. Use of isopropanol or 3-A alcohol for the solvent is limited to one granulator at any given time.

3. The granulation process may operate continuously, 8760 hrs/yr.

SPECIFIC CONDITIONS:

4. Each granulator is limited to 1 lot per 24 hours. Not more than 75 kg of isopropanol or 3-A alcohol will be used in any one lot. The permittee shall maintain records of the number of lots and the quantity of alcohol used in each granulator for 2 years for department inspection.

5. Emissions from the dust collector serving the granulation process shall not exceed the following:

Particulate matter - 0.004 lb/hr and 0.02 TPY or 5% opacity
VOC - 20.7 lb/hr, 165.2 lbs/day, and 30.2 TPY (for continuous operation)

Compliance with the particulate matter standard by Method 5 described in 40 CFR 60, Appendix A, shall be waived if visible emissions determined by Method 9 described in 40 CFR 60, Appendix A, does not exceed 5% opacity during any consecutive 6 minute period.

Compliance with the VOC standard shall be based on records of the quantity of alcohol used in the process. These records shall be retained for a minimum of two years for department review.

6. The process shall not cause, suffer, allow, or permit the discharge of air pollutants which cause or contribute to an objectionable odor.

7. The permittee shall submit a complete application for a permit to operate this equipment, which must include an emissions test report, to the SE District office at least 90 days prior to the expiration date of this construction permit. The permittee may continue to operate this source, if it is in compliance with all conditions of this construction permit, until its expiration date.

8. Upon obtaining a permit to operate, the permittee will be required to submit annual operation reports to the DER SE District office and the Dade County Department of Environmental Resources Management which shall include as a minimum: total quantity of solvent input; and a recent emissions test report for visible emissions as specified in Specific Condition No. 5.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129897
Expiration Date: January 1, 1988

SPECIFIC CONDITIONS:

Issued this_____day of_____, 19___

STATE OF FLORIDA DEPARTMENT OF
ENVIRONMENTAL REGULATION

_____
Dale Twachtmann, Secretary

____ pages attached

P 408 530 526

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to James R. Confroy	
Street and No. Key Pharmaceuticals, Inc. 50 N.W. 176th Street	
P.O., State and ZIP Code Miami, Florida 33169	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt Showing to whom and Date Delivered	
Return Receipt Showing to whom, Date, and Address of Delivery	
TOTAL Postage and Fees	$
Postmark or Date 3/27/87 AC 13-129894 -129895	

PS Form 3800, Feb. 1982

PS Form 3811, July 1983 447-845

SENDER: Complete items 1, 2, 3 and 4.

Put your address in the "RETURN TO" space on the reverse side. Failure to do this will prevent this card from being returned to you. The return receipt fee will provide you the name of the person delivered to and the date of delivery. For additional fees the following services are available. Consult postmaster for fees and check box(es) for service(s) requested.

1. ☒ Show to whom, d[redacted]y.
2. ☐ Restricted Delivery.

3. Article Addressed to:
James R. Confroy
Key Pharmaceuticals, Inc.
50 N. W. 176th Street
Miami, Florida 33169

4. Type of Service:	Article Number
☐ Registered ☐ Insured ☒ Certified ☐ COD ☐ Express Mail	P 408 530 526

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature – Addressee
X

6. Signature – Agent
X

7. Date of Delivery
MAR 3 1 1987

8. Addressee's Address *(ONLY if requested and fee paid)*

DOMESTIC RETURN RECEIPT

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

March 27, 1987

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Mr. James R. Confroy
Vice President of Operations
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169

Dear Mr. Confroy:

Attached is one copy of the Technical Evaluation and Preliminary Determination, and proposed permits to construct two tablet press room operations at your pharmaceutical plant in Miami, Dade County, Florida.

Please submit, in writing, any comments which you wish to have considered concerning the department's proposed action to Mr. Bill Thomas of the Bureau of Air Quality Management.

Sincerely,

C. H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality
Management

CHF/pa

Attachments

cc: Isidore Goldman
Patrick Wong
John N. Wells, P.E.

BEFORE THE STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

In the Matter of
Application for Permit by:

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307

DER File No. AC 13-129894
AC 13-129895

INTENT TO ISSUE

The Department of Environmental Regulation hereby gives notice of its intent to issue permits (copies attached) for the proposed project as detailed in the application specified above. The Department is issuing this Intent to Issue for the reasons stated in the attached Technical Evaluation and Preliminary Determination.

The applicant, Key Pharmaceuticals, Inc., applied on January 26, 1987, to the Department of Environmental Regulation for permits to modify two existing press room operations at their existing pharmaceutical plant in Miami, Dade County, Florida.

The Department has permitting jurisdiction under Chapter 403, Florida Statutes and Florida Administrative Code Rules 17-2 and 17-4. The project is not exempt from permitting procedures. The Department has determined that air construction permits were needed for the proposed work.

Pursuant to Section 403.815, F.S. and DER Rule 17-103.150, FAC, you (the applicant) are required to publish at your own expense the enclosed Notice of Proposed Agency Action on permit application. The notice must be published one time only in a section of a major local newspaper of general circulation in the county in which the project is located and within thirty (30)

days from receipt of this intent. Proof of publication must be provided to the Department within seven days of publication of the notice. Failure to publish the notice and provide proof of publication within the allotted time may result in the denial of the permits.

The Department will issue the permits with the attached conditions unless petition for an administrative proceeding (hearing) is filed pursuant to the provisions of Section 120.57, F.S. A person whose substantial interests are affected by the Department's proposed permitting decision may petition for an administrative proceeding (hearing) in accordance with Section 120.57, Florida Statutes. Petitions must comply with the requirement of Florida Administrative Code Rules 17-103.155 and 28-5.201 (copies enclosed) and be filed with (received by) the Office of General Counsel of the Department at 2600 Blair Stone Road, Tallahassee, Florida 32301-8241. Petitions filed by the permit applicant must be filed within fourteen (14) days of receipt of this intent. Petitions filed by other persons must be filed within fourteen (14) days of publication of the public notice or within fourteen (14) days of receipt of this intent, whichever first occurs. Failure to file a petition within this time period shall constitute a waiver of any right such person may have to request an administrative determination (hearing) under Section 120.57, Florida Statutes, concerning the subject permit application. Petitions which are not filed in accordance with the above provisions will be dismissed.

Executed in Tallahassee, Florida.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL REGULATION

C. H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality Management

Copies furnished to:

James R. Confroy
Isidore Goldman
Patrick Wong

CERTIFICATE OF SERVICE

The undersigned duly designated deputy clerk hereby certifies that this NOTICE OF INTENT TO ISSUE and all copies were mailed before the close of business on March 27, 1987.

FILING AND ACKNOWLEDGEMENT
FILED, on this date, pursuant to §120.52(9), Florida Statutes, with the designated Department Clerk, receipt of which is hereby acknowledged.

R Bruce Mitchell
Clerk

3/27/87
Date

State of Florida
Department of Environmental Regulation
Notice of Proposed Agency Action
on Permit Application

The Department of Environmental Regulation gives notice of its intent to issue two permits to Key Pharmaceuticals, Inc. for the tablet press room operations at their existing pharmaceutical plant located at 50 N.W. 176th Street, Miami, Dade County, Florida. The tablet press room operations will result in emissions of less than 1 TPY particulate matter. A determination of best control technology (BACT) was not required.

Persons whose substantial interests are affected by the department's proposed permitting decision may petition for an administrative proceeding (hearing) in accordance with Section 120.57, Florida Statutes. The petition must conform to the requirements of Chapters 17-103 and 28-5, Florida Administrative Code, and must be filed (received) in the Office of General Counsel of the Department at 2600 Blair Stone Road, Twin Towers Office Building, Tallahassee, Florida 32301, within fourteen (14) days of publication of this notice. Failure to file a request for hearing within this time period shall constitute a waiver of any right such person may have to request an administrative determination (hearing) under Section 120.57, Florida Statutes.

If a petition is filed, the administrative hearing process is designed to formulate agency action. Accordingly, the Department's final action may be different from the position taken by it in this preliminary statement. Therefore, persons who may not object to the proposed agency action may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Model Rule 28-5.207 at least five (5) days before the final hearing and be filed with the hearing officer if one has been assigned at the Division of Administrative Hearings, Department of Administration, 2009 Apalachee Parkway, Tallahassee, Florida 32301. If no hearing officer has been assigned, the petition is to be filed with the Department's Office of General Counsel, 2600 Blair Stone Road, Tallahassee, Florida 32301. Failure to petition to intervene within the allowed time frame constitutes a waiver of any right such person has to request a hearing under Section 120.57, Florida Statutes.

The applications are available for public inspection during normal business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays, at:

Dept. of Environmental Regulation
Southeast District
3301 Gun Club Road
West Palm Beach, Florida 33402

Dept. of Environmental Regulation
Bureau of Air Quality Management
2600 Blair Stone Road
Tallahassee, Florida 32301

Dade County Department of Environmental
Resources Management
Metro Dade Governmental Center
Suite 310
111 N.W. 1st Street
Miami, Florida 33128

Any person may send written comments on the proposed action to Mr. Bill Thomas at the department's Tallahassee address. All comments mailed within 30 days of the publication of this notice will be considered in the department's final determination.

Technical Evaluation
and
Preliminary Determination

Key Pharmaceuticals, Inc.
Miami, Florida
Dade County

Sources	File Numbers
Tablet Press Rooms Nos. 1 and 2 With Dust Collector	AC 13-129894
Tablet Press Rooms Nos. 3 and 4 With Dust Collector	AC 13-129895

Florida Department of Environmental Regulation
Bureau of Air Quality Management
Central Air Permitting

March 27, 1987

I. General Information

A. Applicant

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169

B. Request

Mr. Thomas Flachmeyer, Manager of Environmental Engineering and Waste Management for Key Pharmaceuticals, Inc., delivered an application for permit to construct four tablet presses on January 26, 1987. The application was considered complete on receipt.

C. Project and Location

Key Pharmaceuticals, Inc. operates four tablet presses at their pharmaceutical plant (SIC 2834) located at 50 N.W. 176th Street in Miami, Dade County, Florida. The UTM coordinates of this facility are zone 17, 579.9 km E and 2868 km N. These existing presses are currently permitted and in operation. The department requested the applicant reapply for permits for this process equipment, operating at its full potential, for any drug they may manufacture. This application is for the administrative changes for the existing press permit requested by the department. No construction or new sources is included in this request.

Emissions from the four presses are controlled by two dust collectors. Tablet Press Rooms Nos. 1 and 2 are controlled by a common dust collector. Tablet Press Room No. 3 and 4 are also controlled by a common dust collector. Tablet Press Rooms Nos. 1 and 2, with its dust collector, is considered to be a single source. Tablet Press Rooms Nos. 3 and 4, with its dust collector, is considered to be another source. The sources will be reviewed together but issued separate permits.

D. Air Pollutant Emissions

Various drug ingredients produced in other process equipment at this facility are converted into tablets or capsules by the presses. Each press room can produce approximately 1,500 1.2 gram tablets per minute (238 lb/hr of tablets). Dust in the ambient air in the room and from the tablet presses (tablet dedusting stage) is exhausted through a Torit dust collector designed to remove 99% of the particulate matter (PM). The uncontrol PM to each dust collector is estimated to be 2.4 lbs/hr. The emissions from each dust collector are estimated at 0.024 lbs/hr and, for continuous operation, 0.1 TPY PM. Total PM emissions from the two dust collectors serving the four tablet

press rooms, including process equipment, is appoximately 0.05 lbs/hr and 0.2 TPY. At this low level of emissions, the discharge from the dust collectors should have no visible emissions.

The PM collected by the dust collectors is placed in drums and disposed of at an off-site facility. For continuous operations of all tablet press rooms, up to 20.6 TPY of PM in 120 drums would be sent to the approved disposal facility.

II. Rule Applicability

A. State Regulations

The proposed projects are subject to preconstruction review under the provisions of Chapter 403, Florida Statutes, and Chapter 17-2, Florida Administrative Code.

The pharmaceutical plant (SIC 2834) is located in an area designated nonattainment for ozone (Rule 17-2.410, FAC), and attainment for the other criteria pollutants.

Pharmaceutical plants are classified as chemical process plants which are listed on Table 500-1, Major Facility Categories (list of 28). The plant is a major facility (17-2.100) because the potential emissions of VOC exempt from New Source Review for Nonattainment Areas (17-2.510(2)(a)) presently exceed 100 TPY. It is a minor source for the regulated VOC because these emissions are less than 100 TPY. The increase in emissions resulting from the proposed project is less than the significant emission rate for PM, the only pollutant emitted by this process, listed in Table 500-2, Regulated Air Pollutants Significant Emission Rates.

The project is not subject to the prevention of significant deterioration regulation (17-2.500) and new source review for nonattainment areas (17-2.510) because the modification does not result in a significant net emissions increase of any criteria pollutant (17-2.500(2)(d)4.a.(ii) and 17-2.510(2)(d)4.a.).

The project will be reviewed under Rule 17-2.520, Sources Not Subject to Prevention of Significant Deterioration or Nonattainment Requirements. Allowable particulate matter emissions shall be based on 17-2.610(1), the process weight table. An alternate standard of no visible emissions shall be substituted for the particulate matter standard (17-2.700(3)(d)).

Higher emissions would subject this operation to review under other regulations.

B. Federal Regulations

The proposed project, a minor modification to a major facility, is not subject to review under federal regulations because the modification will not result in a significant net emissions increase of any criteria pollutant.

III. Technical Evaluation

Dust generated by handling the ingredients used to make the tablets is captured in 99% efficient Torit dust collectors. The PM concentration in the discharge from the dust colletors is estimated to average less than 0.1 grain per cubic foot. The concentration of PM in the discharge from the dust collector should produce no visible emissions. Each dust collector discharges approximately 4,000 ACFM of 70°F air from the roof level (11 foot) through a 12" x 12" duct.

No organic solvents are used in the tablet press process. Therefore, there will be no VOC emissions from these sources.

IV. Air Quality Impact

The manufacture of the tablets will not result in a significant net emissions increase as set forth in Rule 17-2.500(2)(e)2, FAC. Therefore, no air quality analysis is required by the regulation. The impact of the emissions from this process are insignificant.

V. Conclusion

Based on the data submitted by the applicant, the department has concluded that the emissions from both dust collectors serving the tablet press rooms comply with the state regulations. The department proposes to issue two construction permits that will authorize continuous operation of the existing sources. The General and Specific Conditions in the proposed permits (drafts attached) will assure compliance of these sources with the state's air pollution control regulations.

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

PERMITTEE:
Key Pharmaceuticals, Inc.
50 NW 176th Street
Miami, Florida 33169-1307

Permit Number: AC 13-129894
Expiration Date: October 1, 1987
County: Dade
Latitude/Longitude: 25° 56' 03" N
80° 11' 42" W
Project: Tablet Press Rooms Nos. 1 and 2

This permit is issued under the provisions of Chapter 403, Florida Statutes, and Florida Administrative Code Rule(s) 17-2 and 17-4. The above named permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents attached hereto or on file with the department and made a part hereof and specifically described as follows:

Authorization to operate two existing tablet press rooms containing tablet presses with air from the rooms and process equipment exhausted through a Torit dust collector. The Torit dust collector will discharge 4,000 ACFM of air at 70 °F from the process at roof level (11 feet) through a 12" x 12" duct. This equipment is located at the pharmaceutical plant at 50 N.W. 176th Street in Miami, Dade County, Florida. The UTM coordinates of this plant are zone 17, 579.9 km E and 2868.4 km N.

The operation shall be in accordance with the attached permit application, plans, documents, and drawings except as noted in the Specific Conditions of this permit.

Attachment:

1. Application for Permit to Construct 4 Tablet Presses received by BAQM on January 26, 1987.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129894
Expiration Date: October 1, 1987

GENERAL CONDITIONS:

1. The terms, conditions, requirements, limitations, and restrictions set forth herein are "Permit Conditions" and as such are binding upon the permittee and enforceable pursuant to the authority of Sections 403.161, 403.727, or 403.859 through 403.861, Florida Statutes. The permittee is hereby placed on notice that the department will review this permit periodically and may initiate enforcement action for any violation of the "Permit Conditions" by the permittee, its agents, employees, servants or representatives.

2. This permit is valid only for the specific processes and operations applied for and indicated in the approved drawings or exhibits. Any unauthorized deviation from the approved drawings, exhibits, specifications, or conditions of this permit may constitute grounds for revocation and enforcement action by the department.

3. As provided in Subsections 403.087(6) and 403.722(5), Florida Statutes, the issuance of this permit does not convey any vested rights or any exclusive privileges. Nor does it authorize any injury to public or private property or any invasion of personal rights, nor any infringement of federal, state or local laws or regulations. This permit does not constitute a waiver of or approval of any other department permit that may be required for other aspects of the total project which are not addressed in the permit.

4. This permit conveys no title to land or water, does not constitute state recognition or acknowledgement of title, and does not constitute authority for the use of submerged lands unless herein provided and the necessary title or leasehold interests have been obtained from the state. Only the Trustees of the Internal Improvement Trust Fund may express state opinion as to title.

5. This permit does not relieve the permittee from liability for harm or injury to human health or welfare, animal, plant or aquatic life or property and penalties therefore caused by the construction or operation of this permitted source, nor does it allow the permittee to cause pollution in contravention of Florida Statutes and department rules, unless specifically authorized by an order from the department.

GENERAL CONDITIONS:

6. The permittee shall at all times properly operate and maintain the facility and systems of treatment and control (and related appurtenances) that are installed or used by the permittee to achieve compliance with the conditions of this permit, as required by department rules. This provision includes the operation of backup or auxiliary facilities or similar systems when necessary to achieve compliance with the conditions of the permit and when required by department rules.

7. The permittee, by accepting this permit, specifically agrees to allow authorized department personnel, upon presentation of credentials or other documents as may be required by law, access to the premises, at reasonable times, where the permitted activity is located or conducted for the purpose of:

a. Having access to and copying any records that must be kept under the conditions of the permit;

b. Inspecting the facility, equipment, practices, or operations regulated or required under this permit; and

c. Sampling or monitoring any substances or parameters at any location reasonably necessary to assure compliance with this permit or department rules.

Reasonable time may depend on the nature of the concern being investigated.

8. If, for any reason, the permittee does not comply with or will be unable to comply with any condition or limitation specified in this permit, the permittee shall immediately notify and provide the department with the following information:

a. a description of and cause of non-compliance; and

b. the period of noncompliance, including exact dates and times; or, if not corrected, the anticipated time the noncompliance is expected to continue, and steps being taken to reduce, eliminate, and prevent recurrence of the noncompliance.

GENERAL CONDITIONS:

The permittee shall be responsible for any and all damages which may result and may be subject to enforcement action by the department for penalties or revocation of this permit.

9. In accepting this permit, the permittee understands and agrees that all records, notes, monitoring data and other information relating to the construction or operation of this permitted source, which are submitted to the department, may be used by the department as evidence in any enforcement case arising under the Florida Statutes or department rules, except where such use is proscribed by Sections 403.73 and 403.111, Florida Statutes.

10. The permittee agrees to comply with changes in department rules and Florida Statutes after a reasonable time for compliance, provided however, the permittee does not waive any other rights granted by Florida Statutes or department rules.

11. This permit is transferable only upon department approval in accordance with Florida Administrative Code Rules 17-4.12 and 17-30.30, as applicable. The permittee shall be liable for any non-compliance of the permitted activity until the transfer is approved by the department.

12. This permit is required to be kept at the work site of the permitted activity during the entire period of construction or operation.

13. This permit also constitutes:

( ) Determination of Best Available Control Technology (BACT)
( ) Determination of Prevention of Significant Deterioration (PSD)
( ) Compliance with New Source Performance Standards.

14. The permittee shall comply with the following monitoring and record keeping requirements:

a. Upon request, the permittee shall furnish all records and plans required under department rules. The retention period for all records will be extended automatically, unless otherwise stipulated by the department, during the course of any unresolved enforcement action.

GENERAL CONDITIONS:

b. The permittee shall retain at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation), copies of all reports required by this permit, and records of all data used to complete the application for this permit. The time period of retention shall be at least three years from the date of the sample, measurement, report or application unless otherwise specified by department rule.

c. Records of monitoring information shall include:

- the date, exact place, and time of sampling or measurements;
- the person responsible for performing the sampling or measurements;
- the date(s) analyses were performed;
- the person responsible for performing the analyses;
- the analytical techniques or methods used; and
- the results of such analyses.

15. When requested by the department, the permittee shall within a reasonable time furnish any information required by law which is needed to determine compliance with the permit. If the permittee becomes aware that relevant facts were not submitted or were incorrect in the permit application or in any report to the department, such facts or information shall be submitted or corrected promptly.

SPECIFIC CONDITIONS:

1. The dust collector system must be operating properly when the tablet presses are in use. Any malfunction of the air pollution control system shall be repaired promptly.

2. The tablet press process may operate continously, 8760 hrs/year.

3. Particulate matter (PM) emissions shall not exceed 0.024 lb/hr (0.1 TPY) as determined by Method 5 described in 40 CFR 60, Appendix A. Visible emissions from the rooms and dust collector for this process shall not exceed 5% opacity as determined by Method 9 which is described in 40 CFR 60, Appendix A. The department (SE District) must be notified 15 days prior to any compliance test. The PM test will be waived if visible emissions do not exceed 5% opacity.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129894
Expiration Date: October 1, 1987

SPECIFIC CONDITIONS:
(continued)

4. The process shall not cause, suffer, allow, or permit the discharge of air pollutants which cause or contribute to an objectionable odor.

5. Use of VOC solvents in the tablet press process is prohibited.

6. The permittee shall submit a complete application for a permit to operate this equipment, which must include an emissions test report, to the SE District office at least 90 days prior to the expiration date of this construction permit. The permittee may continue to operate this source, if it is in compliance with all conditions of this construction permit, until its expiration date.

7. Upon obtaining a permit to operate, the permittee will be required to submit annual operation reports to the DER SE District office which shall include as a minimum a recent visible emissions test report as specified in Specific Condition No. 3.

Issued this_____day of_____, 19___

STATE OF FLORIDA DEPARTMENT OF
ENVIRONMENTAL REGULATION

_____
Dale Twachtmann, Secretary

____ pages attached

P 408 530 525

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to James R. Confroy	
Street and No. Key Pharmaceuticals, Inc. 50 NW 176th Street	
P.O., State and ZIP Code Miami, FL 33169	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt Showing to whom and Date Delivered	
Return Receipt Showing to whom, Date, and Address of Delivery	
TOTAL Postage and Fees	$
Postmark or Date 3/26/87 AC 13-129893	

PS Form 3800, Feb. 1982

PS Form 3811, July 1983 447-845

SENDER: Complete items 1, 2, 3 and 4.

Put your address in the "RETURN TO" space on the reverse side. Failure to do this will prevent this card from being returned to you. The return receipt fee will provide you the name of the person delivered to and the date of delivery. For additional fees the following services are available. Consult postmaster for fees and check box(es) for service(s) requested.

1. ☒ Show to whom, [redacted].
2. ☐ Restricted Delivery.

3. Article Addressed to:
James R. Confroy
Key Pharmaceuticals, Inc.
50 NW 176th Street
Miami, FL 33169

4. Type of Service:	Article Number
☐ Registered ☐ Insured ☒ Certified ☐ COD ☐ Express Mail	P 408 530 525

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature – Addressee
X

6. Signature – Agent
X

7. Date of Delivery
MAR 31 1987

8. Addressee's Address *(ONLY if requested and fee paid)*

DOMESTIC RETURN RECEIPT

File Copy

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

March 26, 1987

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Mr. James R. Confroy
Vice President of Operations
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169

Dear Mr. Confroy:

Attached is one copy of the Technical Evaluation and Preliminary Determination, and proposed permit for construction of a carbon adsorption and solvent recovery system to serve existing, permitted, and new process equipment at your pharmaceutical plant in Miami, Dade County, Florida.

Please submit, in writing, any comments which you wish to have considered concerning the department's proposed action to Mr. Bill Thomas of the Bureau of Air Quality Management.

Sincerely,

C. H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality
Management

CHF/pa

Attachments

cc: Isidore Goldman
Patrick Wong
John N. Wells, P.E.

State of Florida
Department of Environmental Regulation
Notice of Proposed Agency Action
on Permit Application

The Department of Environmental Regulation gives notice of its intent to issue a permit to Key Pharmaceuticals, Inc. for the construction of a carbon adsorption and solvent recovery system to serve existing, permitted, and new process equipment at their existing pharmaceutical plant located at 50 N.W. 176th Street, Miami, Dade County, Florida. Annual emissions from the carbon adsorption system will not exceed 370.1 TPY methylene chloride, 38.1 TPY methanol, and 0.23 TPY particulate matter. The modification will increase methylene chloride emissions by 1,217 TPY. A determination of best available control technology (BACT) was not required.

Persons whose substantial interests are affected by the department's proposed permitting decision may petition for an administrative proceeding (hearing) in accordance with Section 120.57, Florida Statutes. The petition must conform to the requirements of Chapters 17-103 and 28-5, Florida Administrative Code, and must be filed (received) in the Office of General Counsel of the Department at 2600 Blair Stone Road, Twin Towers Office Building, Tallahassee, Florida 32301, within fourteen (14) days of publication of this notice. Failure to file a request for hearing within this time period shall constitute a waiver of any right such person may have to request an administrative determination (hearing) under Section 120.57, Florida Statutes.

If a petition is filed, the administrative hearing process is designed to formulate agency action. Accordingly, the Department's final action may be different from the position taken by it in this preliminary statement. Therefore, persons who may not object to the proposed agency action may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Model Rule 28-5.207 at least five (5) days before the final hearing and be filed with the hearing officer if one has been assigned at the Division of Administrative Hearings, Department of Administration, 2009 Apalachee Parkway, Tallahassee, Florida 32301. If no hearing officer has been assigned, the petition is to be filed with the Department's Office of General Counsel, 2600 Blair Stone Road, Tallahassee, Florida 32301. Failure to petition to intervene within the allowed time frame constitutes a waiver of any right such person has to request a hearing under Section 120.57, Florida Statutes.

The application is available for public inspection during normal business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays, at:

Dept. of Environmental Regulation
Southeast District
3301 Gun Club Road
West Palm Beach, Florida 33402

Dept. of Environmental Regulation
Bureau of Air Quality Management
2600 Blair Stone Road
Tallahassee, Florida 32301

Dade County Department of Environmental
Resources Management
909 Southeast 1st Avenue
Brickell Plaza
Miami, Florida 33131

Any person may send written comments on the proposed action to Mr. Bill Thomas at the department's Tallahassee address. All comments mailed within 14 days of the publication of this notice will be considered in the department's final determination.

BEFORE THE STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

In the Matter of
Application for Permit by:

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307

DER File No. AC 13-129893

INTENT TO ISSUE

The Department of Environmental Regulation hereby gives notice of its intent to issue a permit (copy attached) for the proposed project as detailed in the application specified above. The Department is issuing this Intent to Issue for the reasons stated in the attached Technical Evaluation and Preliminary Determination.

The applicant, Key Pharmaceuticals, Inc, applied on January 26, 1987, to the Department of Environmental Regulation for a permit to construct a carbon adsorption solvent recovery system to serve existing, permitted, and new process equipment at their existing pharmaceutical plant in Miami, Dade County, Florida.

The Department has permitting jurisdiction under Chapter 403, Florida Statutes and Florida Administrative Code Rules 17-2 and 17-4. The project is not exempt from permitting procedures. The Department has determined that an air construction permit was needed for the proposed work.

Pursuant to Section 403.815, F.S. and DER Rule 17-103.150, FAC, you (the applicant) are required to publish at your own expense the enclosed Notice of Proposed Agency Action on permit application. The notice must be published one time only in a section of a major local newspaper of general circulation in the county in which the project is located and within thirty (30) days from receipt of this intent. Proof of publication must be provided to the Department within seven days of publication of

the notice. Failure to publish the notice and provide proof of publication within the allotted time may result in the denial of the permit.

The Department will issue the permit with the attached conditions unless petition for an administrative proceeding (hearing) is filed pursuant to the provisions of Section 120.57, F.S. A person whose substantial interests are affected by the Department's proposed permitting decision may petition for an administrative proceeding (hearing) in accordance with Section 120.57, Florida Statutes. Petitions must comply with the requirement of Florida Administrative Code Rules 17-103.155 and 28-5.201 (copies enclosed) and be filed with (received by) the Office of General Counsel of the Department at 2600 Blair Stone Road, Tallahassee, Florida 32399-2400. Petitions filed by the permit applicant must be filed within fourteen (14) days of receipt of this intent. Petitions filed by other persons must be filed within fourteen (14) days of publication of the public notice or within fourteen (14) days of receipt of this intent, whichever first occurs. Failure to file a petition within this time period shall constitute a waiver of any right such person may have to request an administrative determination (hearing) under Section 120.57, Florida Statutes, concerning the subject permit application. Petitions which are not filed in accordance with the above provisions will be dismissed.

Executed in Tallahassee, Florida.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL REGULATION

C. H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality
Management

Copies furnished to:

James R. Confroy
Isidore Goldman
Patrick Wong

CERTIFICATE OF SERVICE

The undersigned duly designated deputy clerk hereby certifies that this NOTICE OF INTENT TO ISSUE and all copies were mailed before the close of business on March 26, 1987.

FILING AND ACKNOWLEDGEMENT
FILED, on this date, pursuant to §120.52(9), Florida Statutes, with the designated Department Clerk, receipt of which is hereby acknowledged.

R Bruce Mitchell
Clerk

3/26/87
Date

Technical Evaluation
and
Preliminary Determination

Key Pharmaceuticals, Inc.
Miami, Florida
Dade County

Construction of a Carbon Adsorption
and Solvent Recovery System to Serve Existing,
Permitted, and New Process Equipment

File No. AC 13-129893

Florida Department of Environmental Regulation
Bureau of Air Quality Management
Central Air Permitting

March 25, 1987

I. A. Applicant

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307

B. Request

Mr. Thomas Flachmeyer, Manager of Environmental Engineering and Waste Management for Key Pharmaceuticals, Inc., delivered three applications for permits to construct a carbon adsorption/ solvent recovery system, one new fluidized bed coating unit (Glatt), and two pan coating process units (Accela-Cota) on January 26, 1987. The applications, which will be reviewed as a single project, were considered complete on receipt (January 26, 1987).

C. Project and Location

The applicant proposes to construct a new carbon adsorption/solvent recovery system to replace an existing scrubber/activated sludge system. The new system will recover both methanol and methylene chloride, the solvents used in the processes. The scrubber being replaced controlled only methanol. The new system will be sized to serve the existing three Glatt units (two in operation and one permitted but not constructed), one new Glatt (4th unit), and two new Accela-Cota units. This evaluation includes the construction of the new Glatt and two Accela-Cota units. The location of this equipment is at the pharmaceutical plant (SIC 2834) at 50 N.W. 176th Street in Miami, Dade County, Florida. The UTM coordinates of this facility are zone 17, 579.9 km E and 2868.4 km N.

D. Process and Emissions

The applicant presently operates two fluid bed processors (Glatts) and has a permit to construct the third Glatt. In this process, solids are mixed with two solvents, methanol and methylene chloride, and sprayed on a substrate in a fluid bed processor. The air from the process, carrying the evaporated solvents and traces of dust, goes to an air pollution control system that removes most of the particulate matter and methanol from the air stream before it is discharged to the atmosphere.

The applicant proposes to install another fluid bed processor, the fourth Glatt unit, install two new pan coating or Accela-Cota units (which operate similar to the Glatt), and replace the methanol scrubber system with a new carbon adsorption/solvent recovery system that will control the air pollution from all existing and new process equipment discussed in this evaluation. The new air pollution control equipment will

remove methylene chloride, in addition to particulate matter and methanol.

The following table lists the process input and emissions from the existing and proposed process equipment.

	Process Input (lb/hr avg)***			Emission (lb/hr max)		
Unit	Methylene Chloride	Methanol	Solid	Methylene Chloride	Methanol	Solid ****
Glatt No. 1*	113	10.4	0.7	20.9	1.9	T
Glatt No. 2*	194	18.0	1.2	26.7	2.5	T
Glatt No. 3**	194	18.0	1.2	26.7	2.5	T
Glatt No. 4	194	18.0	1.2	26.7	2.5	T
Accela-Cota No. 1	75	11.3	0.5	20.0	3.0	T
Accela-Cota No. 2	75	11.3	0.5	20.0	3.0	T
Total	845	87.0	5.3	141.0	15.4	0.1

*existing
**permitted
***8760 hr/yr
****trace, VE <5% opacity

Annual emissions for all existing and new units controlled by the carbon adsorption system will not exceed 370.1 TPY methylene chloride, 38.1 TPY methanol, and 0.23 TPY particulate matter.

II. Rule Applicability

A. State Regulations

The proposed project is subject to preconstruction review under the provisions of Chapter 403, Florida Statutes, and Chapter 17-2, Florida Administrative Code.

The pharmaceutical plant (SIC 2834) is located in an area designated nonattainment for ozone (Rule 17-2.410, FAC), and attainment for the other criteria pollutants.

Pharmaceutical plants are classified as chemical process plants which are listed on Table 500-1, Major Facility Categories (list of 28). The plant is a major facility (17-2.100) because the potential emissions of exempt VOC presently exceed 100 TPY. It is a minor source for the regulated VOC because these emissions are less than 100 TPY. The increase in emissions resulting from the proposed project is less than the significant

emission rate listed in Table 500-2, Regulated Air Pollutants Significant Emission Rates.

The project is not subject to the prevention of significant deterioration regulation (17-2.500) and new source review for nonattainment areas (17-2.510) because the modification does not result in a significant net emissions increase of any criteria pollutant (17-2.500(2)(d)4.a.(ii) and 17-2.510(2)(d)4.a.).

The project will be reviewed under Rule 17-2.520, Sources Not Subject to Prevention of Significant Deterioration or Nonattainment Requirements. Allowable VOC emissions will be based on the requirement for reasonable controls, Rule 17-2.620, FAC, and Consent Order No. 84-0644. Allowable particulate matter emissions shall be based on 17-2.610(1), the process weight table. An alternate standard of no visible emissions will be substituted for the particulate matter standard (17-2.700(3)(d)).

Higher emissions would subject this operation to review under other regulations.

B. Federal Regulations

The proposed project, a minor modification to a major facility, is not subject to review under federal regulations because the modification will not result in a significant net emissions increase of any criteria pollutant.

III. Technical Evaluation

A dust collector, with an estimated efficiency of 99%, will remove particulate matter from the air carrying the solvents from the products before the air enters this carbon adsorption unit. Particulate matter loading will be reduced from 5.3 to 0.1 lb/hr. Annual particulate matter emissions from the air pollution control system are estimated to be 0.23 TPY.

The carbon adsorption unit, which will contain three carbon adsorbers, will be designed to remove 90% of the methanol and 90% of the methylene chloride. The scrubber system it is replacing was designed to remove 90% of the methanol and 0% of the methylene chloride. The solvents captured by the carbon adsorption system will be sent to a solvent recovery system that will recycle methylene chloride to the process and dispose of the methanol recovered by using it as boiler fuel. Any solvent contaminated air from the recovery system and solvent storage tanks will be returned to the solvent recovery system.

The solvent recovery system will be designed to reduce the maximum potential emissions to 141 lb/hr methylene chloride and

15.4 lb/hr methanol. Average annual emissions of these solvents will be 370.1 TPY methylene chloride and 38.1 TPY methanol.

IV. Air Quality Analysis

The proposed project will not result in a significant net emissions increase as set fourth in Rule 17-2.500(2)(e)2., FAC. Therefore, no air quality analysis is required by the regulation. Screening model (MPTPLU) results shows that the maximum one hour concentration of methylene chloride and methanol in the atmosphere from these emissions will be 1,059 and 116 ug/m^3, respectively. These impacts are less than 2% of the TLV-TWA. Although the department has not established ambient air quality standards for these compounds, other states have set standards at 1-2% of the TLV-TWA. Based on this analysis, the department has reasonable assurance that the emissions of the solvents from this process will not endanger public health.

V. Conclusion

Based on the data submitted by the applicant, the department has concluded that the emissions from the carbon adsorption unit controlling air pollution from four Glatts and the two Accela-Cota units will comply with the state's regulation. The department proposes to issue a construction permit that will authorize the construction of the new process and air pollution control equipment. The General and Specific Conditions in the proposed permit (attached) will assure compliance of the source with the state air pollution control regulations.

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

PERMITTEE:
Key Pharmaceuticals, Inc.
50 NW 176th Street
Miami, Florida 33169-1307

Permit Number: AC 13-129893
Expiration Date: January 1, 1989
County: Dade
Latitude/Longitude: 25° 56' 03" N
80° 11' 42" W
Project: Construction of Carbon Adsorption & Solvent Recovery System to Serve Existng, Permitted, & New Process Equipment

This permit is issued under the provisions of Chapter 403, Florida Statutes, and Florida Administrative Code Rule(s) 17-2 and 17-4. The above named permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents attached hereto or on file with the department and made a part hereof and specifically described as follows:

Authorization to replace the existing methanol scrubber/activated sludge treatment system with a 90% efficient carbon adsorption/solvent recovery system to control the emissions from four fluid bed processors (Glatt) and two pan coating (Accela-Cota) units. Two of the Glatt units are existing equipment and a construction permit has been issued for the third Glatt (AC 13-100437). This permit authorizes the construction of the fourth Glatt, two Accela-Cota units, and the carbon adsorption/solvent recovery system. This equipment will be located at the pharmaceutical plant at 50 N.W. 176th Street, Miami, Dade County, Florida. The UTM coordinates of this plant are zone 17, 579.9 km E and 2868.4 km N.

The construction and operation shall be in accordance with the attached permit applications, plans, documents, and drawings except as noted in the Specific Conditions of this permit.

Attachments:

1. Key's Application No. 2 - 4 Fluid Bed Processors; 2 Pan Coaters; and Carbon Adsorption Unit, Received by BAQM on January 26, 1987.

2. Key's Application No. 3 - 1 Fluid Bed Processor with Carbon Adsorption/Solvent Recovery, Received by BAQM on January 26, 1987.

3. Key's Application No. 4 - 2 Pan Coating Units, Received by BAQM on January 26, 1987.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129893
Expiration Date: January 1, 1989

GENERAL CONDITIONS:

1. The terms, conditions, requirements, limitations, and restrictions set forth herein are "Permit Conditions" and as such are binding upon the permittee and enforceable pursuant to the authority of Sections 403.161, 403.727, or 403.859 through 403.861, Florida Statutes. The permittee is hereby placed on notice that the department will review this permit periodically and may initiate enforcement action for any violation of the "Permit Conditions" by the permittee, its agents, employees, servants or representatives.

2. This permit is valid only for the specific processes and operations applied for and indicated in the approved drawings or exhibits. Any unauthorized deviation from the approved drawings, exhibits, specifications, or conditions of this permit may constitute grounds for revocation and enforcement action by the department.

3. As provided in Subsections 403.087(6) and 403.722(5), Florida Statutes, the issuance of this permit does not convey any vested rights or any exclusive privileges. Nor does it authorize any injury to public or private property or any invasion of personal rights, nor any infringement of federal, state or local laws or regulations. This permit does not constitute a waiver of or approval of any other department permit that may be required for other aspects of the total project which are not addressed in the permit.

4. This permit conveys no title to land or water, does not constitute state recognition or acknowledgement of title, and does not constitute authority for the use of submerged lands unless herein provided and the necessary title or leasehold interests have been obtained from the state. Only the Trustees of the Internal Improvement Trust Fund may express state opinion as to title.

5. This permit does not relieve the permittee from liability for harm or injury to human health or welfare, animal, plant or aquatic life or property and penalties therefore caused by the construction or operation of this permitted source, nor does it allow the permittee to cause pollution in contravention of Florida Statutes and department rules, unless specifically authorized by an order from the department.

GENERAL CONDITIONS:

6. The permittee shall at all times properly operate and maintain the facility and systems of treatment and control (and related appurtenances) that are installed or used by the permittee to achieve compliance with the conditions of this permit, as required by department rules. This provision includes the operation of backup or auxiliary facilities or similar systems when necessary to achieve compliance with the conditions of the permit and when required by department rules.

7. The permittee, by accepting this permit, specifically agrees to allow authorized department personnel, upon presentation of credentials or other documents as may be required by law, access to the premises, at reasonable times, where the permitted activity is located or conducted for the purpose of:

a. Having access to and copying any records that must be kept under the conditions of the permit;

b. Inspecting the facility, equipment, practices, or operations regulated or required under this permit; and

c. Sampling or monitoring any substances or parameters at any location reasonably necessary to assure compliance with this permit or department rules.

Reasonable time may depend on the nature of the concern being investigated.

8. If, for any reason, the permittee does not comply with or will be unable to comply with any condition or limitation specified in this permit, the permittee shall immediately notify and provide the department with the following information:

a. a description of and cause of non-compliance; and

b. the period of noncompliance, including exact dates and times; or, if not corrected, the anticipated time the noncompliance is expected to continue, and steps being taken to reduce, eliminate, and prevent recurrence of the noncompliance.

GENERAL CONDITIONS:

The permittee shall be responsible for any and all damages which may result and may be subject to enforcement action by the department for penalties or revocation of this permit.

9. In accepting this permit, the permittee understands and agrees that all records, notes, monitoring data and other information relating to the construction or operation of this permitted source, which are submitted to the department, may be used by the department as evidence in any enforcement case arising under the Florida Statutes or department rules, except where such use is proscribed by Sections 403.73 and 403.111, Florida Statutes.

10. The permittee agrees to comply with changes in department rules and Florida Statutes after a reasonable time for compliance, provided however, the permittee does not waive any other rights granted by Florida Statutes or department rules.

11. This permit is transferable only upon department approval in accordance with Florida Administrative Code Rules 17-4.12 and 17-30.30, as applicable. The permittee shall be liable for any non-compliance of the permitted activity until the transfer is approved by the department.

12. This permit is required to be kept at the work site of the permitted activity during the entire period of construction or operation.

13. This permit also constitutes:

( ) Determination of Best Available Control Technology (BACT)
( ) Determination of Prevention of Significant Deterioration (PSD)
( ) Compliance with New Source Performance Standards.

14. The permittee shall comply with the following monitoring and record keeping requirements:

a. Upon request, the permittee shall furnish all records and plans required under department rules. The retention period for all records will be extended automatically, unless otherwise stipulated by the department, during the course of any unresolved enforcement action.

GENERAL CONDITIONS:

b. The permittee shall retain at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation), copies of all reports required by this permit, and records of all data used to complete the application for this permit. The time period of retention shall be at least three years from the date of the sample, measurement, report or application unless otherwise specified by department rule.

c. Records of monitoring information shall include:

- the date, exact place, and time of sampling or measurements;
- the person responsible for performing the sampling or measurements;
- the date(s) analyses were performed;
- the person responsible for performing the analyses;
- the analytical techniques or methods used; and
- the results of such analyses.

15. When requested by the department, the permittee shall within a reasonable time furnish any information required by law which is needed to determine compliance with the permit. If the permittee becomes aware that relevant facts were not submitted or were incorrect in the permit application or in any report to the department, such facts or information shall be submitted or corrected promptly.

SPECIFIC CONDITIONS:

1. The fluid bed unit (Glatt No. 4) and two pan coating units (Accela-Cota Nos. 1 and 2) shall not be placed in service before the dust collector and carbon adsorption/solvent recovery system are able to control their air pollutant emissions.

2. Production shall not exceed the following without prior approval of the department (BAQM):

Glatt Unit No. 1 - 461 lots/year
Glatt Unit No. 2 - 796 lots/year
Glatt Unit No. 3 - 796 lots/year
Glatt Unit No. 4 - 796 lots/year

SPECIFIC CONDITIONS:

Each Glatt lot uses approximately 2,140 lbs methylene chloride, 200 lbs methanol, and 665 lbs solids (excipients).

Accela-Cota No. 1 - 1095 lots per year
Accela-Cota No. 2 - 1095 lots per year

Each Accela-Cota lot uses approximately 600 lbs methylene chloride, 90 lbs methanol, and 400 lbs solids (excipients).

Other solvents shall not be used in by this process equipment without prior approval of the department (BAQM).

The permittee shall keep logs on the process equipment that shows the number of lots produced by each unit. These records shall be available for department inspection for two years.

3. The process equipment may operate continuously (8760 hr/yr) if the carbon adsorption/solvent recovery system is operating properly.

4. The carbon adsorption/solvent recovery system shall remove a minimum of 90% of the methylene chloride and methanol emitted by the process equipment (Glatts and Accela-Cotas). Compliance with this standard shall be determined using the data from the continuous monitors on the inlet and discharge of the carbon adsorbers.

5. Allowable emissions from the air pollution control system are a function of the number of units in operation and shall not exceed the following:

Unit	Methylene Chloride			Methanol			PM	
	lb/hr	lb/day	TPY	lb/hr	lb/day	TPY	lb/hr	TPY
Glatt No. 1	20.9	271.2	49.5	1.9	25.0	4.6		
Glatt No. 2	26.7	465.6	85.0	2.5	43.2	7.9		
Glatt No. 3	26.7	465.6	85.0	2.5	43.2	7.9	Trace	
Glatt No. 4	26.7	465.6	85.0	2.5	43.2	7.9		
Accela-Cota No. 1	20.0	180.0	32.8	3.0	27.1	4.9		
Accela-Cota No. 2	20.0	180.0	32.8	3.0	27.1	4.9		
Total	141.0	2028.0	370.1	15.4	208.8	38.1	0.1	0.23

The maximum TPY emissions listed above are based on continuous operation of all units. If any unit is not operated continuously (producing the number of lots listed in Specific Condition No. 2), the allowable emissions are reduced accordingly.

SPECIFIC CONDITIONS:

Compliance with hourly standards (for the solvent) shall be determined by reference methods 25, 25A, or 18 as described in 40 CFR 60, Appendix A, or other methods as approved by the department. Compliance with the annual standards shall be based on production records and the measured efficiency of the carbon adsorption unit.

An alternate standard of no visible emissions from the stacks and equipment as determined by Method 9 described in 40 CFR 60, Appendix A, is substituted for the particulate matter standard.

VOC emission tests, based on production records and the carbon absorption unit monitoring data, are required as each additional unit is placed in service.

The department (SE District) shall be notified 15 days prior to any compliance test. Test results shall be submitted to the department (SE District) within 45 days of any test.

6. This operation (Glatts, Accela-Cotas, Carbon Adsorption/Solvent Recovery) shall not cause, suffer, allow, or permit the discharge of air pollutants which cause or contribute to an objectionable odor.

7. The construction shall reasonably conform to the plans and schedule submitted in the application. If the permittee is unable to complete construction on schedule, he must notify the department in writing 60 days prior to the expiration of the construction permit and submit a new schedule and request for an extension of the construction permit. (FAC Rule 17-4.09)

8. To obtain a permit to operate, the permittee must demonstrate compliance with the conditions of the construction permit and submit a complete application for an operating permit, including the application fee, along with test results and Certificate of Completion, to the department's district office 90 days prior to the expiration date of the construction permit. The permittee may continue to operate in compliance with all terms of the construction permit until its expiration date. Operation beyond the construction permit expiration date requires a valid permit to operate. (FAC Rule 17-4.22 and 17-4.23)

9. If the construction permit expires prior to the permittee requesting an extension or obtaining a permit to operate, then all activities at the project must cease and the permittee must apply for a new permit to construct which can take up to 90 days to process a complete application. (FAC Rule 17-4.10)

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129893
Expiration Date: January 1, 1989

SPECIFIC CONDITIONS:

STATE OF FLORIDA DEPARTMENT OF
ENVIRONMENTAL REGULATION

Dale Twachtmann, Secretary

____ pages attached

Best Available Copy

P 408 531 175

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to James R. Confroy Key Pharmaceuticals, Inc.	
P.O., State and ZIP Code 50 N.W. 176th Street Miami, FL 33169	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt Showing to whom and Date Delivered	
Return Receipt Showing to whom, Date, and Address of Delivery	
TOTAL Postage and Fees	$
Postmark or Date 3/18/87 AC 13-129891	

PS Form 3800, Feb. 1982

PS Form 3811, July 1983 447-845

SENDER: Complete items 1, 2, 3 and 4.

Put your address in the "RETURN TO" space on the reverse side. Failure to do this will prevent this card from being returned to you. The return receipt fee will provide you the name of the person delivered to and the date of delivery. For additional fees the following services are available. Consult postmaster for fees and check box(es) for service(s) requested.

1. ☐ Show to whom, date and address of delivery.
2. ☒ Restricted Delivery.

3. Article Addressed to:
James R. Confroy
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, FL 33169

4. Type of Service:
☐ Registered ☐ Insured
☒ Certified ☐ COD
☐ Express Mail

Article Number
P 408 531 175

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature – Addressee
X

6. Signature – Agent
X

7. Date of Delivery
MAR 23 '87

8. Addressee's Address *(ONLY if requested and fee paid)*

DOMESTIC RETURN RECEIPT

Willard's copy

91

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

March 18, 1987

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Mr. James R. Confroy
Vice President of Operations
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169

Dear Mr. Confroy:

Attached is one copy of the Technical Evaluation and Preliminary Determination, and proposed permit to modify the operations of 3 Glatt units at your pharmaceutical plant in Miami, Dade County, Florida.

Please submit, in writing, any comments which you wish to have considered concerning the department's proposed action to Mr. Bill Thomas of the Bureau of Air Quality Management.

Sincerely,

C. H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality
Management

CHF/pa

Attachments

cc: Isidore Goldman
Patrick Wong
John N. Wells, P.E.

State of Florida
Department of Environmental Regulation
Notice of Proposed Agency Action
on Permit Application

The Department of Environmental Regulation gives notice of its intent to issue a permit to Key Pharmaceuticals, Inc. for the modification of the operation of 3 fluidized bed coating units (Glatts) at their existing pharmaceutical plant located at 50 N.W. 176th Street, Miami, Dade County, Florida. The modification will increase methylene chloride emissions by 1,217 TPY. A determination of best available control technology (BACT) was not required.

Persons whose substantial interests are affected by the department's proposed permitting decision may petition for an administrative proceeding (hearing) in accordance with Section 120.57, Florida Statutes. The petition must conform to the requirements of Chapters 17-103 and 28-5, Florida Administrative Code, and must be filed (received) in the Office of General Counsel of the Department at 2600 Blair Stone Road, Twin Towers Office Building, Tallahassee, Florida 32301, within fourteen (14) days of publication of this notice. Failure to file a request for hearing within this time period shall constitute a waiver of any right such person may have to request an administrative determination (hearing) under Section 120.57, Florida Statutes.

If a petition is filed, the administrative hearing process is designed to formulate agency action. Accordingly, the Department's final action may be different from the position taken by it in this preliminary statement. Therefore, persons who may not object to the proposed agency action may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Model Rule 28-5.207 at least five (5) days before the final hearing and be filed with the hearing officer if one has been assigned at the Division of Administrative Hearings, Department of Administration, 2009 Apalachee Parkway, Tallahassee, Florida 32301. If no hearing officer has been assigned, the petition is to be filed with the Department's Office of General Counsel, 2600 Blair Stone Road, Tallahassee, Florida 32301. Failure to petition to intervene within the allowed time frame constitutes a waiver of any right such person has to request a hearing under Section 120.57, Florida Statutes.

The application is available for public inspection during normal business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays, at:

Dept. of Environmental Regulation
Southeast District
3301 Gun Club Road
West Palm Beach, Florida 33402

Dept. of Environmental Regulation
Bureau of Air Quality Management
2600 Blair Stone Road
Tallahassee, Florida 32301

Dade County Department of Environmental
Resources Management
909 Southeast 1st Avenue
Brickell Plaza
Miami, Florida 33131

Any person may send written comments on the proposed action to Mr. Bill Thomas at the department's Tallahassee address. All comments mailed within 30 days of the publication of this notice will be considered in the department's final determination.

BEFORE THE STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

In the Matter of
Application for Permit by:

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307

DER File No. AC 13-129891

INTENT TO ISSUE

The Department of Environmental Regulation hereby gives notice of its intent to issue a permit (copy attached) for the proposed project as detailed in the application specified above. The Department is issuing this Intent to Issue for the reasons stated in the attached Technical Evaluation and Preliminary Determination.

The applicant, Key Pharmaceuticals, Inc, applied on January 26, 1987, to the Department of Environmental Regulation for a permit to modify the operations of 3 existing fluidized bed coating units (Glatt) at their existing pharmaceutical plant in Miami, Dade County, Florida.

The Department has permitting jurisdiction under Chapter 403, Florida Statutes and Florida Administrative Code Rules 17-2 and 17-4. The project is not exempt from permitting procedures. The Department has determined that an air construction permit was needed for the proposed work.

Pursuant to Section 403.815, F.S. and DER Rule 17-103.150, FAC, you (the applicant) are required to publish at your own expense the enclosed Notice of Proposed Agency Action on permit application. The notice must be published one time only in a section of a major local newspaper of general circulation in the county in which the project is located and within thirty (30) days from receipt of this intent. Proof of publication must be provided to the Department within seven days of publication of

the notice. Failure to publish the notice and provide proof of publication within the allotted time may result in the denial of the permit.

The Department will issue the permit with the attached conditions unless petition for an administrative proceeding (hearing) is filed pursuant to the provisions of Section 120.57, F.S. A person whose substantial interests are affected by the Department's proposed permitting decision may petition for an administrative proceeding (hearing) in accordance with Section 120.57, Florida Statutes. Petitions must comply with the requirement of Florida Administrative Code Rules 17-103.155 and 28-5.201 (copies enclosed) and be filed with (received by) the Office of General Counsel of the Department at 2600 Blair Stone Road, Tallahassee, Florida 32399-2400. Petitions filed by the permit applicant must be filed within fourteen (14) days of receipt of this intent. Petitions filed by other persons must be filed within fourteen (14) days of publication of the public notice or within fourteen (14) days of receipt of this intent, whichever first occurs. Failure to file a petition within this time period shall constitute a waiver of any right such person may have to request an administrative determination (hearing) under Section 120.57, Florida Statutes, concerning the subject permit application. Petitions which are not filed in accordance with the above provisions will be dismissed.

Executed in Tallahassee, Florida.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL REGULATION

C. H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality
Management

Copies furnished to:

James R. Confroy
Isidore Goldman
Patrick Wong

CERTIFICATE OF SERVICE

The undersigned duly designated deputy clerk hereby certifies that this NOTICE OF INTENT TO ISSUE and all copies were mailed before the close of business on March 18, 1987.

FILING AND ACKNOWLEDGEMENT
FILED, on this date, pursuant to §120.52(9), Florida Statutes, with the designated Department Clerk, receipt of which is hereby acknowledged.

R Bruce Mitchell
Clerk

3/18/87
Date

Technical Evaluation
and
Preliminary Determination

Key Pharmaceuticals, Inc.
Miami, Florida
Dade County

Modification of the Operations of
3 Fluidized Bed Coating Units (Glatts)

File No. AC 13-129891

Florida Department of Environmental Regulation
Bureau of Air Quality Management
Central Air Permitting

March 13, 1987

I. General Information

A. Applicant

Key Pharmaceuticals, Inc
50 N.W. 176th Street
Miami, Florida 33169-1307

B. Request

Mr. Thomas Flachmeyer, Manager of Environmental Engineering and Waste Management for Key Pharmaceuticals, Inc., submitted an application for permit to modify the operations of three fluidized bed coating units (Glatts) on January 26, 1987. The application was considered complete on receipt (January 26, 1987).

C. Project and Location

Key Pharmaceuticals, Inc. requested permission to increase the production of 3 Glatt units (2 existing, AO 13-114316 and 1 permitted, AC 13-100437) at their pharmaceutical plant (SIC 2834) located at 50 N.W. 176th Street in Miami, Dade County, Florida. The UTM coordinates of this facility are zone 17, 579.9 km E and 2868.4 km N. They also propose to change the ratio of methylene chloride to methanol used in the process. The existing dust collector and scrubber will continue to be used to control the particulate matter and methanol emissions from the process. No physical changes to the process or air pollution control equipment are required for this modification.

A more detailed description of the process equipment and air pollution control system is in the May 10, 1985, Technical Evaluation and Preliminary Determination for Key Pharmaceuticals, Inc. No. 2 Fluidized Bed Coating Unit. This document is available for public inspection at the department's offices in West Palm Beach and Tallahassee.

D. Air Pollutant Emissions

Particulate matter (PM), methanol - a volatile organic compound (VOC), and methylene chloride - an exempt VOC (Rule 17-2.650(1)(d), FAC), are emitted from the process. A dust collector removes the PM and a scrubber with an activated sludge treatment system removes most of the methanol. All of the methylene chloride escapes from the system.

The ratio of methylene chloride to methanol used in the process is being increased from 83:17 to 90:10.

Allowable operation time is being increased from 8,400 to 8,760 hours per year.

The efficiency of the Torit 3DF60 dust collector controlling PM is estimated to be 99 percent. The efficiency of the scrubber with an activated sludge treatment system in controlling methylene chloride and methanol is estimated to be 0 and 90 percent, respectively.

The permitted emissions from the 3 Glatt units, before and after the proposed modification, are listed in the following table.

Emissions from 3 Glatt Units

	PM		Methanol (VOC)		Methylene Chloride (exempt)	
	lb/hr	TPY	lb/hr	TPY	lb/hr	TPY
Proposed	0.47	0.14	6.9	20.3	743	2195
Present	0.02	0.07	13.2	19.2	660	978
Change	+0.45	+0.07	-6.3	+1.1	+83	+1217

Except for methylene chloride, the changes in emissions as a result of the modification are insignificant. An application for permit to construct a carbon adsorption unit (file No. AC 13-129893) to recover methylene chloride from these 3 Glatt Units and other manufacturing equipment is being processed by the department. The carbon absorption unit is schedules to be in operation in early 1988 and is expected to reduce methylene chloride emissions to 141 lb/hr and 370.1 TPY.

II. Rule Applicability

A. State Regulations

The proposed project, modification of the operations of 3 Glatt units, is subject to preconstruction review under the provisions of Chapter 403, Florida Statutes, and Chapter 17-2, Florida Administrative Code.

The pharmaceutical plant (SIC 2834) is located in an area designated nonattainment for ozone (Rule 17-2.410, FAC), and attainment for the other criteria pollutants.

Pharmaceutical plants are classified as chemical process plants which are listed on Table 500-1, Major Facility Categories (list of 28). The plant is a major facility (17-2.100) because the potential emissions of exempt VOC presently exceed 100 TPY. It is a minor source for the regulated VOC because these emissions are less than 100 TPY. The increase in emissions resulting from the proposed project is less than the significant emission rates listed in Table 500-2, Regulated Air Pollutants-Significant Emission Rates.

The project is not subject to the prevention of significant deterioration regulation (17-2.500) and new source review for

nonattainment areas (17-2.510) because the modification does not result in a significant net emissions increase of any criteria pollutant (17-2.500(2)(d)4.a.(ii) and 17-2.510(2)(d)4.a.).

The project will be reviewed under Rule 17-2.520, Sources Not Subject to Prevention of Significant Deterioration or Nonattainment Requirements. Allowable VOC emissions will be based on the requirement for reasonable controls, Rule 17-2.620, FAC, and Consent Order No. 84-0644. Allowable particulate matter emissions shall be based on 17-2.610(1), the process weight table. An alternate standard of 5% opacity may be substituted for the particulate matter standard (17-2.700(3)(d)).

Higher emission would subject this operation to review under other regulations.

B. Federal Regulations

The proposed project, a minor modification to a major source, is not subject to review under federal regulations because the modification will not result in a significant net emissions increase of any criteria pollutant.

III. Technical Evaluation

Presently, the Glatt units are permitted to operate 8400 hours per year. The three units are allowed an average consumption of 45.7 lb/hr methanol and 233 lb/hr methylene chloride. The scrubber removes 90% of the methanol from the air emissions. Thus, the units are permitted to discharge 19.2 TPY methanol. Basically, none of the methylene chloride, an exempt VOC, is removed by the air pollution control system. Thus, the equipment is currently permitted to emit 978 TPY methylene chloride.

The company is requesting permission to operate the three units continuously, 8760 hr/yr. They also plan to increase the ratio of methylene chloride to methanol from approximately 83:17 to 90:10. The average permitted consumption of the solvents after this modification would be 46.4 lb/hr methanol and 501 lb/hr methylene chloride. The removal efficiency of the scrubber is expected to remain the same. The permitted emissions of methanol being requested is 20.3 TPY, a slight increase over the present value. However, the permitted emissions of methylene chloride will increase from 978 TPY to 2195 TPY.

Although the department is concerned about this quantity of emissions, the ambient air impact of this pollutant, based on modeling, will not endanger health. See Section IV.

Know and existing vapor control system exist that will reduce methylene chloride emissions. The department deems some reduction in this quantity of emissions is necessary. Key

Pharmaceuticals, Inc. has submitted a separate application for permit to construct (File No. AC 13-129893) an air pollution control device (carbon absorption unit) for these Glatt and other process equipment that will reduce the emissions of methylene chloride. The proposed carbon absorption unit will replace the existing scrubber. The construction of this control device will be required as a condition of this permit. As the proposed emissions will not endanger health, the department will allow the carbon absorption unit to be installed after the modification proposed in this application. Thus, there will be a temporary increase in methylene chloride emissions.

IV. Ambient Air Impact

The modifications proposed by the applicant will increase the maximum permitted emissions of methylene chloride, an exempt VOC, from 660 to 743 lb/hr. No air quality analysis for this modification is required by the regulations. However, modeling of the proposed emissions shows that the maximum 24 hour concentration of methylene chloride in the ambient air will be slightly less than 1 ppmv. The TLV value for methylene Chloride is 100 ppm. The department's policy is to approve applications if the impact of the toxic pollutants are less than 1-2 percent of the TLV value. This proposal meets that criteria. Also, the impact will be reduced significantly when the proposed carbon absorption pollution control system for this process is placed in service. Based on this analysis, the department has reasonable assurance that the emisions of methylene chloride from this process will not endanger public health.

V. Conclusion

Based on the data submitted by the applicant, the department has concluded that the temporary emissions from the modified process will not endanger public health. After the replacement of the scrubber with the carbon absorption unit, the process will be in compliance with the state regulations. The department proposes to issue a construction permit that will authorized the modifications proposed by the applicant in this application. A condition to this permit will be that the applicant install an air pollution control system for methylene chloride within a reasonable time. The General and Specific Conditions in the proposed permit (attached) will assure compliance of the modified operation with the state air pollution control regulations.

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32399-2400

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

PERMITTEE:
Key Pharmaceuticals, Inc.
50 NW 176th Street
Miami, Florida 33169-1307

Permit Number: AC 13-129891
Expiration Date: January 1, 1988
County: Dade
Latitude/Longitude: 25° 56' 04" N
80° 12' 11" W
Project: 3 Fluidized Bed
Processors with Scrubber

This permit is issued under the provisions of Chapter 403, Florida Statutes, and Florida Administrative Code Rule(s) 17-2 and 17-4. The above named permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents attached hereto or on file with the department and made a part hereof and specifically described as follows:

Modification of the operations of Nos. 1, 2, and 3 fluidized bed coating units (Glatts) by increasing the allowable hours of operation and changing the ratio of methylene chloride to methanol to 90:10 Glatt Nos. 1, 2, and 3 can manufacture up to 2,053 lots of drugs per year. Each lot uses approximately 3,000 lbs of solvent and excipients. Emissions are controlled by a Torit 3DF60 dust collector and a packed bed scrubber designed by Koch Engineering Company and equipped with a 50 foot high, 2.5 foot diameter stack that discharges approximately 18,000 scfm of air.

The facility location is bounded on the west by S.R. 441, on the east and south by Interstate Highway 95, and on the north by NW 176th Street in Miami, Dade County, Florida. The UTM coordinates of this site are zone 17, 579.9 km E and 2868.4 km N.

The operation of Glatt Nos. 1, 2, and 3 shall be in accordance with the application for permit to construct 3 fluidized bed processors with scrubber that was delivered to the department on January 26, 1987.

Attachments:

1. Application for 3 Fluidized Bed Processors with Scrubber received by BAQM on January 26, 1987.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129891
Expiration Date: January 1, 1988

GENERAL CONDITIONS:

1. The terms, conditions, requirements, limitations, and restrictions set forth herein are "Permit Conditions" and as such are binding upon the permittee and enforceable pursuant to the authority of Sections 403.161, 403.727, or 403.859 through 403.861, Florida Statutes. The permittee is hereby placed on notice that the department will review this permit periodically and may initiate enforcement action for any violation of the "Permit Conditions" by the permittee, its agents, employees, servants or representatives.

2. This permit is valid only for the specific processes and operations applied for and indicated in the approved drawings or exhibits. Any unauthorized deviation from the approved drawings, exhibits, specifications, or conditions of this permit may constitute grounds for revocation and enforcement action by the department.

3. As provided in Subsections 403.087(6) and 403.722(5), Florida Statutes, the issuance of this permit does not convey any vested rights or any exclusive privileges. Nor does it authorize any injury to public or private property or any invasion of personal rights, nor any infringement of federal, state or local laws or regulations. This permit does not constitute a waiver of or approval of any other department permit that may be required for other aspects of the total project which are not addressed in the permit.

4. This permit conveys no title to land or water, does not constitute state recognition or acknowledgement of title, and does not constitute authority for the use of submerged lands unless herein provided and the necessary title or leasehold interests have been obtained from the state. Only the Trustees of the Internal Improvement Trust Fund may express state opinion as to title.

5. This permit does not relieve the permittee from liability for harm or injury to human health or welfare, animal, plant or aquatic life or property and penalties therefore caused by the construction or operation of this permitted source, nor does it allow the permittee to cause pollution in contravention of Florida Statutes and department rules, unless specifically authorized by an order from the department.

GENERAL CONDITIONS:

6. The permittee shall at all times properly operate and maintain the facility and systems of treatment and control (and related appurtenances) that are installed or used by the permittee to achieve compliance with the conditions of this permit, as required by department rules. This provision includes the operation of backup or auxiliary facilities or similar systems when necessary to achieve compliance with the conditions of the permit and when required by department rules.

7. The permittee, by accepting this permit, specifically agrees to allow authorized department personnel, upon presentation of credentials or other documents as may be required by law, access to the premises, at reasonable times, where the permitted activity is located or conducted for the purpose of:

a. Having access to and copying any records that must be kept under the conditions of the permit;

b. Inspecting the facility, equipment, practices, or operations regulated or required under this permit; and

c. Sampling or monitoring any substances or parameters at any location reasonably necessary to assure compliance with this permit or department rules.

Reasonable time may depend on the nature of the concern being investigated.

8. If, for any reason, the permittee does not comply with or will be unable to comply with any condition or limitation specified in this permit, the permittee shall immediately notify and provide the department with the following information:

a. a description of and cause of non-compliance; and

b. the period of noncompliance, including exact dates and times; or, if not corrected, the anticipated time the noncompliance is expected to continue, and steps being taken to reduce, eliminate, and prevent recurrence of the noncompliance.

GENERAL CONDITIONS:

The permittee shall be responsible for any and all damages which may result and may be subject to enforcement action by the department for penalties or revocation of this permit.

9. In accepting this permit, the permittee understands and agrees that all records, notes, monitoring data and other information relating to the construction or operation of this permitted source, which are submitted to the department, may be used by the department as evidence in any enforcement case arising under the Florida Statutes or department rules, except where such use is proscribed by Sections 403.73 and 403.111, Florida Statutes.

10. The permittee agrees to comply with changes in department rules and Florida Statutes after a reasonable time for compliance, provided however, the permittee does not waive any other rights granted by Florida Statutes or department rules.

11. This permit is transferable only upon department approval in accordance with Florida Administrative Code Rules 17-4.12 and 17-30.30, as applicable. The permittee shall be liable for any non-compliance of the permitted activity until the transfer is approved by the department.

12. This permit is required to be kept at the work site of the permitted activity during the entire period of construction or operation.

13. This permit also constitutes:

( ) Determination of Best Available Control Technology (BACT)
( ) Determination of Prevention of Significant Deterioration (PSD)
( ) Compliance with New Source Performance Standards.

14. The permittee shall comply with the following monitoring and record keeping requirements:

a. Upon request, the permittee shall furnish all records and plans required under department rules. The retention period for all records will be extended automatically, unless otherwise stipulated by the department, during the course of any unresolved enforcement action.

GENERAL CONDITIONS:

b. The permittee shall retain at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation), copies of all reports required by this permit, and records of all data used to complete the application for this permit. The time period of retention shall be at least three years from the date of the sample, measurement, report or application unless otherwise specified by department rule.

c. Records of monitoring information shall include:

- the date, exact place, and time of sampling or measurements;
- the person responsible for performing the sampling or measurements;
- the date(s) analyses were performed;
- the person responsible for performing the analyses;
- the analytical techniques or methods used; and
- the results of such analyses.

15. When requested by the department, the permittee shall within a reasonable time furnish any information required by law which is needed to determine compliance with the permit. If the permittee becomes aware that relevant facts were not submitted or were incorrect in the permit application or in any report to the department, such facts or information shall be submitted or corrected promptly.

SPECIFIC CONDITIONS:

1. The Nos. 1, 2, and 3 fluidized bed processor (Glatts) may operate continuously, 8760 hours per year, provided the air pollution control system serving these units is operating properly.

2. The maximum production of each Glatt unit shall not exceed the following without prior approval of the department (BAQM):

Glatt Unit No. 1 - 461 lots/year
Glatt Unit No. 2 - 796 lots/year
Glatt Unit No. 3 - 796 lots/year

The approximate composition of each lot is 2,139 lbs of methylene chloride, 198 lbs methanol, and 665 lbs of excipients.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129891
Expiration Date: January 1, 1988

SPECIFIC CONDITIONS:

The permittee shall maintain records of the number of lots manufactured by each Glatt unit and the composition of each lot for a minumum of 2 years for department inspection.

3. The maximum emissions (with 3 Glatt units in operation) from the Scrubber air pollution control system shall not exceed:

Methanol-(VOC) 6.9 lbs/hr (max) and 4.64 lbs/hr (avg), and 20.3 TPY (VOC)

Particulate Matter - ~~0.5 lbs/hr and 0.14 TPY or~~ 5% opacity

Methylene Chloride (exempt VOC) - 743 lbs/hr (max), 501 lbs/hr (avg), and 2195 TPY

Compliance with the standards listed above shall be determined as follows:

Methanol (VOC) - The efficiency and maximum emissions of the scrubber shall be determined by a Method 25, 25A, or 18 test as described in 40 CFR 60, Appendix A, prior to the expiration of this permit and each time a permit to operate is applied for (every five years).

Compliance with the particulate matter standard shall be determined by ~~Method 5, described in 40 CFR 60, Appendix A, or (at the option of the permittee)~~ an alternate standard of no visible emissions (5 percent opacity maximum) as determined by Method 9, 40 CFR 60, Appendix A, ~~may be substituted for the particulate matter standard.~~

Compliance with the methylene chloride standard (exempt VOC) shall be calculated from inventory records and logs for the Glatt units.

The allowable emissions are lower (prorated based on design calculations in the application) when any of the Glatt units are not in operation.

4. The permittee shall install a carbon absorption system to reduce methylene chloride emissions (after department (BAQM) approval) before July 1, 1988.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129891
Expiration Date: January 1, 1988

SPECIFIC CONDITIONS:

5. The permittee shall prove compliance with all conditions of this permit ~~(except Specific Condition No. 4)~~ and submit a complete application for permit to operate to the department (SE District) ~~by October 1, 1987~~ 90 days prior to expiration. The application for the permit to operate shall include a status report and schedule for the installation of the carbon absorption system. The permittee may continue to operate in compliance with all terms of this construction permit until its expiration date.

6. Upon obtaining a permit to operate, the permittee will be required to submit annual reports on the actual operation of the facility. These reports shall include, as a minimum, a recent Method 9 test on the scrubber, the number of lots manufactured by the 3 Glatt units, and the calculated emissions of methylene chloride and methanol based on plant records.

Issued this_____day of_____, 19___

STATE OF FLORIDA DEPARTMENT OF
ENVIRONMENTAL REGULATION

_____
Dale Twachtmann, Secretary

____ pages attached

129891

BEST AVAILABLE COPY

RECEIVED
1985
M. F. NATHAN

KOCH ENGINEERING COMPANY, INC.

Reply to:
161 EAST 42nd STREET
NEW YORK, N.Y. 10017
PHONE: 212 - 682-5755

March 4, 1985

Crawford and Russell
17 Amelia Place
Stamford, CT. 06904

Attention: Dr. Marvin Nathan, Corp. Mgr.
Environmental Engineering

Reference: C & R Project 85021

Gentlemen:

For the Key Pharmaceutical, Inc. facility in Miami, Florida, an 8 ft. diameter Koch high efficiency absorber column with Koch FLEXIPAC® packing and internals will provide 90% or higher removal of methanol from 80,214 lb/hr. of inlet air at 140°F with 141.7 lb./hr. of methanol. Design rate is 100 gpm of inlet water with maximum of 100 ppm methanol with inlet and outlet temperature of 100°F maximum.

The Koch high efficiency absorber will be packed with approximately 10 ft. of regularly structured Koch Flexipac packing which provides high efficiency, low pressure and high operating flexibility. The packing provides high surface area for efficiency and is also very open to allow high capacity with low pressure drop. The packing geometry insures good mixing and radial distribution of the liquid and gas streams. The Koch absorber will also provide high operating flexibility to maintain high efficiency performance even with varying loading conditions.

Literature is enclosed on Koch Flexipac packing.

Sincerely,

KOCH ENGINEERING COMPANY, INC.

Joseph H. Hill

Joseph H. Hill
JHH:tb
Enc. - KFP-3 (2)

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Key Pharm Inc

Carbon Adsorp / Solvent Recy

AQDHS-II MASTER FILE TRANSACTION EDIT PROGRAM - DIAGNOSTIC REPORT PAGE 1110

INPUT TRANSACTIONS ERRORS

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2/2/87

Key Pharmaceutical, Inc. Carbon Absorption / Solvent Recovery System

7

MPTPLU
-- MODEL FOR SCREENING MAXIMUM CONCENTRATIONS FOR MULTIPLE SOURCES
MODIFIED FROM PTPLU

*** TITLE OF SOURCE # 1 ***

*** TEST OF MPTPLU ***

)))INPUT PARAMETERS(((

OPTIONS
IF = 1, USE OPTION
IF = 0, IGNORE OPTION
IOPT(1) = 0 (GRAD PLUME RISE)
IOPT(2) = 0 (STACK DOWNWASH)
IOPT(3) = 0 (BUOY. INDUCED DISP.)
IOPT(4) = 1 (EXTRAPOLATED WIND)

METEOROLOGY
AMBIENT AIR TEMPERATURE = 293.00 (K)
MIXING HEIGHT = 2000.00 (M)
ANEMOMETER HEIGHT = 10.00 (M)
WIND EXTRAPOLATION EXPONENTS = A: .10, B: .15, C: .20
D: .25, E: .30, F: .50

RECEPTOR HEIGHT = .00 (M)

SOURCE
EMISSION RATE = 1.78E+01 (G/SEC) 141 lb/hr methylene Chloride
STACK HEIGHT = 10.67 (M)
EXIT TEMP. = 302.44 (K)
EXIT VELOCITY = 16.90 (M/SEC)
STACK DIAM. = 1.07 (M)
VOLUME FLOW = 1.51E+01 (M**3/SEC)

)))CALCULATED PARAMETERS(((

VOLUMETRIC FLOW = 1.51E+01 (M**3/SEC)

New Plans Inc.

Carbon Absorb / Solvent Recovery System

** ACGIH

* FL Toxic Air Contaminants Program

	TLV	1% TLV
* Methylene Chloride (moderate toxic)	350,000 ug/m3	3500 ug/m3
** Methanol	260,000 ug/m3	2600 ug/m3

WIND EXTRAPOLATION EXPONENTS = A: .10, B: [illegible] .20
C: .25, D: .30, E: [illegible]

RECEPTOR HEIGHT = .00 (M)

SOURCE
EMISSION RATE = 1.78E+01 (G/SEC) 141 lb/hr methylene chloride
STACK HEIGHT = 10.67 (M)
EXIT TEMP. = 302.44 (K)
EXIT VELOCITY = 16.90 (M/SEC)
STACK DIAM. = 1.07 (M)
VOLUME FLOW = 1.51E+01 (M**3/SEC)

)))CALCULATED PARAMETERS(((

VOLUMETRIC FLOW = 1.51E+01 (M**3/SEC)
BUOYANCY FLUX PARAMETER = 1.47 (M**4/SEC**3)

** methanol 260,000 ug/m³

BEST AVAILABLE COPY

*** MAXIMUM CONCENTRATION FOR SOURCE # 1 ***

**** STACK TOP WINDS EXTRAPOLATED FROM 10.0 METERS ****

*** WIND SPEED AT 10.0 METER HEIGHT IS GIVEN HERE ***

STABILITY	WIND SPEED (M/SEC)	MAX CONC (UG/CU M)	DIST OF MAX (KM)	PLUME HT (M)
3	5.00	1.0705E+03	.12*	21.3

*** CORRESPONDING SPATIAL DISTRIBUTION ***

DISTANCE (KM)	CONCENTRATION (UG/M**3)
.1	1.9[illegible]E+03
.2	1.0590E+03
.3	9.2[illegible]E+02
.5	5.0[illegible]E+02
.7	3.021[illegible]E+02
1.0	1.6663E+02
1.5	8.2131E+01
2.0	4.9224E+01
3.0	2.3767E+01
5.0	9.4569E+00
7.0	5.1519E+00
10.0	2.7077E+00
15.0	1.3049E+00
20.0	7.7849E-01
30.0	3.8709E-01
50.0	2.0855E-01

1,059 ug/m³ max 1 hr impact

1059 x 0.7 = 741 ug/m³ 8 hr avg conc

1059 x 0.4 = 424 ug/m³ 24 hr avg conc

*** SPATIAL DISTRIBUTION OF WORST CONDITIONS ***
(CUMULATED FOR THE LAST 1 SOURCE(S))

DISTANCE (KM)	MAX CONC (UG/M**3)	STABILITY	WIND (M/S)
.1	7.1859E+02	2	5.00
.2	1.0590E+03	3	5.00
.3	1.0017E+03	3	5.00
.5	6.9172E+02	4	5.00
.7	7.8039E+02	4	5.00
1.0	6.4826E+02	4	5.00
1.5	5.2857E+02	5	1.00
2.0	8.2289E+02	6	1.00
3.0	8.0592E+02	6	1.00
5.0	5.3997E+02	6	1.00
7.0	4.4246E+02	6	1.00
10.0	3.[illegible]E+02	6	1.00
15.0	2.0331E+02	6	1.00
20.0	1.4969E+02	6	1.00
30.0	9.6262E+01	6	1.00
50.0	5.5677E+01	6	1.00

STOP = Program terminated

$$\text{methanol (1hr max)} = \frac{15.4\%}{141}(1059\ \text{ug/m}^3) = 116\ \text{ug/m}^3\ \text{(1hr max)}$$

8 hr 0.7 (116) = 81 ug/m³

24 hr 0.4 (116) = 46 ug/m³

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200
Telex: 808235

January 12, 1987

Mr. C.H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: APPLICATION FOR PERMIT TO CONSTRUCT 3 FLUIDIZED BED COATING UNITS.

Dear Mr. Fancy:

Attached please find an "Application to Construct Air Pollution Sources". The application attached is for the construction of 3 fluidized bed coating units. The application replaces Permit No. AC 13-100437 and ACO 13-114316. Key Pharmaceuticals is not requesting a permit to install additional units, above and beyond those permitted under Permit AC 13-100437, with this permit application. This submittal has been initiated due to the realization of higher production capacities from the Glatt equipment than originally anticipated and a change in the manufacturing formulation.

The two specific issues that necessitated this application are:

- By June, 1987, Key will have three Glatt units (fluidized bed coating) in operation. The specific models are: one (1) Glatt WSG-300; and two (2) Glatt GPCG-300's. The difference between the two units is that the GPCG is a new version of the WSG. All production development work was done with a WSG and a lot cycle of 20 hours per lot was established. During the production effort in the past 12 months is has been found that the cleaning time for a WSG unit can be reduced consistently by 2 hours and that a GPCG unit has a 3-hour cleaning requirement and an 8-hour spray requirement, thereby reducing the overall lot cycle by 9 hours. This decrease in lot cycle time has significantly increased the emission rate potential.

- It has been found that the change in ratio of methylene chloride to methanol from an 83:17 ratio to a 90:10 ratio enhances the performance of the drug.

RE: APPLICATION FOR PERMIT TO CONSTRUCT 3 FLUIDIZED BED COATING UNITS.

Key feels that these two changes have altered the emission significantly and warrants a new application for permit.

Your cooperation in this matter is greatly appreciated. Should you have any questions please do not hesitate to call me at 305-654-2240.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

attachment

cc: S. Brooks (S.E. Florida District)
P. Wong (DERM Office)

STATE OF FLORIDA AC 13-129491

DEPARTMENT OF ENVIRONMENTAL REGULATION

SOUTHEAST FLORIDA DISTRICT
3301 GUN CLUB ROAD
P.O. BOX 3858
WEST PALM BEACH, FLORIDA 33402

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

ROY DUKE
DISTRICT MANAGER

APPLICATION TO OPERATE/CONSTRUCT AIR POLLUTION SOURCES

SOURCE TYPE: AIR POLLUTION [x] New[1] [ ] Existing[1]

APPLICATION TYPE: [X] Construction [ ] Operation [ ] Modification

COMPANY NAME: KEY PHARMACEUTICALS, INC. COUNTY: DADE

Identify the specific emission point source(s) addressed in this application (i.e. Lime Kiln No. 4 with Venturi Scrubber; Peaking Unit No. 2, Gas Fired) 3 FLUIDIZED BED PROCESSORS WITH SCRUBBER

SOURCE LOCATION: Street 50 N.W. 176 STREET City MIAMI

UTM: East 57987 North 2868445

Latitude 25 ° 56 ' 03 "N Longitude 80 ° 11 ' 42 "W

APPLICANT NAME AND TITLE: JAMES R. CONFROY, VICE PRESIDENT OPERATIONS

APPLICANT ADDRESS: 50 N.W. 176 STREET, MIAMI, FLORIDA 33169

SECTION I: STATEMENTS BY APPLICANT AND ENGINEER

A. APPLICANT

I am the undersigned owner or authorized representative* of KEY PHARMACEUTICALS, INC.

I certify that the statements made in this application for a CONSTRUCTION permit are true, correct and complete to the best of my knowledge and belief. Further, I agree to maintain and operate the pollution control source and pollution control facilities in such a manner as to comply with the provision of Chapter 403, Florida Statutes, and all the rules and regulations of the department and revisions thereof. I also understand that a permit, if granted by the department, will be non-transferable and I will promptly notify the department upon sale or legal transfer of the permitted establishment.

*Attach letter of authorization

Signed: James R Confroy

JAMES R. CONFROY, VICE PRESIDENT OPERATIONS
Name and Title (Please Type)

Date: 1/12/87 Telephone No. 305-654-2200

B. PROFESSIONAL ENGINEER REGISTERED IN FLORIDA (where required by Chapter 471, F.S.) *

~~This is to certify that the engineering features of this pollution control project have been designed/examined by me and found to be in conformity with modern engineering principles applicable to the treatment and disposal of pollutants characterized in the permit application. There is reasonable assurance, in my professional judgment, that~~

[1] See Florida Administrative Code Rule 17-2.100(57) and (104)

* SEE NOTE PAGE 2

I HAVE REVIEWED THE CALCULATIONS USED TO DETERMINE THE STATED LEVELS OF PARTICULATE AND VOC EMISSIONS AND FIND THEM TO BE ACCURATE BASED ON PROJECTED MANUFACTURING LEVELS OF THE PRODUCT.

~~the pollution control facilities, when properly maintained and operated, will discharge an effluent that complies with all applicable statutes of the State of Florida and the rules and regulations of the department. It is also agreed that the undersigned will furnish, if authorized by the owner, the applicant a set of instructions for the proper maintenance and operation of the pollution control facilities and, if applicable, pollution sources.~~

Signed John N. Wells, P.E.

JOHN N. WELLS, P.E.
Name (Please Type)

KEY PHARMACEUTICALS, INC.
Company Name (Please Type)

50 N.W. 176 STREET, MIAMI, FLORIDA 33169
Mailing Address (Please Type)

Florida Registration No. 33917 Date: 1/09/87 Telephone No. 305-654-2200

SECTION II: GENERAL PROJECT INFORMATION

A. Describe the nature and extent of the project. Refer to pollution control equipment, and expected improvements in eource performance as a result of installation. State whether the project will result in full compliance. Attach additional sheet if necessary.

RAW MATERIAL CRYSTALS ARE ADDED TO A FLUID BED COATING UNIT. THEY ARE FLUIDIZED BY HIGH VOLUME AIR FLOW THROUGH THE BASE OF THE UNIT. A SLURRY OF EXCIPIENTS IN A MIXTURE OF METHYLENE CHLORIDE AND METHANOL IS SPRAYED ONTO THE FLUIZIDED CRYSTALS. THE FINAL MATERIAL IS INSPECTED AND COMPRESSED INTO TABLETS, PACKAGED, INSPECTED, RELEASED AND SHIPPED.

B. Schedule of project covered in this application (Construction Permit Application Only)

Start of Construction JAN 1, 1985 Completion of Construction JUL 1, 1987

C. Costs of pollution control system(s): (Note: Show breakdown of estimated costs only for individual components/units of the project serving pollution control purposes. Information on actual costs shall be furnished with the application for operation permit.)

$500,000

D. Indicate any previous DER permits, orders and notices associated with the emission point, including permit issuance and expiration dates.

(1) CONSENT ORDER NO. 83-0373

(2) PERMIT TO CONSTRUCT FOR MFG GUANIDINE & QUINORA ACB-115383

(3) PERMIT TO CONSTRUCT FOR MFG OF K-DUR ACB 13-100437

E. Requested permitted equipment operating time: hrs/day 24 ; days/wk 7 ; wks/yr 52 ;
if power plant, hrs/yr N/A ; if seasonal, describe: N/A

F. If this is a new source or major modification, answer the following questions. (Yes or No)

1. Is this source in a non-attainment area for a particular pollutant? YES

   a. If yes, has "offset" been applied? NO

   b. If yes, has "Lowest Achievable Emission Rate" been applied? NO

   c. If yes, list non-attainment pollutants. OZONE

2. Does best available control technology (BACT) apply to this source? If yes, see Section VI. NO

3. Does the State "Prevention of Significant Deterioriation" (PSD) requirement apply to this source? If yes, see Sections VI and VII. NO

4. Do "Standards of Performance for New Stationary Sources" (NSPS) apply to this source? NO

5. Do "National Emission Standards for Hazardous Air Pollutants" (NESHAP) apply to this source? NO

H. Do "Reasonably Available Control Technology" (RACT) requirements apply to this source? NO

   a. If yes, for what pollutants?

   b. If yes, in addition to the information required in this form, any information requested in Rule 17-2.650 must be submitted.

Attach all supportive information related to any answer of "Yes". Attach any justification for any answer of "No" that might be considered questionable.

SECTION III: AIR POLLUTION SOURCES & CONTROL DEVICES (Other than Incinerators)

A. Raw Materials and Chemicals Used in your Process, if applicable:

Description	Contaminants		Utilization Rate - lbs/hr	Relate to Flow Diagram
	Type	% Wt		
METHANOL	VOC	10	46.4	" A "
METHYLENE CHLORIDE	VOC	90	501	" A "

B. Process Rate, if applicable: (See Section V, Item 1)

1. Total Process Input Rate (lbs/hr): 702 LB/HR

2. Product Weight (lbs/hr): 155 LB/HR

C. Airborne Contaminants Emitted: (Information in this table must be submitted for each emission point, use additional sheets as necessary)

Name of Contaminant	Emission[1]		Allowed[2] Emission Rate per Rule 17-2	Allowable[3] Emission lbs/hr	Potential[4] Emission		Relate to Flow Diagram
	Maximum lbs/hr	Actual T/yr			lbs/yr	T/yr	
VOC	6.9	20.3	N/A	N/A		203.2	" A "
PARTICULATE	0.47	0.14	N/A	N/A		13.7	" A "
METHYLENE CHLORIDE	743	2195	N/A	N/A		2195	" A "

[1]See Section V, Item 2.

[2]Reference applicable emission standards and units (e.g. Rule 17-2.600(5)(b)2. Table II, E. (1) - 0.1 pounds per million BTU heat input)

[3]Calculated from operating rate and applicable standard.

[4]Emission, if source operated without control (See Section V, Item 3).

D. Control Devices: (See Section V, Item 4)

Name and Type (Model & Serial No.)	Contaminant	Efficiency	Range of Particles Size Collected (in microns) (If applicable)	Basis for Efficiency (Section V Item 5)
SCRUBBER	VOC	90%	N/A	SUPPLIER'S DESIGN
DUST COLLECTOR	PARTICULATE	99.0%	2 micron or larger	SUPPLIER'S DESIGN
TORIT 3DF60				

E. Fuels

Type (Be Specific)	Consumption*		Maximum Heat Input (MMBTU/hr)
	avg/hr	max./hr	

*Units: Natural Gas--MMCF/hr; Fuel Oils--gallons/hr; Coal, wood, refuse, other--lbs/hr.

Fuel Analysis:

Percent Sulfur:_____ Percent Ash:_____

Density: _____ lbs/gal Typical Percent Nitrogen:_____

Heat Capacity: _____ BTU/lb _____ BTU/gal

Other Fuel Contaminants (which may cause air pollution):_____

F. If applicable, indicate the percent of fuel used for space heating.

Annual Average _____ Maximum _____

G. Indicate liquid or solid wastes generated and method of disposal.

24,660/YR PARTICULATES FROM FILTER EQUIVALENT TO ABOUT 62 DRUMS/YEAR TO OFF-SITE DISPOSAL. 650 TONS/YEAR AEROBIC ACTIVATED SLUDGE METHANOL DIGESTION TO DISPOSAL. BOTH ARE NON-HAZARDOUS.

H. Emission Stack Geometry and Flow Characteristics (Provide data for each stack):

Stack Height: 50' ft. Stack Diameter: 2'6" ft.

Gas Flow Rate: 18,000 scfm DSCFM Gas Exit Temperature: 90° °F.

Water Vapor Content: 2.75 VOL % Velocity: 60 FPS @ 90°F FPS

SECTION IV: INCINERATOR INFORMATION

Type of Waste	Type 0 (Plastics)	Type I (Rubbish)	Type II (Refuse)	Type III (Garbage)	Type IV (Pathological)	Type V (Liq.& Gas By-prod.)	Type VI (Solid By-prod.)
Actual lb/hr Incinerated							
Uncontrolled (lbs/hr)							

Description of Waste _____

Total Weight Incinerated (lbs/hr) _____ Design Capacity (lbs/hr) _____

Approximate Number of Hours of Operation per day _____ day/wk _____ wks/yr. _____

Manufacturer _____

Date Constructed _____ Model No. _____

	Volume $(ft)^3$	Heat Release (BTU/hr)	Fuel		Temperature (°F)
			Type	BTU/hr	
Primary Chamber					
Secondary Chamber					

Stack Height: _____ ft. Stack Diamter: _____ Stack Temp. _____

Gas Flow Rate: _____ ACFM _____ DSCFM* Velocity: _____ FPS

*If 50 or more tons per day design capacity, submit the emissions rate in grains per standard cubic foot dry gas corrected to 50% excess air.

Type of pollution control device: [ ] Cyclone [ ] Wet Scrubber [ ] Afterburner

[ ] Other (specify) _____

Brief description of operating characteristics of control devices: _____

_____

_____

_____

_____

Ultimate disposal of any effluent other than that emitted from the stack (scrubber water, ash, etc.):

_____

_____

_____

_____

NOTE: Items 2, 3, 4, 6, 7, 8, and 10 in Section V must be included where applicable.

SECTION V: SUPPLEMENTAL REQUIREMENTS

Please provide the following supplements where required for this application.

1. Total process input rate and product weight -- show derivation [Rule 17-2.100(127)]

2. To a construction application, attach basis of emission estimate (e.g., design calculations, design drawings, pertinent manufacturer's test data, etc.) and attach proposed methods (e.g., FR Part 60 Methods 1, 2, 3, 4, 5) to show proof of compliance with applicable standards. To an operation application, attach test results or methods used to show proof of compliance. Information provided when applying for an operation permit from a construction permit shall be indicative of the time at which the test was made.

3. Attach basis of potential discharge (e.g., emission factor, that is, AP42 test).

4. With construction permit application, include design details for all air pollution control systems (e.g., for baghouse include cloth to air ratio; for scrubber include cross-section sketch, design pressure drop, etc.)

5. With construction permit application, attach derivation of control device(s) efficiency. Include test or design data. Items 2, 3 and 5 should be consistent: actual emissions = potential (1-efficiency).

6. An 8 1/2" x 11" flow diagram which will, without revealing trade secrets, identify the individual operations and/or processes. Indicate where raw materials enter, where solid and liquid waste exit, where gaseous emissions and/or airborne particles are evolved and where finished products are obtained.

7. An 8 1/2" x 11" plot plan showing the location of the establishment, and points of airborne emissions, in relation to the surrounding area, residences and other permanent structures and roadways (Example: Copy of relevant portion of USGS topographic map).

8. An 8 1/2" x 11" plot plan of facility showing the location of manufacturing processes and outlets for airborne emissions. Relate all flows to the flow diagram.

9. The appropriate application fee in accordance with Rule 17-4.05. The check should be made payable to the Department of Environmental Regulation.

10. With an application for operation permit, attach a Certificate of Completion of Construction indicating that the source was constructed as shown in the construction permit.

SECTION VI: BEST AVAILABLE CONTROL TECHNOLOGY

A. Are standards of performance for new stationary sources pursuant to 40 C.F.R. Part 60 applicable to the source?

[ ] Yes [ ] No

Contaminant	Rate or Concentration

B. Has EPA declared the best available control technology for this class of sources (If yes, attach copy)

[ ] Yes [ ] No

Contaminant	Rate or Concentration

C. What emission levels do you propose as best available control technology?

Contaminant	Rate or Concentration

D. Describe the existing control and treatment technology (if any).

1. Control Device/System: 2. Operating Principles:

3. Efficiency:* 4. Capital Costs:

*Explain method of determining

5. Useful Life:

6. Operating Costs:

7. Energy:

8. Maintenance Cost:

9. Emissions:

Contaminant	Rate or Concentration

10. Stack Parameters

a. Height: ft.

b. Diameter: ft.

c. Flow Rate: ACFM

d. Temperature: °F.

e. Velocity: FPS

E. Describe the control and treatment technology available (As many types as applicable, use additional pages if necessary).

1.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

2.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

3.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to conatruct with control device, install in available space, and operate within proposed levels:

4.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Costs:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availsbility of construction materials and procesa chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, inatall in available apace, and operate within proposed levels:

F. Deacribe the control technology selected:

1. Control Device:

2. Efficiency:[1]

3. Capital Cost:

4. Useful Life:

5. Operating Coat:

6. Energy:[2]

7. Maintenance Cost:

8. Manufacturer:

9. Other locations where employed on similar processes:

a. (1) Company:

(2) Mailing Addreaa:

(3) City:

(4) State:

[1]Explain method of determining efficiency.
[2]Energy to be reported in unita of electrical power - KWH design rate.

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

b. (1) Company:

(2) Mailing Address:

(3) City: (4) State:

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

10. Reason for selection and description of systems:

[1]Applicant must provide this information when available. Should this information not be available, applicant must state the reason(s) why.

SECTION VII - PREVENTION OF SIGNIFICANT DETERIORATION

A. Company Monitored Data

1. _____no. sites _____ TSP _____( ) SO^2* _____ Wind spd/dir

Period of Monitoring _____/____/____ to _____/____/____
month day year month day year

Other data recorded _____

Attach all data or statistical summaries to this application.

*Specify bubbler (B) or continuous (C).

2. Instrumentation, Field and Laboratory

a. Was instrumentation EPA referenced or its equivalent? [ ] Yes [ ] No

b. Was instrumentation calibrated in accordance with Department procedures?

[ ] Yes [ ] No [ ] Unknown

B. Meteorological Data Used for Air Quality Modeling

1. _____ Year(s) of data from _____/_____/_____ to _____/_____/_____
month day year month day year

2. Surface data obtained from (location)_____

3. Upper air (mixing height) data obtained from (location)_____

4. Stability wind rose (STAR) data obtained from (location)_____

C. Computer Models Used

1. _____ Modified? If yes, attach description.

2. _____ Modified? If yes, attach description.

3. _____ Modified? If yes, attach description.

4. _____ Modified? If yes, attach description.

Attach copies of all final model runs showing input data, receptor locations, and principle output tables.

D. Applicants Maximum Allowable Emission Data

Pollutant	Emission Rate	
TSP	_____	grams/sec
SO^2	_____	grams/sec

E. Emission Data Used in Modeling

Attach list of emission sources. Emission data required is source name, description of point source (on NEDS point number), UTM coordinates, stack data, allowable emissions, and normal operating time.

F. Attach all other information supportive to the PSD review.

G. Discuss the social and economic impact of the selected technology versus other applicable technologies (i.e., jobs, payroll, production, taxes, energy, etc.). Include assessment of the environmental impact of the sources.

H. Attach scientific, engineering, and technical material, reports, publications, journals, and other competent relevant information describing the theory and application of the requested best available control technology.

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

C E R T I F I C A T E

To Whom It May Concern:

This is to certify that Robert A. Franke, Director of Engineering of Key Pharmaceuticals, Inc., is duly authorized to represent Key Pharmaceuticals, Inc., along with his designate, Thomas W. Flachmeyer, Manager Environmental Engineering and Waste Management; for the purposes of making Application for Permit to Construct or Operate Pollution Control Facilities for said company.

Key Pharmaceuticals, Inc.

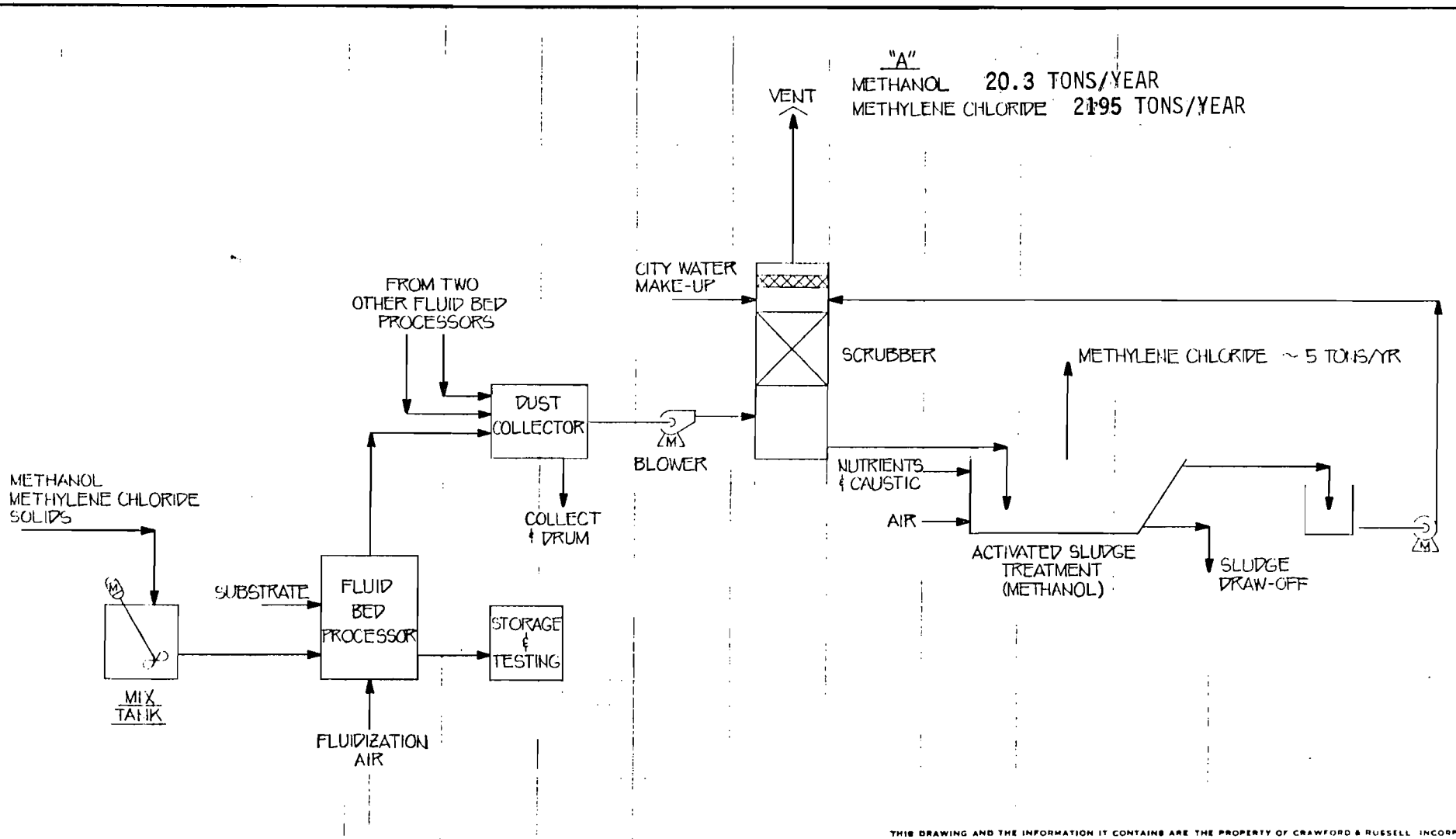
James R. Confroy, Vice President

Miami and Puerto Rico Operations

JRC/db

STATE OF FLORIDA
COUNTY OF DADE
Sworn to and subscribed before me
this 21st day of October A.D. 1986.

NOTARY PUBLIC STATE OF FLORIDA
MY COMMISSION EXP. DEC 18,1989
BONDED THRU GENERAL INS. UND.



THIS DRAWING AND THE INFORMATION IT CONTAINS ARE THE PROPERTY OF CRAWFORD & RUSSELL INCORPORATED

REVISIONS	DATE	BY	DATE
DESCRIPTION	DRAWN	SRG	2/16/82
	CHK'D		
	APPR.		
	APPR		
NO	SCALE: NONE		

JOHN BROWN
Crawford & Russell Incorporated
Process Plants Stamford, CT

FLUID BED COATING PROCESS

FOR KEY PHARMACEUTICALS, INC MIAMI BEACH, FLA

CR-85021

SRUN-NG 44-232 54577 1

KEY PHARMACEUTICALS, INC.
APPLICATION #1

I. PRODUCT

A. Termed product K-DUR (Prescription Drug)

B. Solvents Involved:

Methylene Chloride

Methanol

C. Process description (see attached Flow Sheet I)

D. Process Quantities

Basis - 461 lots of product for fluid bed process unit # 1 (Glatt 1)

796 lots of product for fluid bed process units # 2 and # 3 each (Glatts 2 and 3)

Methanol - 203.2 tons/year total all units

Methylene Chloride - 2195 tons/year total all units

Solids - 683 tons/year total all units

E. Overall plant loadings for product

Stage 1 - two fluid bed processors by about Feb'86

Stage 2 - add 1 fluid bed processor about Jul'87

Stage 3 - add 1 fluid bed processor in latter half'87

II. SOLVENT TREATMENT - Scrubber followed by water treatment

Description (see attached Flow Sheet II)

Process air (about 5500 scfm per fluid bed processor) is passed up through a packed column (9 to 10 ft in diameter) designed to give about 350 ft/min air velocity based on three units (i.e. fluid bed processors) operating. The column is filled with packing. Water flows down the column at a rate of about 33 gal/minute per fluid bed processor or 48,000 gal/day/processor. Note this system only treats Chloride. The water absorbs 90% of the Methanol and less than 0.5% of the Methylene Chloride. Water containing the Methanol and Methylene Chloride is directed to a water treatment plant (about 1200 ppm to 1400 ppm Methanol and 35 ppm to 40 ppm Methylene Chloride). The Methylene Chloride will flash off and the Methanol is treated biologically. The water is returned to the Scrubber. Evaporation losses are made up by City water. There is no effluent to the sewer system from this plant.

KEY PHARMACEUTICALS, INC.
APPLICATION #1

The Methylene Chloride effluent (660 lb/hour) has been modeled (as per EPA workbook) for discharge from a 50 ft high stack. Methylene Chloride downwind concentrations for 743 lb/hour (2195 tons/year) have been extrapolated from the previous model. The maximum flow rate of solvent (Methylene Chloride) is about 743 lb/hour for three processors. The maximum ground level concentration calculations are based on a 5 mph wind to less than 2.7 ppmv of Methylene Chloride. The OSHA and ACGIH TLV's are 500 ppmv and 100 ppmv, respectively. The average emission rate is about 2/3 of the maximum which equals 1.8 ppmv. This number is based (as per attached) on a 3 minute sample. The ratio from 3 minutes to 24 hours is multiplied by 0.36 which gives 0.66 ppmv. Based upon conversations with EPA's Bruce Turner, the ratio of 24 hour data to 1 year data is no more than 1/10. Therefore, average daily Methylene Chloride concentra- tions downwind of the stack are less than 0.066 ppmv. Based upon the stringent New York State AAL Standard, the average value should be less than 1/300 of the TLV. Even using the ACGIH TLV, this is 0.33 ppmv. We are at less than 1/5 of that.

STAGE 2 PRODUCTION:

	TOTAL IN (TONS/YEAR)	TOTAL OUT (TONS/YEAR)
METHANOL	203	20.3
METHYLENE CHLORIDE	2195	2195

SUMMARY

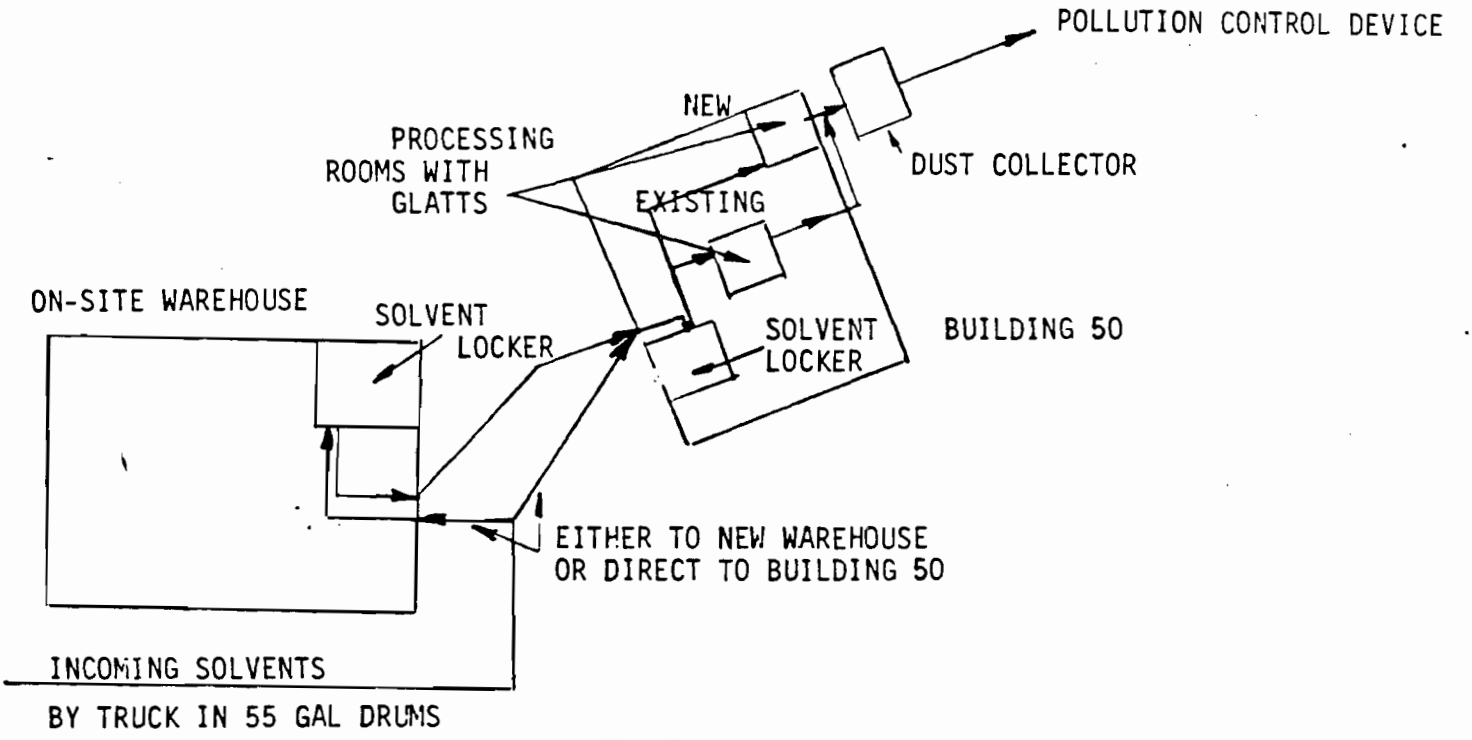
Based on the information presented:

1. Key Pharmaceuticals, Inc. should be allowed to produce a new product (K-DUR) involving a substantial amount of both Methanol and Methylene Chloride at 50 N.W. 176 Street in Miami, which is in the East Drive Well Field.

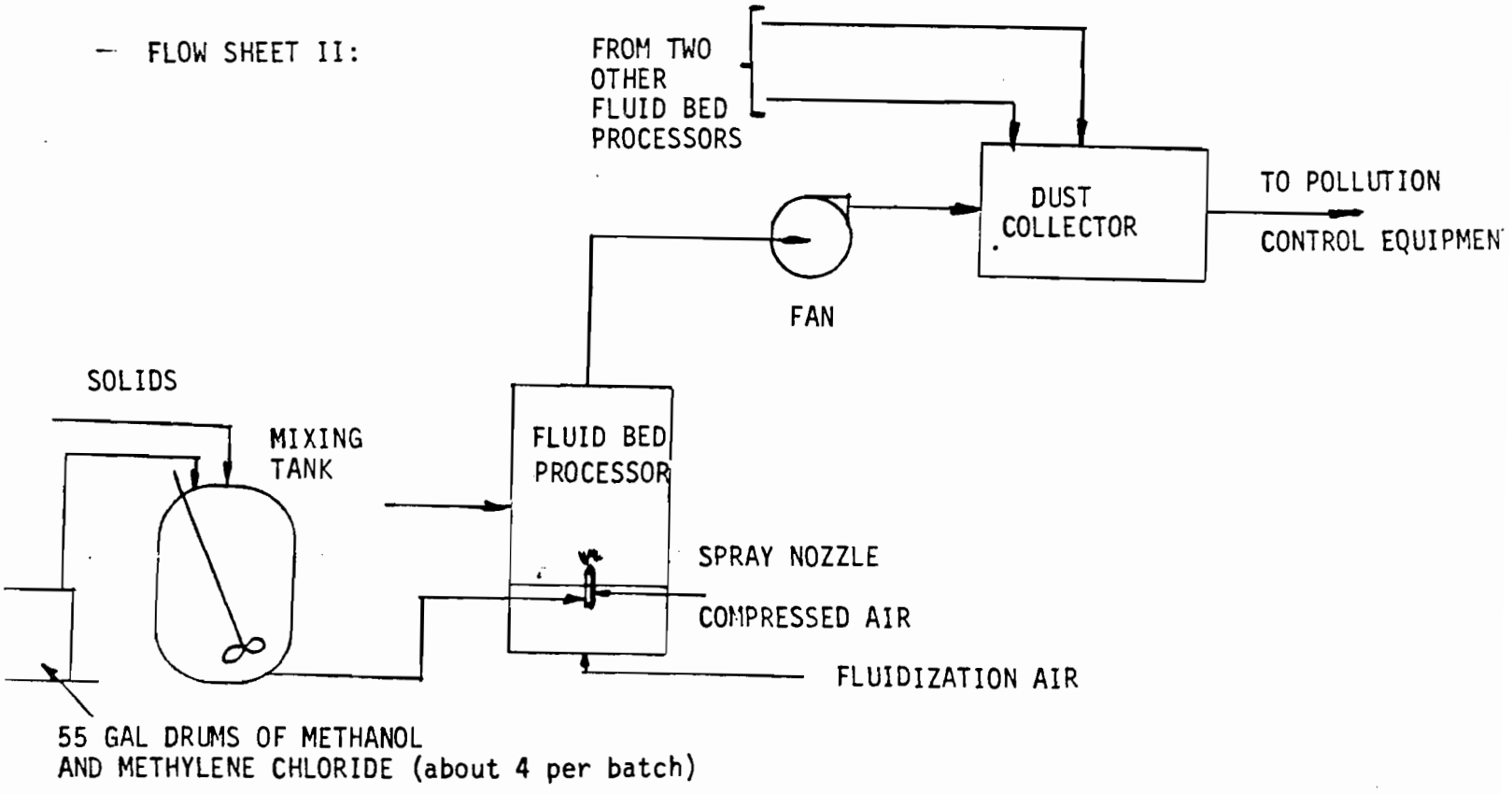
2. The Pollution Control Device for the processes through Stage 2 by scrubbing with water followed by waste water treatment (biological). There will be no effluent to the sewer system.

FLOW SHEET I

SOLVENT HANDLING



FLOW SHEET II:



CHARGE K-Dur Environmental DATE 1-12-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 1 of FILE NO. 0410

SUBJECT Process Emission Calculations for Fluid Bed processor (Glatt) units 1, 2 and 3

Basis

Manufacturing Max Capacity:

Unit #1 - 461 lots per year
Unit #2 - 796 lots per year
Unit #3 - 796 lots per year

Lot Specification

Methylene Chloride	2,139 #
Methanol	198 #
Solids (Excipients)	665 #

A. Methylene Chloride Emissions

(i) Maximum Instantaneous Emissions

Unit #1	209 #/Hr
Unit #2	267 #/Hr
Unit #3	267 #/Hr

Max Instantaneous Emissions 743 lb/Hr

(ii) Annual Emissions

Unit #1	493 Tons/year
	113 #/Hr
Unit #2	851 Tons/year
	194 #/Hr
Unit #3	851 Tons/year
	194 #/Hr

Average Annual Emissions 2,195 Tons/yr

501 lb/Hr

CHARGE K-Dur Environmental DATE 1-12-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 2 of FILE NO. 0410

SUBJECT _____

B. Methanol Emissions

(i) Max. Instantaneous Emission Potential

Unit #1	19.3 #/Hr
Unit #2	24.8 #/Hr
Unit #3	24.8 #/Hr

Total Potential 68.9 #/Hr

(ii) Max. Instantaneous Emissions

Scrubber Design - 90% efficient

∴ Max. Instantaneous Emissions 6.9 #/Hr

(iii) Annual Emission Potential

Unit #1	45.6 Tons/year 10.4 #/Hr.
Unit #2	78.8 Tons/year 18.0 #/Hr
Unit #3	78.8 Tons/year 18.0 #/Hr

Total Potential 203.2 Tons/year
46.4 #/Hr

(iv) Annual Emissions

Scrubber Design - 90% efficient

∴ Average Annual Emissions 20.3 T/y
4.6 #/Hr

CHARGE _____ DATE 1-12-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 3 of FILE NO. 0410

SUBJECT _____

C. Particulate Emissions

(i) Max. Instantaneous Emission Potential

Emission potential from Glatt is 2% of Solids

Unit #1	1.3 #/Hr
Unit #2	1.7 #/Hr
Unit #3	1.7 #/Hr

Total Potential 4.7 #/Hr

(ii) Max. Instantaneous Emissions

Dust Collector - 99% efficient

∴ Max Instantaneous Emissions 0.47 lb/Hr

(iii) Annual Emission Potential

Unit #1	3.1 Tons/year 0.7 lb/Hr
Unit #2	5.3 Tons/year 1.2 lb/Hr
Unit #3	5.3 Tons/year 1.2 #/Hr

Total Potential 13.7 Ton/year
3.1 #/Hr

(iv) Annual Emissions
Dust Collector - 99% efficient

∴ Average Annual Emissions 0.137 T/y
0.03 #/Hr

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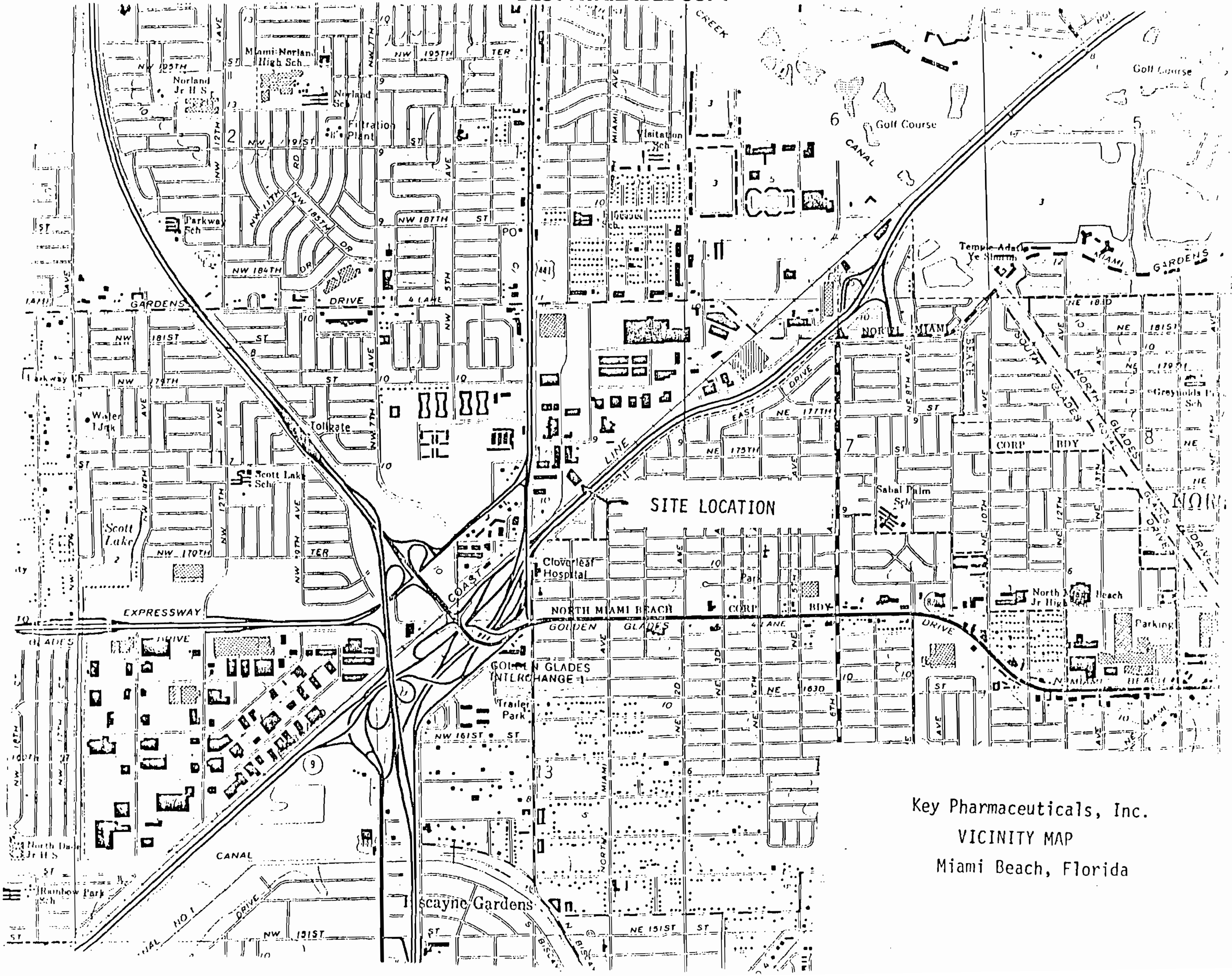

Key Pharmaceuticals, Inc.
VICINITY MAP
Miami Beach, Florida

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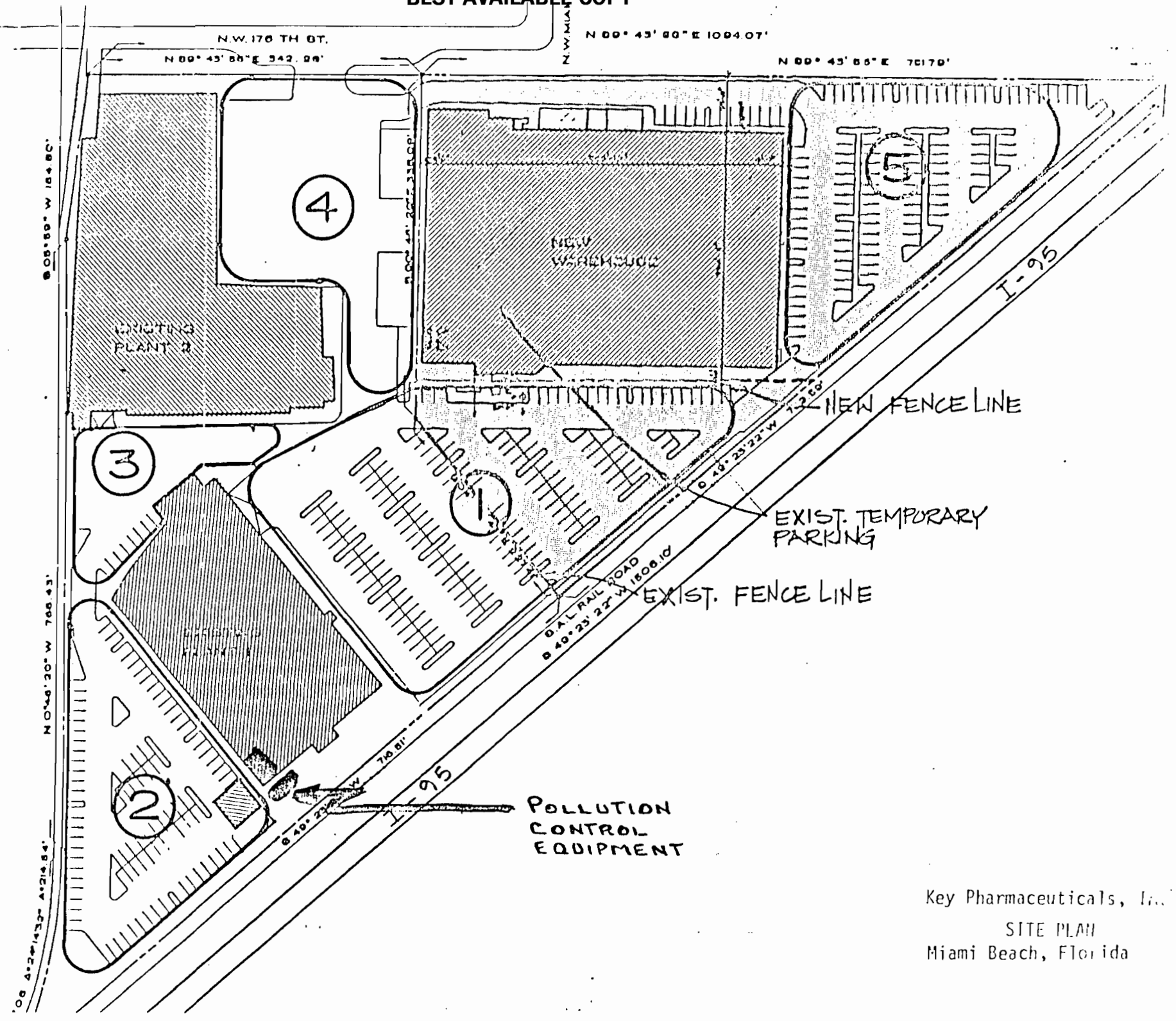
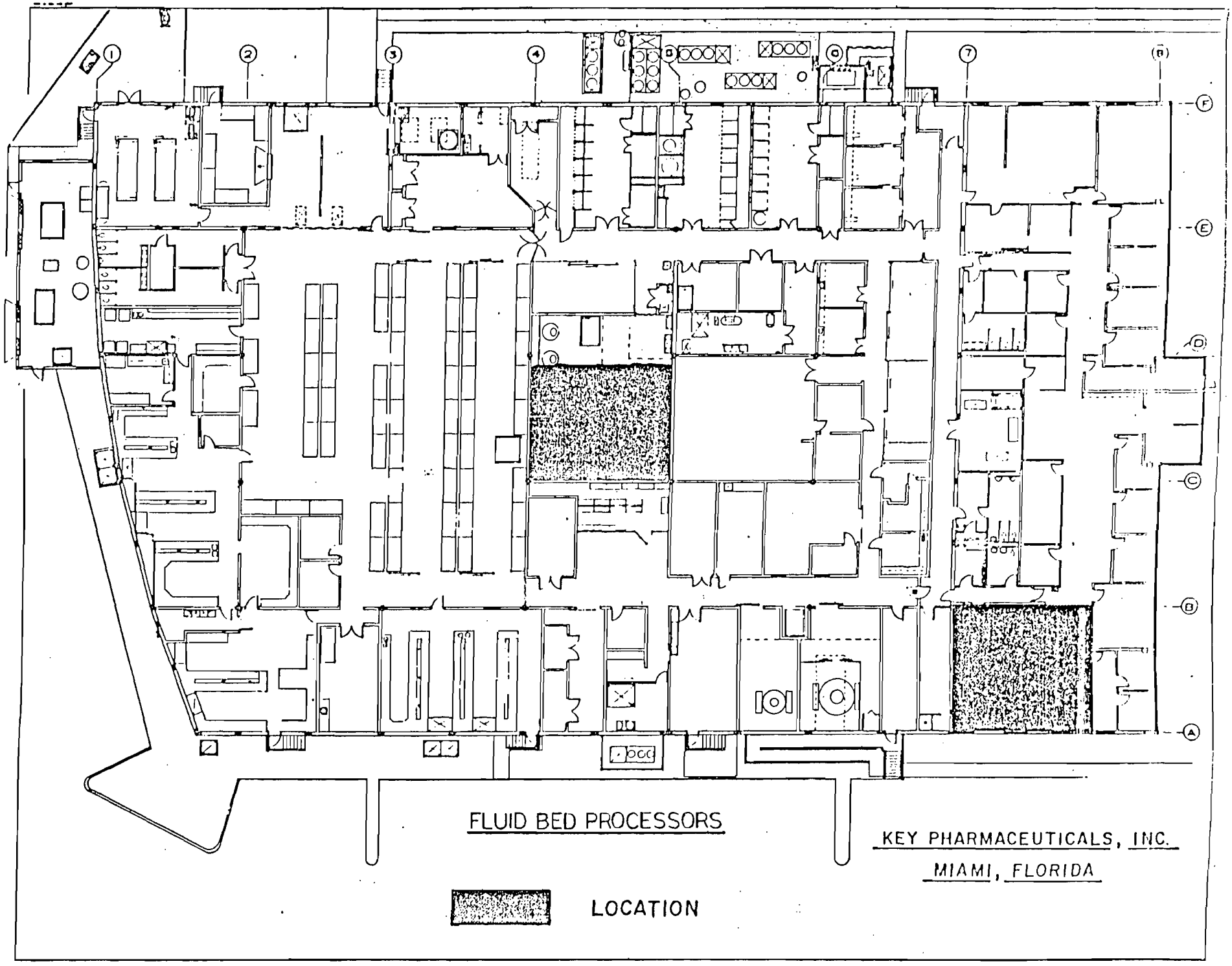


Key Pharmaceuticals, I...

SITE PLAN

Miami Beach, Florida


FLUID BED PROCESSORS
KEY PHARMACEUTICALS, INC.
MIAMI, FLORIDA
LOCATION

BEST AVAILABLE COPY

JOHN BROWN

PROCESS VESSEL SPECIFICATION

REVISION			NOZZLE SCHEDULE				
NO.	DATE	BY	MK	SIZE	NO.	SERVICE	RATING
			A	36"	1	GAS INLET	150# DRIL
			B	30"	1	Gas outlet +	↓
			C	6"	1	Liquor outlet	150 lb
			D	3"	1	Liquor Inlet	150#
			M 1/2	20	2	Manholes/cover And Davits	STD
			P 1/3	1 1/2	3	Pressure taps	150#

PROJECT NO. 85021

ITEM NO. ____

FOR Koch [illegible]

TITLE Scrubber

CAPACITY, GAL. ____

I.D.-O.D. 8'-0" T. TO T. 26'-0"

CODE None	SHELL	JACK OR COIL
MATL. CONST.	FRP *	
CORR. ALL.,"		
OPER. PSI G	-0.2	
@ °F	100	
DESIGN PSIG	±2	
@ °F	200	
CONTENTS	AIR/water	
SP. GR. CONT.	0.069/1.0	

FINISH Mfg STD

INTERNALS As NOTED

HEADS Dished top/bottom

STRESS RELIEVE ____ X-RAY ____

PAINTING CS only

INSULATION NONE

METHOD OF SUPPORT LUGS

MIXER NONE

Notes Cont. (Location [illegible])

1) Packing - Koch type 2 Flexipac 8'-0" ⌀ x 10'-0" TEFLON

2) Packing Support Plate Koch Figure 104 style - Grid type plate - Hetron 800 FRP - no exposed metal permitted.
Provide Support Ring (Hetron 800 FRP) at least 2 1/2". Gas loading 1637 lb/hr/ft²

3) Liquid Distributor Koch model [illegible] weir type (Liquid loading [illegible]) ([illegible]). Hetron 800 FRP or teflon. Provide At least 2 1/2" Support ring Hetron 800 FRP

4) Demister Pad Koch Style 911 [illegible] Separator 8" [illegible] teflon.

Notes:

A)+ Design nozzle for 30 in ⌀ x 10' tall stack FRP, weight ≥ 200 lbs

B) Design wind loading, 125 mph [illegible] ([illegible])

C)* HETRON 800 FRP

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Crawford & Russell Incorporated

MATERIAL REQUISITION

REQUISITION NO.	DATE
A5021	Feb. 1985

PURCHASE ORDER NO.

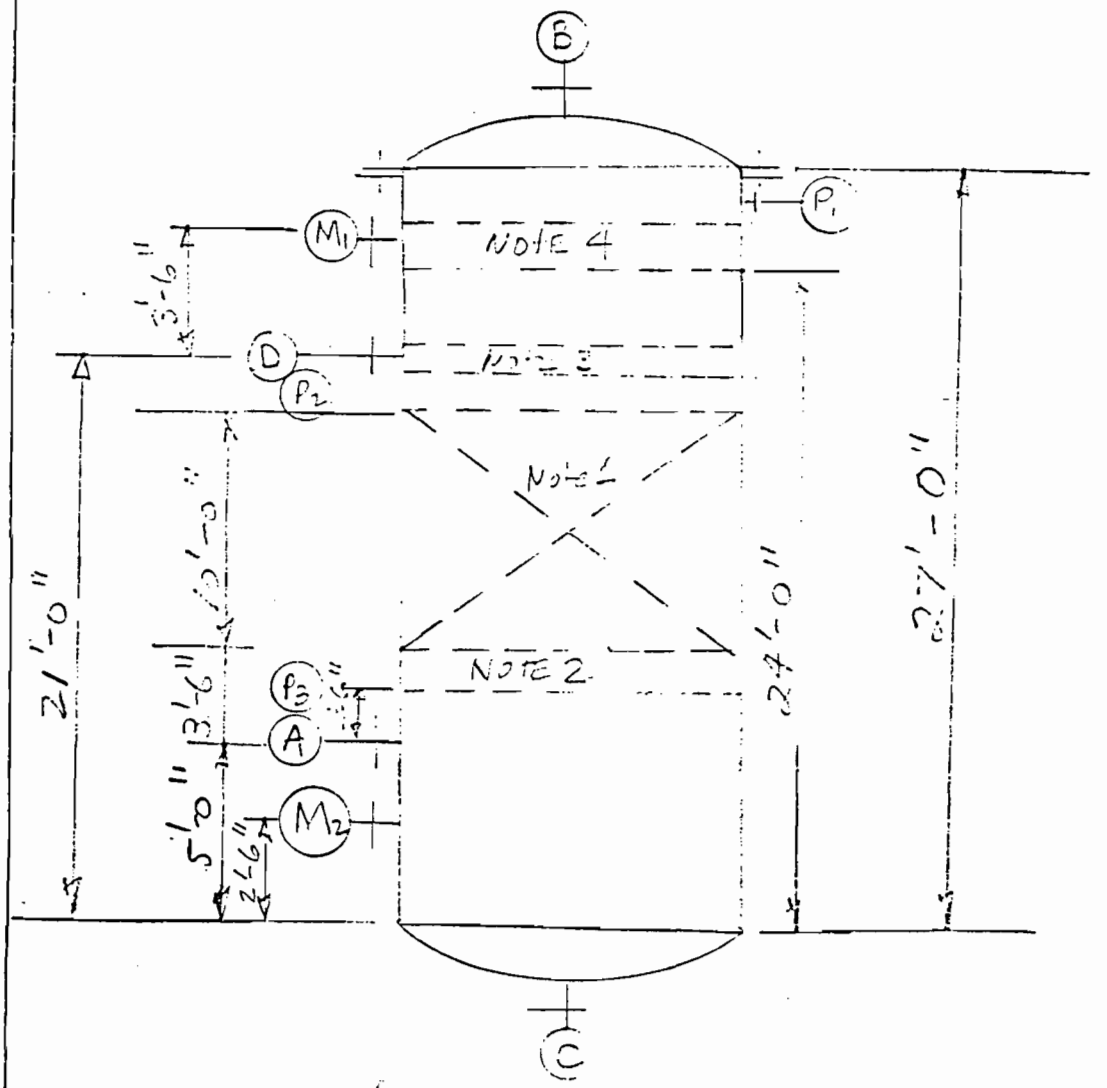
CUSTOMER KEY PLASTICS

VENDOR

LOCATION MIAMI BEACH

ITEM NO.	MATERIAL
	SCRUBBER

REV. NO.	DATE	APPV'D	REV. NO.	DATE	APPV'D



C

MADE BY

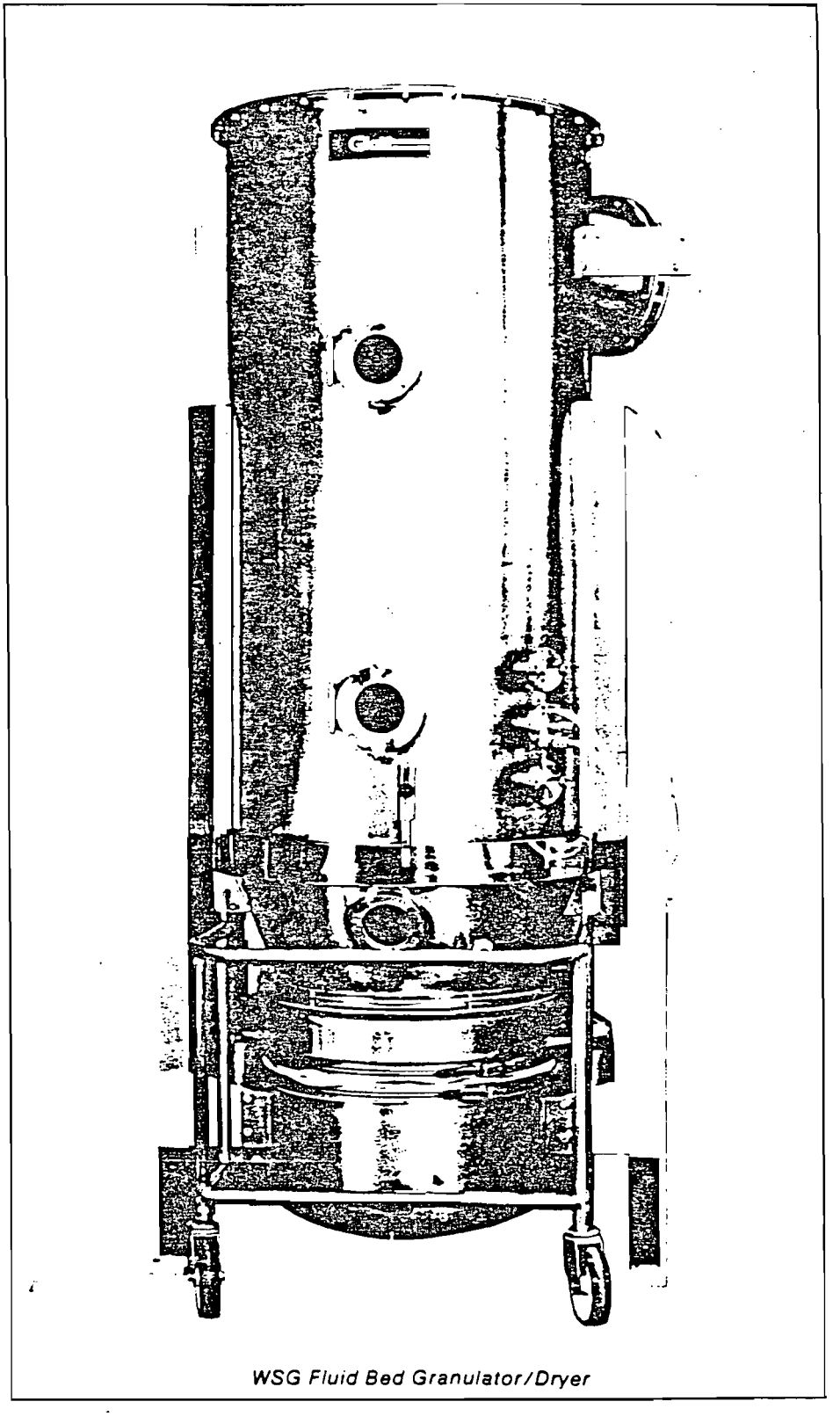
C & R APPROVED

CUSTOMER APPROVED

Fluid Bed Granulator/Dryers

WSG

Batch or batch-continuous granulating and drying. Agglomeration and instantizing of blended products. Coating of small and intermediate size particles. Dedusting, by agglomeration, of materials with large quantities of fines.



WSG Fluid Bed Granulator/Dryer

Air Handling

- remote fan for quieter, safer, and cleaner operation
- 80 micron pocket prefilter
- efficient, high capacity galvanized steel heating coils

Product Handling

- exclusive product bowl design for effective circulation of material providing maximum transfer of heat and uniform, rapid drying
- windows for observing product in bowl and expansion area
- multiple nozzle positions for nozzle height adjustment
- quick disconnect coaxial air atomized spray nozzle
- peristaltic pump
- window in filter area to observe filter shaking operation
- rapid change filter bag system
- pneumatic outlet air flap for control of fluidization height

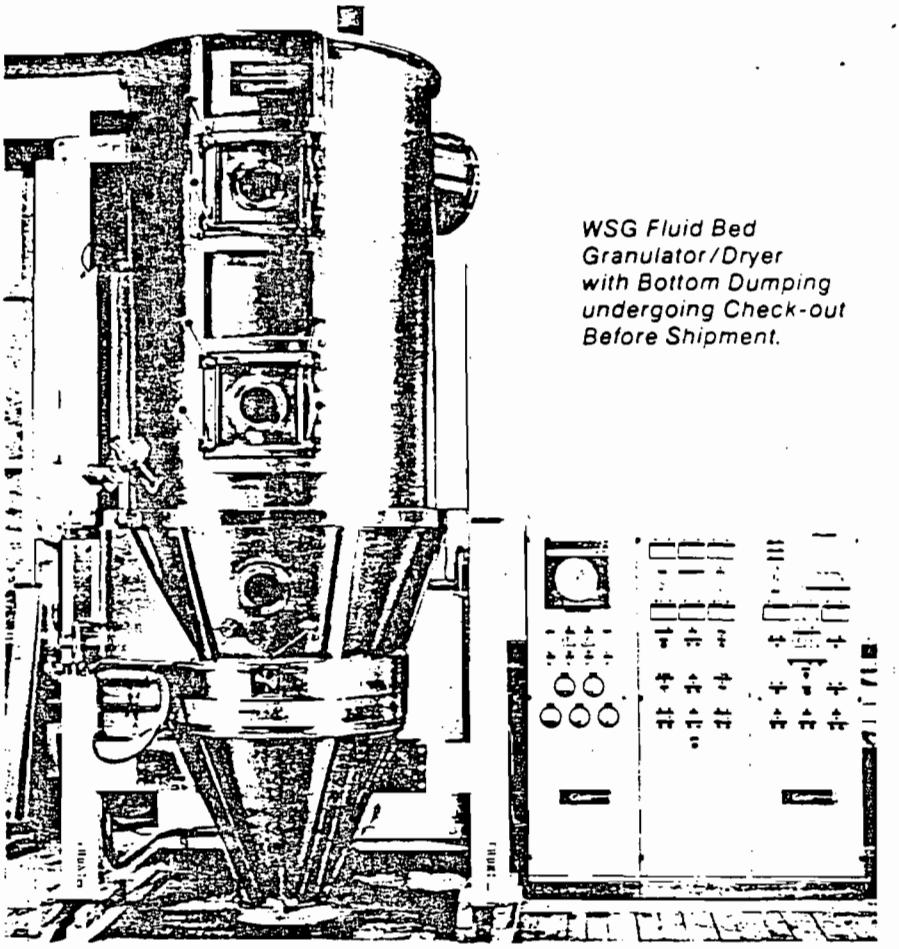
Good Manufacturing Practices (GMP)

- continuous welds
- all product contact parts mirror polished
- all filters and gaskets easily removable for inspection and cleaning
- drains provided in lower plenum
- sufficient doors provided for access to all parts of machine

- remote reinforced fan
- external hydraulic pressing system which seals the machine closed and capable of withstanding a 2 bar pressure differential
- exclusive reinforced lower plenum
- totally pneumatic control system, no electrics in process area
- approved explosion relief vents
- side, rear or top explosion relief venting

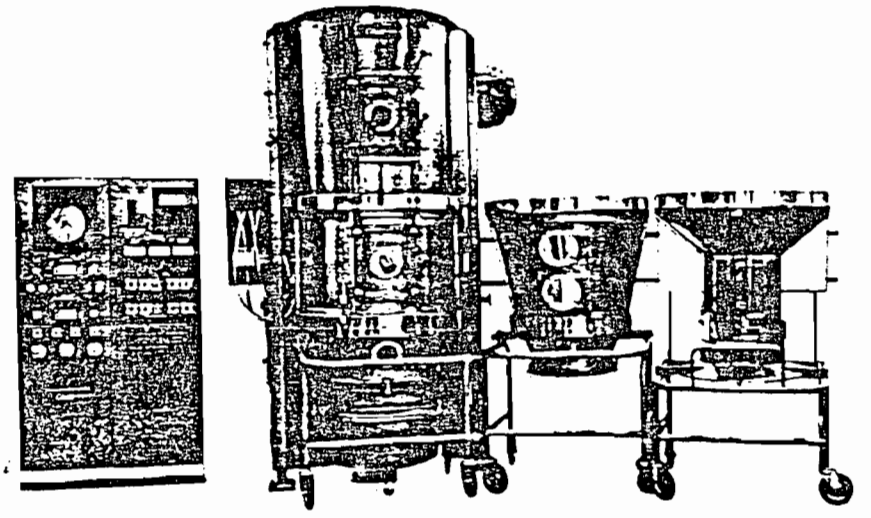
Process Control

- all pneumatic free-standing panel includes:
  - inlet air temperature controller
  - inlet air temperature gauge
  - outlet air temperature gauge
  - automatic filter shaking timers
  - pneumatic outlet air flap controller and indicator
  - pump controls for automatic operation during shake cycle
  - atomization air regulator and indicator



WSG Fluid Bed Granulator/Dryer with Bottom Dumping undergoing Check-out Before Shipment.

- sealing flap
- cooling flap
- magnehelic gauges
- H.E.P.A. filters (inlet or outlet)
- gear-type or piston-type positive displacement liquid pumps
- product bed temperature sensing
- side loading charge port
- automatic process control
- process protection interlock system
- batch-continuous operation
- bottom discharge
- exterior mirror polish finish
- surge hoppers on supply and discharge
- high speed chopper system for delumping of raw materials and/or product densification
- CIP system
- noise attenuation package for remote fan
- fan vibration detector
- less expensive, non-reinforced construction where applications do not present explosion hazard
- solvent recovery systems
- controllable inlet air flap
- doors with windows installed in expansion chamber and filter housing
- face and bypass heat control
- future plans for micro-processor control
- others

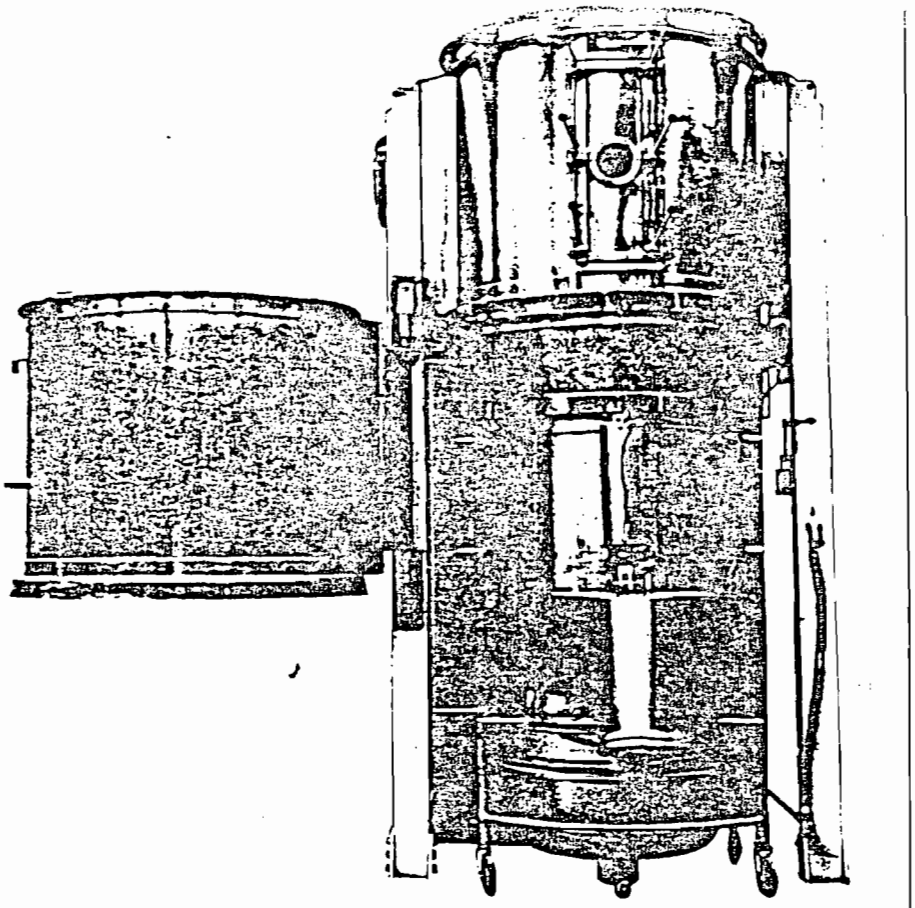


Pilot Plant WSG 60-100 Shown in Reinforced Construction with 30 kg Granulator Change Part and 18" Wurster Change Part

- for use in installations where there is a requirement for conversion parts to reduce the batch size by approximately one-half (i.e., a 30-50 kilogram granulator/dryer can be supplied with change part for batches of 15-25 kilograms).
- to allow conversion of a fluid bed granulator to a fluid bed Wurster tablet and intermediate size particle coater while retaining the use of the original machine's air handling, control and pumping systems.
- to allow greater access to the machine for maintenance and cleaning.

Safety and CGMP Feature Highlights

- The Glatt exclusive hydraulic pressing system for sealing and locking the machine closed insures its 2-bar explosion shock resistant protection without the use of external clamping devices. This method of closing the machine also allows for the selection of the three piece option for WSG granulator/dryers without any further modifications or the addition of external manual or pneumatic clamps. Conversion of the WSG unit to a smaller batch size machine or a Wurster coater is simple, safe and takes only minutes.
- The lower plenum is dome-shaped, completely open and accessible for cleaning, holds a 2-bar pressure shock-resistant rating, and is equipped with a cleanout drain. When installed, it is positioned several inches above the floor to prevent the accumulation of bacteria and contaminants and to provide for easy cleaning of the exterior of the machine and the surrounding process area.
- The exhaust air filter is suspended on a stainless steel ring with metal to metal contact between filter socks and ring for proper grounding. The entire filter system is quickly and easily removeable for cleaning.



WSG 300-500 Granulator/Dryer in Reinforced Construction Shown with Expansion Chamber Swung Away and 46" Wurster Tablet or Nonpareil Coater in Place (Average Capacity 400 kg.)

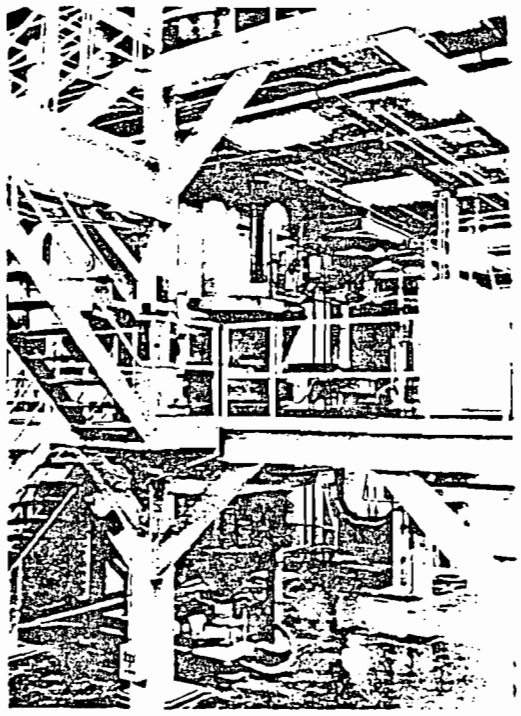
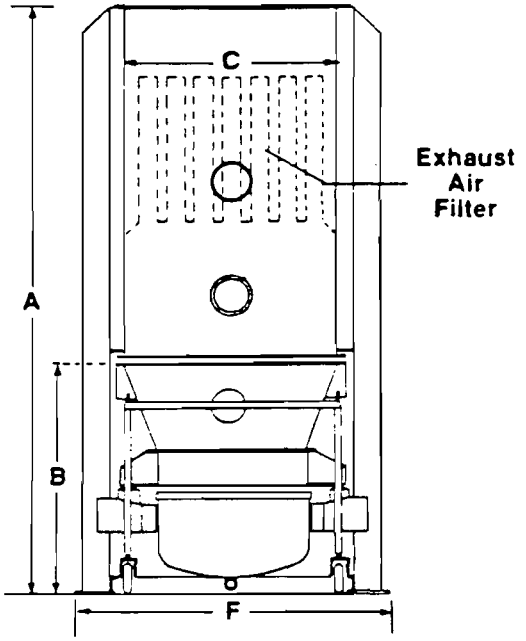
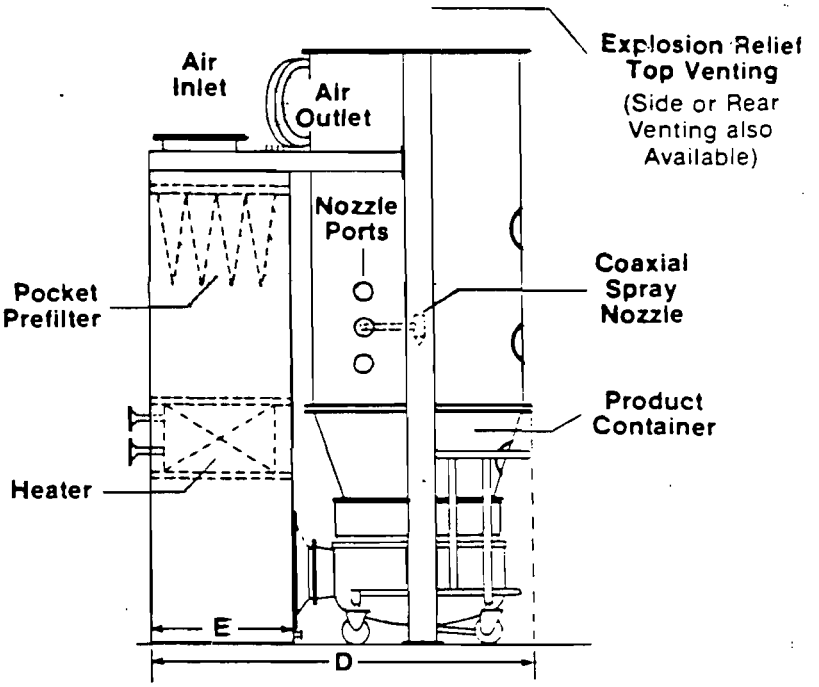


Photo shows a full view of two WSG 1000-1500 granulators showing the three service levels of the machine. The upper level accesses the exhaust air filter housing and bulk material loading facility. The middle section is the process floor where the expansion housing, 3000 liter product container and automatic control panels are located. The lower level contains the discharge surge hopper which receives the finished batch for quick recycle times between batches.





Model Number WSG		5-9	15-25	30-50	60-100	120-180	200-280	300-500	500-800	1000-1500
capacity in liters		22	45	100	220	420	670	1100	1560	3000
F	motor size in KW	5.5	11	18.5	22	30	37	45	55	
A	air capacity in cfm	440	880	1760	2640	3520	4700	5880	7040	
N	static pressure inches of water	40	40	40	40	40	40	40	40	Details
heating capacity in BTU's per hour		64.000	120.000	240.000	360.000	440.000	720.000	840.000	1.008.000	Available
DIMENSIONS in MM	A	2400	2700	3000	3200	3500	4000	4200	5000	On
	B	870	915	985	1175	1375	1590	1760	1980	Request
	C	400	550	720	1000	1200	1400	1590	1800	
	D	1550	1625	1810	2150	2350	2550	2750	3100	
	E	750	750	750	800	800	800	800	900	
	F	800	1020	1160	1500	1700	2060	2360	2600	

All dimensions are approximate and subject to change due to selected options.

*Model number denotes average capacity range in kilograms

Glatt The leader in fluid bed technology

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Ramsey, New Jersey 07446
Tel: (201) 825-8700
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7851 Binzen/Lörrach, West Germany
Tel: (7621) 6049, Telex 773573 glatt d
Cable: Glatt Binzen

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ATTACHMENT 1

Dispersion calculations: maximum ground level concentration of methylene chloride

Dispersion calculations for this source have been accomplished in support of the Construction Permit AC 13-100437. The data utilized for the dispersion calculations and the revised emission data is as follows:

METHYLENE CHLORIDE EMISSIONS:	ACO 13-114316	REVISED 1987
AVG FOR 3 GLATTS, T/Y	978	2,195
MAX FOR 3 GLATTS, LB/HR	660	743

The increase of the emissions is due to a slight increase in methylene chloride utilized and an increase in the on-line factor of the units (i.e. turn around time between lots has been greatly reduced). A linear relationship exists between emission rate and maximum ground level concentration if the only changing variable in the dispersion calculation is the emission rate. Therefore the results obtained from the dispersion modeling for AC 13-100437 can be ratioed to the new emission rates and the data is valid.

Maximum methylene chloride ground level concentration based on maximum emissions of 743 LB/HR

$$= \frac{743}{660} \times 2.4 \text{ ppm} = 2.7 \text{ ppm}$$

Methylene chloride ground level concentration based on average emission

$$= \frac{501}{743} \times 2.7 \text{ ppm} = 1.8 \text{ ppm}$$

24-hour concentration based on average emission of

501 LB/HR = 0.36 x 1.8 = 0.66 ppm

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Dispersion Calculations: Maximum Ground Level Concentrations of Methylene Chloride

Basis of Calculations: Workbook of Atmospheric Dispersion Estimates, D. Bruce Turner, U.S. Environmental Protection Agency, 1970

Figure 3-9; Maximum Concentrations and Distance of Maximum Concentrations

Page 31; Holland's Equation for Plume Rise (correspondence with Dr. Turner indicates Holland's equation generally is conservative.)

Methylene Chloride Emissions:

Average per Glatt: Tons per year	326
Average for 3 Glatts; Tons per year	978
Maximum for 3 Glatts; lbs per hour	660

Air Flow

Maximum	SCFM @ 70°F	18000

Stack exit elevation above grade; feet	50
Stack diameter; inches	30
Stack exit temperature; °F	90
Air temperature; °F	95
Atmospheric pressure; bar	1.0135
Wind speeds considered; MPH	1, 5, 10

Plume Rise - Summer Condition

Holland's Equation

$$\Delta H = \frac{V_s d}{u} \left(1.5 + 2.68 \times 10^{-3} p \frac{(Ts-Ta)}{Ts} d\right)$$

$$Vs = \frac{18000 \text{ SCFM}}{60 \text{ Sec/Min}} \frac{550°R}{530°R} \frac{}{0.785 \times 2.5 \text{ Ft}^2} \times \frac{1}{3.281 \text{ Ft/M}}$$

$$= 19.34 \text{ M/Sec}$$

$$d = \frac{2.5 \text{ Ft}}{3.281 \text{ Ft/M}} = 0.762 \text{ M}$$

u = 1 mph = 0.447 M/Sec

5 mph = 2.234 M/Sec

10 mph = 4.47 M/Sec

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Plume Rise - Summer Condition (cont'd)

p = 1013.5 mb
Ts = 90°F = 305.2°K
Ta = 95°F = 308°K

Wind Vel. mph	ΔH M
1	49.15
5	9.83
10	4.92

Maximum Concentration - Distance of Maximum Concentration

$$Q = \frac{660 \text{ lbs/hr} \times 454 \text{ gms/lb}}{3600 \text{ Sec/Hr}} = 83.23 \text{ gms/sec},$$

Xmax = distance of max concentration, kilometers x 0.6214 $\frac{\text{miles}}{\text{kilometer}}$ = miles

u = 1 mph = o.446 M/Sec
5 mph = 2.234 M/Sec
10 mph = 4.47 M/Sec

H = effective height = plume rise plus stack elevation

X = max ground level conc. gms/M^3 x 1000 mg/gm x 0.278 = ppm (vol)

Wind vel. MPH	Stability Class	Effect Height	$(Xu)/(Q)_{max}$	X gms/M^3	X ppm(v)	x max Miles
1	F	64.4	1.2×10^{-5}	0.00223	0.622	3.54
1	E	64.4	1.7×10^{-5}	0.00315	0.880	1.80
1	D	64.4	2.0×10^{-5}	0.00372	1.04	1.06
1	C	64.4	3.2×10^{-5}	0.00596	1.65	0.46
1	B	64.4	3.4×10^{-5}	0.00633	1.76	0.36
1	A	64.4	3.7×10^{-5}	0.00713	1.98	0.19
5	F	25.1	1.5×10^{-4}	0.00559	1.55	0.78
5	G	25.1	1.7×10^{-4}	0.00633	1.76	0.44
5	D	25.1	1.85×10^{-4}	0.00689	1.91	0.29
5	C	25.1	2.1×10^{-4}	0.00782	1.17	0.17
5	B	25.1	2.2×10^{-4}	0.00819	2.20	0.11
5	A	25.1	2.3×10^{-4}	0.00856	2.38	0.07
10	F	20.2	2.5×10^{-4}	0.00465	1.29	0.56
10	E	20.2	2.8×10^{-4}	0.00521	1.45	0.33
10	D	20.2	3.1×10^{-4}	0.00576	1.60	0.22
10	C	20.2	3.3×10^{-4}	0.00614	1.71	0.12
10	B	20.2	3.2×10^{-4}	0.00595	1.66	0.09
10	A	20.2	3.15×10^{-4}	0.00586	1.63	0.065

K&E 10 X 10 TO THE INCH • 7 X 10 INCHES
KEUFFEL & ESSER CO MADE IN U.S.A.

KEY PHARMACEUTICALS

METHYLENE CHLORIDE MAXIMUM GROUND LEVEL CONCENTRATION

AS FUNCTION OF WIND VELOCITY

Stack Height 50 feet above grade

Stack Exit Velocity 19.34 M/Sec = 63.5 FPS

Stack Exit Temperature 90°F

Maximum Emission Rate of 660 lbs/hr

0 1 2 3 4 5 6 7 8 9 10

Wind Velocity Miles Per Hour

Basis: Turner, EPA
& Holland Plume Rise

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Maximum methylene chloride ground level concentration based on maximum emission of 660 lbs/hr = 2.4 ppm

Average emission of methylene chloride = 978 tons/yr
= 233 lb/hr

Methylene chloride ground level concentration based on average emission

$$\frac{233}{660} \times 2.4 = 0.85 \text{ ppm}$$

Calculation of maximum ground level concentration corresponds to 3 minute sample. Table 5-1, Page 38 of Turner shows relation of 24 hour sample to 3 minute sample resulting from "Increased Meander of Wind Direction"

Sample Time	Ratio of Calculated Concentration to 3 minute concentration
3 minutes	1
24 hours	0.36

24 hr concentration based on average emission of

233 lb/hr = 0.36 x 0.85 = 0.31 ppm (vol)

COMPARISON OF CONCENTRATIONS FOR METHYLENE CHLORIDE

	ppm (vol)
OSHA Standard (29 CFR 1910.1000)	500
TLV of Amer. Conf. Gov. Ind. Hyg. (1981)	100
Odor threshold	150-200
New York State Guideline AAL(1)	0.33
Key 24 hr concentration calculated from average emission of 233.0 lbs/hr	0.31(2)
Key maximum concentration (3 minute) calculated from maximum emission of 660 lbs/hr	2.4

(1) AAL: Acceptable ambient level equal to the annual average ambient concentration not to be exceeded at any off-site receptor

(2) In conversation with Bruce Turner of the EPA, he expressed the opinion that annual average ambient concentration at any off-site receptor will be no more than 1/10 of 24 hour concentration of 0.31 ppm, i.e. 0.031 ppm and probably will be considerably less than 0.031 ppm.

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

January 12, 1987

Mr. C.H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: APPLICATION TO CONSTRUCT (REPLACE) AN AIR POLLUTION CONTROL DEVICE.

Dear Mr. Fancy:

Attached please find an "Application to Construct Air Pollution Control Sources". The application is for the construction of an air pollution control device. The original air pollution control device was permitted under Construction Permit No. AC 13-100437 (AO 13-114316). The unit controlled particulate and methanol emissions from three fluidized bed process units. Recent product and sales projections indicate that one additional fluid bed coater (Permit Application #3) and two pan coating units (Permit Application #4) are required within the next two years to maintain a competitive position in the pharmaceutical manufacturing place. Therefore, Key Pharmaceuticals has opted to replace the emission control technology currently utilized (i.e. emission reduction only) to a state of the art emission control/solvent recovery device. This control device will be capable of reducing the emissions from four fluid bed coating units, two pan coating units, and either two additional fluid bed coating units or two additional pan coating units.

The pollution control technology utilized is dust collection and carbon adsorption/solvent distillation. The design parameters for the system are as follows:

INTO SYSTEM:
1. AIR WITH . . . . .
   PARTICULATE
   METHANOL IN VAPOR FORM
   METHYLENE CHLORIDE IN VAPOR FORM

OUT OF SYSTEM:
1. AIR WITH . . . . .
   PARTICULATE REDUCED BY 99%
   METHANOL REDUCED BY 90%
   METHYLENE CHLORIDE REDUCED BY 90%
2. DRUMMED SOLIDS
3. PURE METHYLENE CHLORIDE FOR RE-USE IN PROCESS
4. PURE METHANOL FOR USE AS BOILER FUEL
5. CLEAN WATER FOR DISCHARGE TO SEWER

Mr. C.H. Fancy 1/12/87

RE: APPLICATION TO CONSTRUCT (REPLACE) AN AIR POLLUTION CONTROL DEVICE.

As you can see this control technology will maintain the current removal efficiency of 99% for particulates and 90% for methanol, while increasing the removal efficiency of methylene chloride from 0% to 90%.

Your cooperation in this matter is greatly appreciated. Should you have any questions please do not hesitate to call me at 305-654-2240.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

attachment

cc: S. Brooks (S.E. Florida District)
P. Wong (DERM Office)

AC 13-129893

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

SOUTHEAST FLORIDA DISTRICT
3301 GUN CLUB ROAD
P.O. BOX 3858
WEST PALM BEACH, FLORIDA 33402

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

ROY DUKE
DISTRICT MANAGER

APPLICATION TO OPERATE/CONSTRUCT AIR POLLUTION SOURCES

SOURCE TYPE: AIR POLLUTION CONTROL [X] New[1] [ ] Existing[1]

APPLICATION TYPE: [X] Construction [ ] Operation [ ] Modification

COMPANY NAME: KEY PHARMACEUTICALS, INC. COUNTY: DADE

Identify the specific emission point source(s) addressed in this application (i.e. Lime Kiln No. 4 with Venturi Scrubber; Peaking Unit No. 2, Gas Fired) 4 FLUID BED PROCESSORS; 2 PAN COATERS; AND CARBON ADSORPTION UNIT.

SOURCE LOCATION: Street 50 N.W. 176TH STREET City MIAMI

UTM: East 57987 North 7868445

Latitude 25 ° 56 ' 03 "N Longitude 80 ° 11 ' 42 "W

APPLICANT NAME AND TITLE: JAMES R. CONFROY, VICE PRESIDENT OPERATIONS

APPLICANT ADDRESS: 50 N.W. 176TH STREET, MIAMI, FLORIDA 33169

SECTION I: STATEMENTS BY APPLICANT AND ENGINEER

A. APPLICANT

I am the undersigned owner or authorized representative* of KEY PHARMACEUTICALS, INC.

I certify that the statements made in this application for a CONSTRUCTION permit are true, correct and complete to the best of my knowledge and belief. Further, I agree to maintain and operate the pollution control source and pollution control facilities in such a manner as to comply with the provision of Chapter 403, Florida Statutes, and all the rules and regulations of the department and revisions thereof. I also understand that a permit, if granted by the department, will be non-transferable and I will promptly notify the department upon sale or legal transfer of the permitted establishment.

*Attach letter of authorization.

Signed: Jan R Confroy

JAMES R. CONFROY, VICE PRESIDENT OPERATIONS
Name and Title (Please Type)

Date: 1/12/87 Telephone No. 305-654-2200

B. PROFESSIONAL ENGINEER REGISTERED IN FLORIDA (where required by Chapter 471, F.S.)*

This is to certify that the engineering features of this pollution control project have been designed/examined by me and found to be in conformity with modern engineering principles applicable to the treatment and disposal of pollutants characterized in the permit application. There is reasonable assurance, in my professional judgment, that

[1] See Florida Administrative Code Rule 17-2.100(57) and (104)

* SEE NOTE PAGE 2

I HAVE REVIEWED THE CALCULATIONS USED TO DETERMINE THE STATED LEVELS OF PARTICULATE AND VOC EMISSIONS AND FIND THEM TO BE ACCURATE BASED ON PROJECTED MANUFACTURING LEVELS OF THE PRODUCT.

the pollution control facilities, when properly maintained and operated, will discharge an effluent that complies with all applicable statutes of the State of Florida and the rules and regulations of the department. It is also agreed that the undersigned will furnish, if authorized by the owner, the applicant a set of instructions for the proper maintenance and operation of the pollution control facilities and, if applicable, pollution sources.

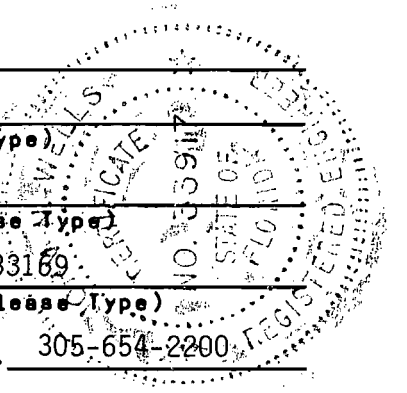
Signed J. N. Wells, P.E.

JOHN N. WELLS, P.E.
Name (Please Type)

KEY PHARMACEUTICALS, INC.
Company Name (Please Type)

50 N.W. 176TH STREET, MIAMI, FL 33169
Mailing Address (Please Type)

Florida Registration No. 33917 Date: 1/12/87 Telephone No. 305-654-2200



SECTION II: GENERAL PROJECT INFORMATION

A. Describe the nature and extent of the project. Refer to pollution control equipment, and expected improvements in source performance as a result of installation. State whether the project will result in full compliance. Attach additional sheet if necessary.

THIS SYSTEM WILL REDUCE THE EMISSIONS FROM VARIOUS MANUFACTURING AREAS. SPECIFIC IMPROVEMENTS ABOVE CURRENT SYSTEM ARE THE REMOVAL EFFICIENCY OF METHYLENE CHLORIDE FROM A CURRENT 0% TO 90% AND THE RECOVERY OF METHANOL AND METHYLENE CHLORIDE FOR BEBEFICIAL RE-USE RATHER THAN DISPOSAL.

B. Schedule of project covered in this application (Construction Permit Application Only)

Start of Construction MAR'87 Completion of Construction FEB'88

C. Costs of pollution control system(s): (Note: Show breakdown of estimated costs only for individual components/units of the project serving pollution control purposes. Information on actual costs shall be furnished with the application for operation permit.)

$2,000,000.00

D. Indicate any previous DER permits, orders and notices associated with the emission point, including permit issuance and expiration dates.

(1) CONSENT ORDER NO. 83-0373 (CLOSED)

(2) PERMIT TO CONSTRUCT FOR MFG GUANIDINE & QUINORA AC13-115383

(3) PERMIT TO CONSTRUCT FOR MFG OF K-DUR AC13-100437

E. Requeeted permitted equipment operating time: hrs/day 24 ; days/wk 7 ; wks/yr 52 ;

if power plant, hrs/yr_____; if seasonal, deecribe:_____

F. If this is a new source or major modification, answer the following questions. (Yea or No)

1. Is this source in a non-attainment area for a particular pollutant?	YES
a. If yes, has "offset" been applied?	NO
b. If yes, hss "Lowest Achievable Emission Rate" been applied?	NO
c. If yea, list non-attainment pollutanta.	OZONE
2. Does best available control technology (BACT) apply to this source? If yes, see Section VI.	NO
3. Does the State "Prevention of Significant Deterioriation" (PSD) requirement apply to this source? If yes, see Sections VI and VII.	NO
4. Do "Standards of Performance for New Stationary Sourcea" (NSPS) apply to this source?	NO
5. Do "National Emission Standards for Hazardous Air Pollutants" (NESHAP) apply to this source?	NO
H. Do "Reasonably Available Control Technology" (RACT) requirements apply to this source?	NO

a. If yes, for what pollutants?_____

b. If yes, in addition to the information required in this form, any information requested in Rule 17-2.650 must be submitted.

Attach all supportive information related to any answer of "Yes". Attach any justification for any answer of "No" that might be considered questionsble.

SECTION III: AIR POLLUTION SOURCES & CONTROL DEVICES (Other than Incinerators)

A. Raw Materials and Chemicals Used in your Process, if applicable:

Description	Contaminants		Utilization Rate - lbs/hr	Relate to Flow Diagram
	Type	% Wt		
METHANOL	VOC	10	78 LB/HR	"C"
METHYLENE CHLORIDE	VOC	90	760 LB/HR	"C"

B. Process Rate, if applicable: (See Section V, Item 1)

1. Total Process Input Rate (lbs/hr): 937 LB/HR

2. Product Weight (lbs/hr): 760 LB/HR METHYLENE CHLORIDE 78 LB/HR METHANOL

C. Airborne Contaminants Emitted: (Information in this table must be submitted for each emission point, use additional sheets as necessary)

Name of Contaminant	Emission[1]		Allowed[2] Emission Rate per Rule 17-2	Allowable[3] Emission lbs/hr	Potential[4] Emission		Relate to Flow Diagram
	Maximum lbs/hr	Actual T/yr			lbs/yr	T/yr	
VOC	15.4	38.1	N/A	N/A		381	"B"
PARTICULATE	0.09	0.23	N/A	N/A		23.2	"D"
METHYLENE CHLORIDE	141	370.1	N/A	N/A		3701	"B"

[1]See Section V, Item 2.

[2]Reference applicable emission standards and units (e.g. Rule 17-2.600(5)(b)2. Table II, E. (1) - 0.1 pounds per million BTU heat input)

[3]Calculated from operating rate and applicable standard.

[4]Emission, if source operated without control (See Section V, Item 3).

D. Control Devices: (See Section V, Item 4)

Name and Type (Model & Serial No.)	Contaminant	Efficiency	Range of Particles Size Collected (in microns) (If applicable)	Basis for Efficiency (Section V Item 5)
DUST COLLECTOR TORIT 3DF60	PARTICULATE	99%	2 MICRON OR LARGER	SUPPLIER'S DESIGN
CARBON ADSORBER	VOC	90%	N/A	SUPPLIER'S DESIGN

E. Fuels

Type (Be Specific)	Conaumption*		Maximum Heat Input (MMBTU/hr)
	avg/hr	max./hr	

*Units: Natural Gas--MMCF/hr; Fuel Oils--gallons/hr; Coal, wood, refuse, other--lbs/hr.

Fuel Analysis:

Percent Sulfur:_____ Percent Ash:_____

Density: _____ lbs/gal Typical Percent Nitrogen:_____

Heat Capacity: _____ BTU/lb _____ BTU/gal

Other Fuel Contaminants (which may cause air pollution):_____

F. If applicable, indicate the percent of fuel used for space heating.

Annual Average _____ Maximum _____

G. Indicate liquid or aolid wastes generated and method of disposal.

40,000 LB/YEAR OF PARTICULATE COLLECTED IN APPROXIMATELY 100 DRUMS. MATERIAL IS NON-HAZARDOUS AND IS DISPOSED AT A PERMITTED LANDFILL (OFF-SITE).

H. Emission Stack Geometry and Flow Characteristics (Provide data for each stack):

Stack Height: 35 ft. Stack Diameter: 3.5 ft.

Gas Flow Rate: 32000 ACFM _____ DSCFM Gas Exit Temperature: 80° to 90° °F.

Water Vapor Content: 25 % Velocity: 55.4 FPS

SECTION IV: INCINERATOR INFORMATION

Type of Waste	Type 0 (Plastics)	Type I (Rubbish)	Type II (Refuae)	Type III (Garbage)	Type IV (Pathological)	Type V (Liq.& Gas By-prod.)	Type VI (Solid By-prod.)
Actual lb/hr Incinerated							
Uncontrolled (lbs/hr)							

Description of Waste _____

Total Weight Incinerated (lbs/hr) _____ Design Capacity (lbs/hr) _____

Approximate Number of Hours of Operation per day _____ day/wk _____ wks/yr. _____

Manufacturer _____

Date Constructed _____ Model No. _____

	Volume $(ft)^3$	Heat Release (BTU/hr)	Fuel		Temperature (°F)
			Type	BTU/hr	
Primary Chamber					
Secondary Chamber					

Stack Height: _____ ft. Stack Diamter: _____ Stack Temp. _____

Gas Flow Rate: _____ ACFM _____ DSCFM* Velocity: _____ FPS

*If 50 or more tons per day design capacity, submit the emissions rate in grains per standard cubic foot dry gas corrected to 50% excess air.

Type of pollution control device: [ ] Cyclone [ ] Wet Scrubber [ ] Afterburner

[ ] Other (specify) _____

Brief description of operating characteristics of control devices: _____

_____

_____

_____

_____

Ultimate disposal of any effluent other than that emitted from the stack (scrubber water, ash, etc.):

_____

_____

_____

_____

NOTE: Items 2, 3, 4, 6, 7, 8, and 10 in Section V must be included where applicable.

SECTION V: SUPPLEMENTAL REQUIREMENTS

Please provide the following supplements where required for this application.

1. Total process input rate and product weight -- show derivation [Rule 17-2.100(127)]

2. To a construction application, attach basis of emission estimate (e.g., design calculations, design drawings, pertinent manufacturer's test data, etc.) and attach proposed methods (e.g., FR Part 60 Methods 1, 2, 3, 4, 5) to show proof of compliance with applicable standards. To an operation application, attach test results or methods used to show proof of compliance. Information provided when applying for an operation permit from a construction permit shall be indicative of the time at which the test was made.

3. Attach basis of potential discharge (e.g., emission factor, that is, AP42 test).

4. With construction permit application, include design details for all air pollution control systems (e.g., for baghouse include cloth to air ratio; for scrubber include cross-section sketch, design pressure drop, etc.)

5. With construction permit application, attach derivation of control device(s) efficiency. Include test or design data. Items 2, 3 and 5 should be consistent: actual emissions = potential (1-efficiency).

6. An 8 1/2" x 11" flow diagram which will, without revealing trade secrets, identify the individual operations and/or processes. Indicate where raw materials enter, where solid and liquid waste exit, where gaseous emissions and/or airborne particles are evolved and where finished products are obtained.

7. An 8 1/2" x 11" plot plan showing the location of the establishment, and points of airborne emissions, in relation to the surrounding area, residences and other permanent structures and roadways (Example: Copy of relevant portion of USGS topographic map).

8. An 8 1/2" x 11" plot plan of facility showing the location of manufacturing processes and outlets for airborne emissions. Relate all flows to the flow diagram.

9. The appropriate application fee in accordance with Rule 17-4.05. The check should be made payable to the Department of Environmental Regulation.

10. With an application for operation permit, attach a Certificate of Completion of Construction indicating that the source was constructed as shown in the construction permit.

SECTION VI: BEST AVAILABLE CONTROL TECHNOLOGY

A. Are standards of performance for new stationary sources pursuant to 40 C.F.R. Part 60 applicable to the source?

[ ] Yes [ ] No

Contaminant	Rate or Concentration

B. Has EPA declared the best available control technology for this class of sources (If yes, attach copy)

[ ] Yes [ ] No

Contaminant	Rate or Concentration

C. What emission levels do you propose as best available control technology?

Contaminant	Rate or Concentration

D. Describe the existing control and treatment technology (if any).

1. Control Device/System:
2. Operating Principles:
3. Efficiency:*
4. Capital Costs:

*Explain method of determining

5. Useful Life:

6. Operating Costs:

7. Energy:

8. Maintenance Cost:

9. Emissions:

Contaminant	Rate or Concentration

10. Stack Parameters

a. Height: ft.

b. Diameter: ft.

c. Flow Rate: ACFM

d. Temperature: °F.

e. Velocity: FPS

E. Describe the control and treatment technology available (As many types as applicable, use additional pages if necessary).

1.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

2.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

3.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

4.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Costs:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

F. Describe the control technology selected:

1. Control Device:

2. Efficiency:[1]

3. Capital Cost:

4. Useful Life:

5. Operating Cost:

6. Energy:[2]

7. Maintenance Cost:

8. Manufacturer:

9. Other locations where employed on similar processes:

a. (1) Company:

(2) Mailing Address:

(3) City:

(4) State:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

b. (1) Company:

(2) Mailing Address:

(3) City: (4) State:

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

10. Reason for selection and description of systems:

[1]Applicant must provide this information when available. Should this information not be available, applicant must state the reason(s) why.

SECTION VII - PREVENTION OF SIGNIFICANT DETERIORATION

A. Company Monitored Data

1. _____no. sites _____ TSP _____( ) SO^{2}* _____ Wind spd/dir

Period of Monitoring _____/_____/_____ to _____/_____/_____
month day year month day year

Other data recorded _____

Attach all data or statistical summaries to this application.

*Specify bubbler (B) or continuous (C).

2. Instrumentation, Field and Laboratory

a. Was instrumentation EPA referenced or its equivalent? [ ] Yes [ ] No

b. Was instrumentation calibrated in accordance with Department procedures?

[ ] Yes [ ] No [ ] Unknown

B. Meteorological Data Used for Air Quality Modeling

1. _____ Year(s) of data from _____/_____/_____ to _____/_____/_____
month day year month day year

2. Surface data obtained from (location)_____

3. Upper air (mixing height) data obtained from (location)_____

4. Stability wind rose (STAR) data obtained from (location)_____

C. Computer Models Used

1. _____ Modified? If yes, attach description.

2. _____ Modified? If yes, attach description.

3. _____ Modified? If yes, attach description.

4. _____ Modified? If yes, attach description.

Attach copies of all final model runs showing input data, receptor locations, and principle output tables.

D. Applicants Maximum Allowable Emission Data

Pollutant	Emission Rate	
TSP	_____	grams/sec
SO^2	_____	grams/sec

E. Emission Data Used in Modeling

Attach list of emission sources. Emission data required is source name, description of point source (on NEDS point number), UTM coordinates, stack data, allowable emissions, and normal operating time.

F. Attach all other information supportive to the PSD review.

G. Discuss the social and economic impact of the selected technology versus other applicable technologies (i.e., jobs, payroll, production, taxes, energy, etc.). Include assessment of the environmental impact of the sources.

H. Attach scientific, engineering, and technical material, reports, publications, journals, and other competent relevant information describing the theory and application of the requested best available control technology.

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

C E R T I F I C A T E

To Whom It May Concern:

This is to certify that Robert A. Franke, Director of Engineering of Key Pharmaceuticals, Inc., is duly authorized to represent Key Pharmaceuticals, Inc., along with his designate, Thomas W. Flachmeyer, Manager Environmental Engineering and Waste Management; for the purposes of making Application for Permit to Construct or Operate Pollution Control Facilities for said company.

Key Pharmaceuticals, Inc.

James R. Confroy, Vice President

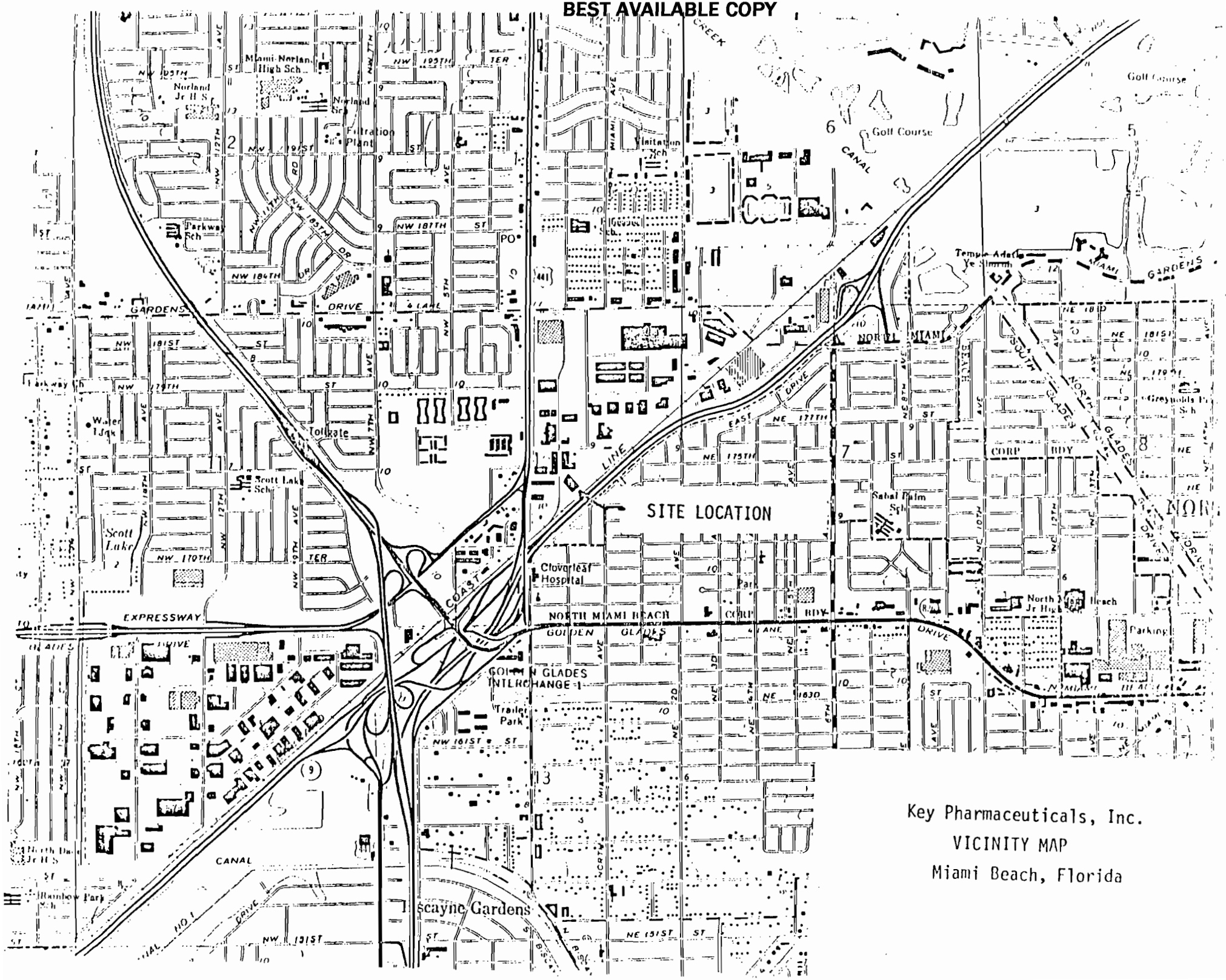
Miami and Puerto Rico Operations

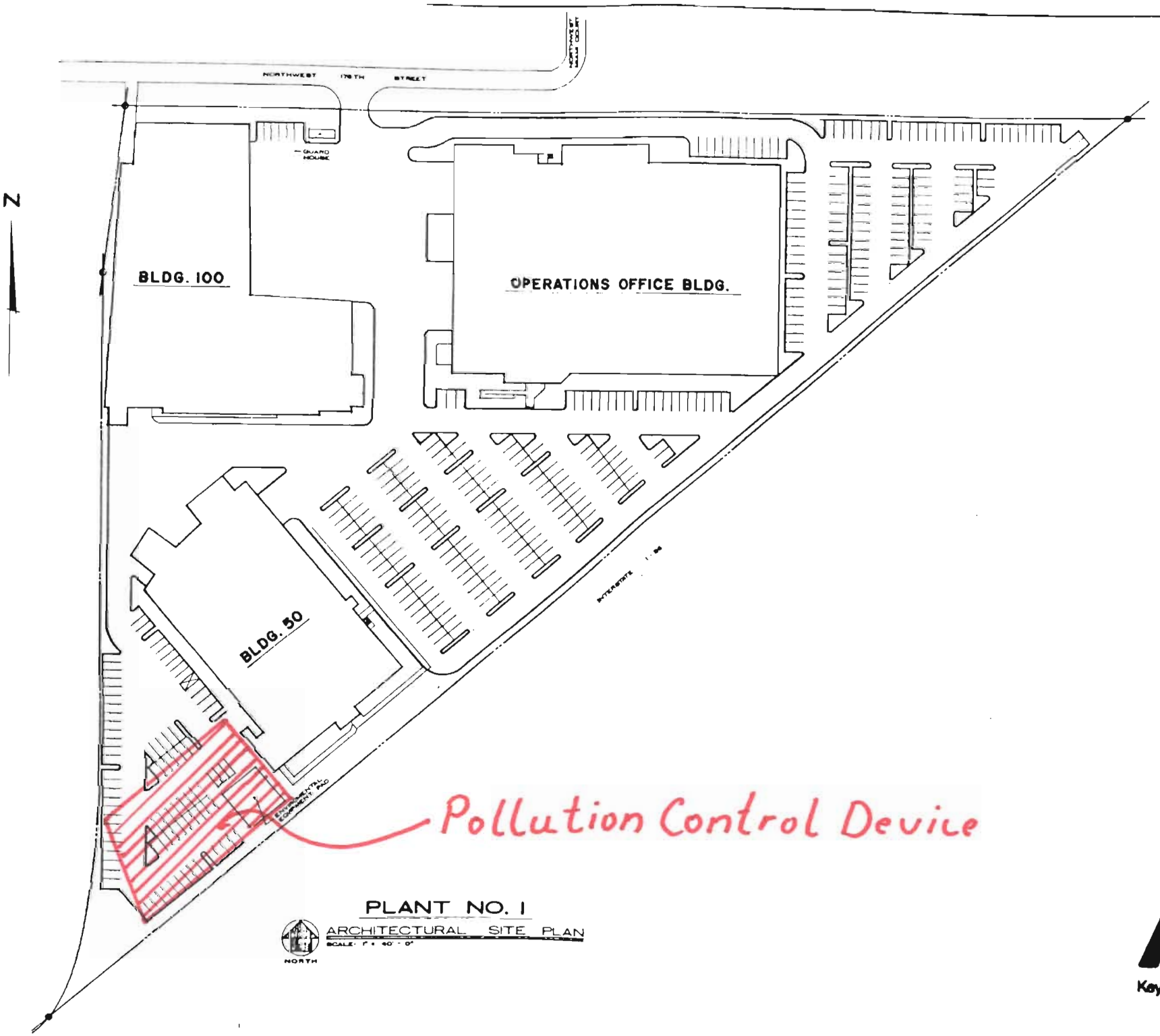
JRC/db

STATE OF FLORIDA
COUNTY OF DADE
Sworn to and subscribed before me
this 21st day of October A.D. 1986.

NOTARY PUBLIC STATE OF FLORIDA
MY COMMISSION EXP. DEC 18,1989
BONDED THRU GENERAL INS. UND.

BEST AVAILABLE COPY





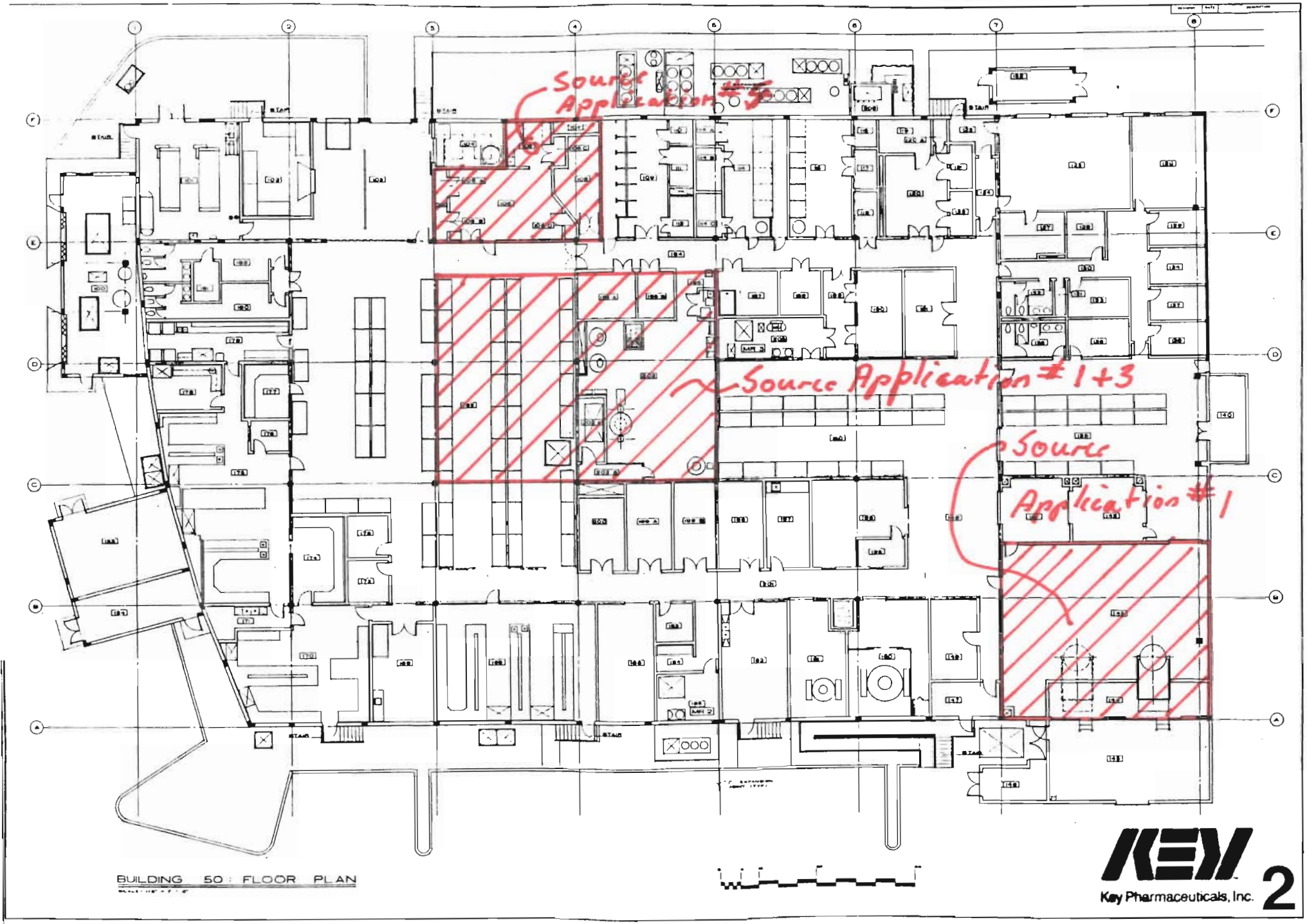
PLANT NO. 1

ARCHITECTURAL SITE PLAN

SCALE: 1" = 40'-0"

NORTH

Key Pharmaceuticals, Inc.



BUILDING 50 : FLOOR PLAN

Key Pharmaceuticals, Inc.

CHARGE Carbon Adsorption / Solvent Recovery - Bldg 50 DATE 1-18-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 1 of 3 FILE NO. _____

SUBJECT Process Emission Calculations with control by Carbon System

Basis

Process input from 4 Fluid Bed (Glatt) Process Units and 2 Pan Coating (Accela-Cota) Units

	Maximum in lb/Hr			Average in lb/Hr		
	$MeCl_2$	MeOH	Part.	$MeCl_2$	MeOH	Part
Fluid Bed Unit						
Glatt #1	209	19.3	1.3	113	10.4	0.7
Glatt #2	267	24.8	1.7	194	18.0	1.2
Glatt #3	267	24.8	1.7	194	18.0	1.2
Glatt #4	267	24.8	1.7	194	18.0	1.2
Pan Coating Unit						
Accela Cota #1	200	30.0	1.3	75	11.3	0.5
Accela Cota #2	200	30.0	1.3	75	11.3	0.5
Total	1,410	153.7	9.0	845	87	5.3

$MeCl_2$ - Methylene Chloride

MeOH - Methanol

Part. - Particulate

CHARGE Carbon Adsorption/Solvent Recovery System DATE 1-18-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 2 of 3 FILE NO. _____

SUBJECT _____

A. Methylene Chloride Emission

(i) Maximum Instantaneous Emission Potential 1,410 lb/hr

(ii) Maximum Instantaneous Emissions 141 lb/Hr

Contol System Design - 90% removal eff.

(iii) Annual Emission Potential

$845 \times 8760 \div 2000 =$ 3,700 Tons/year
845 lb/Hr

(iv) Average Annual Emissions 370.1 Tons/year
84.5 lb/Hr

Control System Design - 90% removal eff.

B. Methanol Emissions

(i) Max. Instantaneous Emission Potential 153.7 lb/Hr

(ii) Max Instantaneous Emissions 15.4 lb/Hr

Control System Design - 90% removal eff.

(iii) Annual Emission Potential

$87 \times 8760 \div 2000 =$ 381.1 Tons/year
87 lb/Hr

(iv) Average Annual Emissions 38.1 Tons/year

Control System Design - 90% removal eff. 8.7 lb/Hr

CHARGE Carbon Adsorption / Solvent Recovery System DATE 1-18-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 3 of 3 FILE NO. _____

SUBJECT _____

C Particulate Emissions

(i) Maximum Instantaneous Emission Potential 9.0 lb/Hr

(ii) Max Instantaneous Emissions

Dust Collector Design - 99% removal eff 0.09 lb/Hr

(iii) Annual Emission Potential

$5.3 \times 8760 \div 2000$ = 23.2 Tons/Year
5.3 lb/Hr

(iv) Annual Emissions

Dust Collector Design - 99% removal eff. 0.23 Tons/Year

0.05 lb/Hr

KEY PHARMACEUTICALS, INC.
APPLICATION #2

I. PROCESS

A. Production Termed - Pharmaceuticals Manufacturing.

B. Air Pollutants Involved:

Particulate

Methylene Chloride

Methanol

C. Process Description

Two types of pharmaceuticals manufacturing equipment are utilized:

1. Fluid Bed Process (Glatt) Unit (see Flow Sheet I)
2. Pan Coating (Accela Coat) Unit (see Flow Sheet II)

The Process Control Device utilized is a combination of dust collection, carbon adsorption and solvent purification (see Flow Sheet III).

D. Overall plant loading for Control Device

Stage 1 Three Fluid Bed Processors and one Pan Coater Processor by DEC'87

Stage 2 One additional Fluid Bed Processor by JAN'88

Stage 3 One additional Pan Coater Processor by MAR'88

The loading to the Control Devices is as follows:

	MAXIMUM $MeCl_2$	MeOH	LB/HR Part	AVERAGE $MeCl_2$	MeOH	LB/HR Part
FLUID BED UNIT						
GLATT #1	209	19.3	1.3	113	10.4	0.7
GLATT #2	267	24.8	1.7	194	18.0	1.2
GLATT #3	267	24.8	1.7	194	18.0	1.2
GLATT #4	267	24.8	1.7	194	18.0	1.2
PAN COATING UNIT						
ACCELA COAT #1	200	30.0	1.3	75	11.3	0.5
ACCELA COAT #2	200	30.0	1.3	75	11.3	0.5
TOTAL:	1,410	153.7	9.0	845	87.0	5.3

$MeCl_2$ = METHYLENE CHLORIDE

MeOH = METHANOL

PART = PARTICULATE

APPLICATION #2

II. CONTROL SYSTEM

Carbon adsorption and solvent recovery (permitted separately, Permit Application #2). See Flow Sheet III - attached.

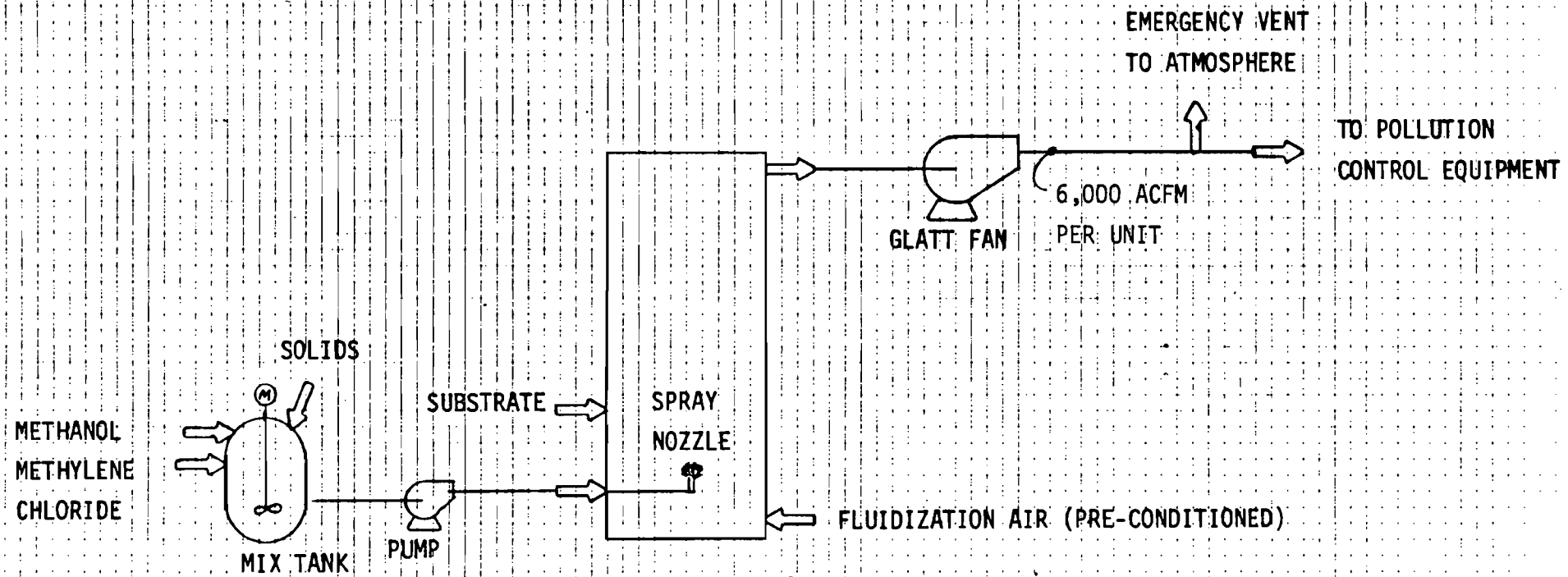
Process air containing methylene chloride, methanol, and particulates is delivered from the process to the suction side of the dust collector. The dust collector removes 99% of all particulates, solids are collected in drums and disposed of off-site by thermal oxidation and landfill. The solvent ladened air is then passed through one of three carbon adsorbers, the adsorbers operate in a configuration of 2 on line and 1 regenerating/stand-by. The carbon adsorbers are designed for a 90% + removal efficiency of both methylene chloride and methanol. The adsorbers are operated on a timed cycle with a breakthrough override mode, thereby guaranteeing the 90% removal efficiency. During the regeneration cycle the solvents are stripped from the carbon utilizing live steam. The stripped material is then condensed. Once all solvent materials have been stripped from the carbon, the carbon is dried and the unit is placed on stand-by. The liquid portion from the stripping operation then goes through various separation, distillation, and purification steps. The final products delivered are pure methylene chloride for re-use in the process, fuel grade methanol for use in the boilers to generate steam and a water discharge to sewer that contains less than 1000 milligrams per liter of 5-day Biological Oxygen Demand (BOD's) and less than 1500 milligrams per liter of Chemical Oxygen Demand (COD). This discharge is permitted separately by the Department of Environmental Regulations Metro Dade.

III. SUMMARY

Based on the above presented information Key Pharmaceuticals, Inc. should be allowed to replace the current pollution control device with a carbon adsorption/solvent recovery system. The following is a tabulation of current and future emissions:

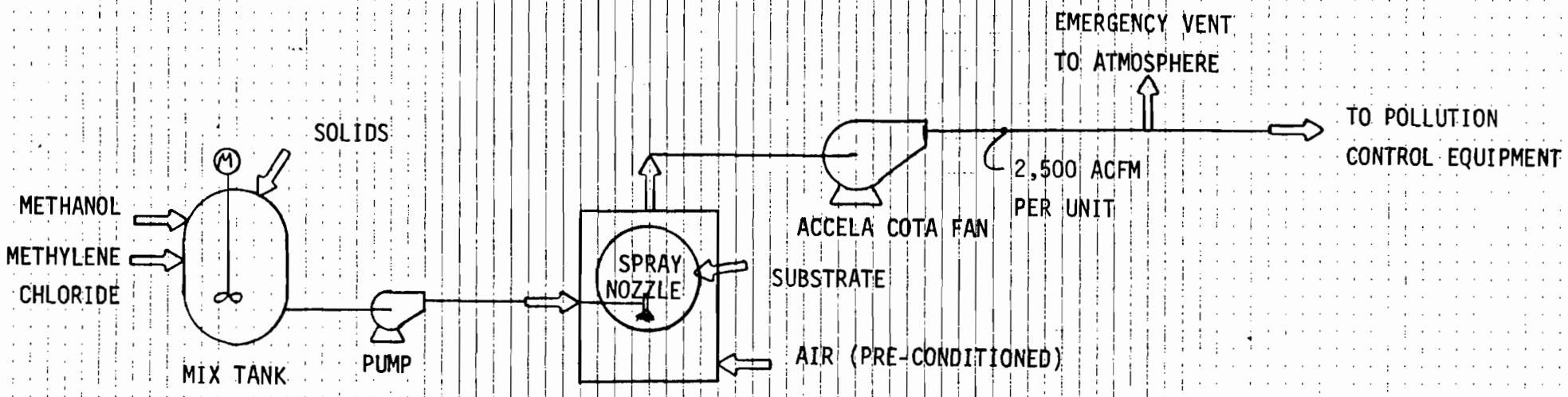
	PERMIT AC 13-100437	APPL #1	APPL #2	FUTURE (#1-#4) WITH CONTROL	SYSTEM MAX DESIGN
MeOH	35.0	20.3	20.3	38.1	108.6
$MeCl_2$	978.0	2195	219.5	370.1	532.6

The control technology proposed is considered state of the art for this application. As indicated by the tabulation of the data even with future projects taken into consideration, methanol emissions will only be increased by less than 10% (3.1 tons/year) and methylene chloride emission will be reduced by more than 60% (608 tons/year) from current permit limitations.



TYPICAL FLOW DIAGRAM
FLUID BED PROCESS

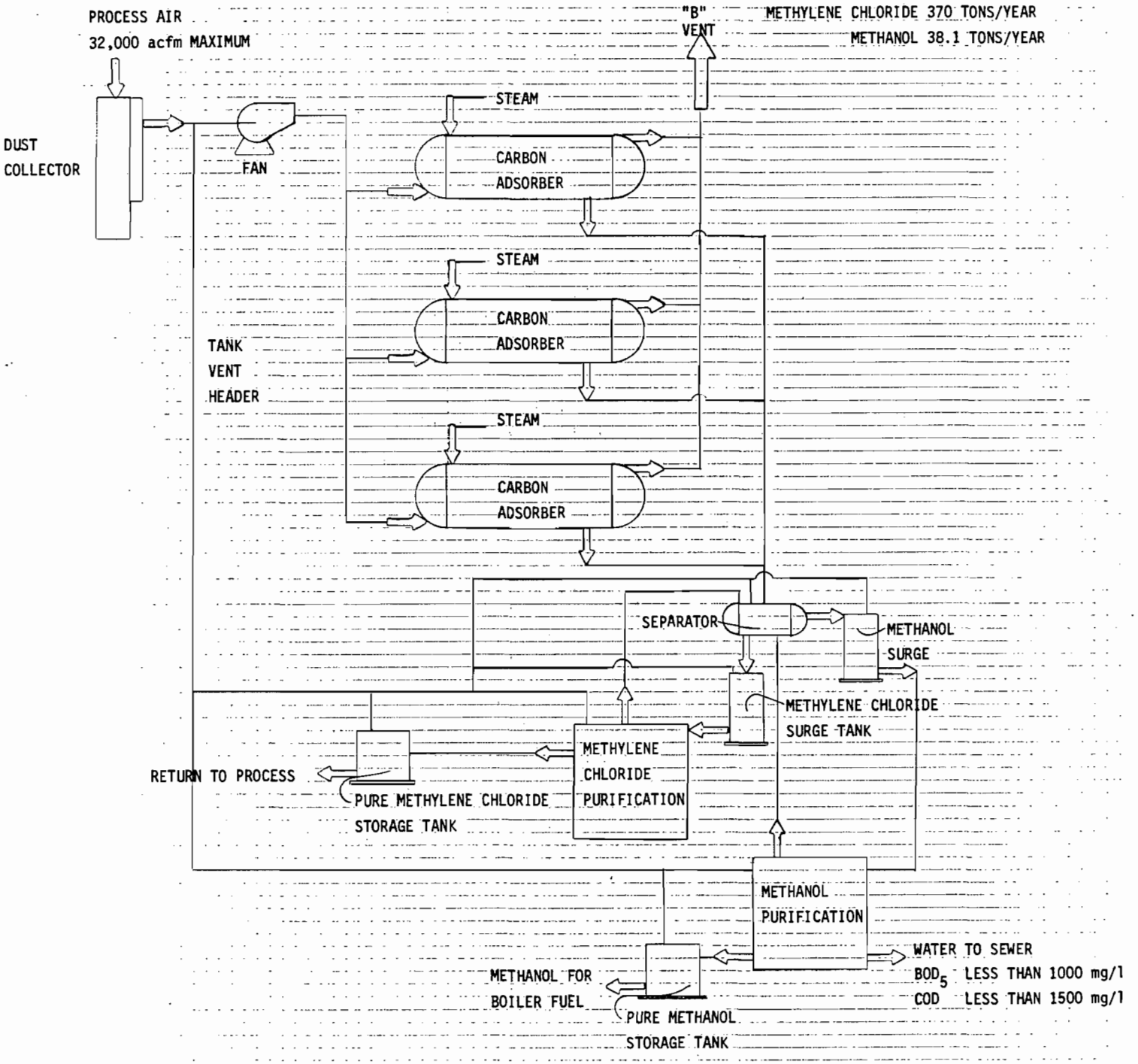
FLOW SHEET I



TYPICAL FLOW DIAGRAM

PAN COATING UNIT

FLOW SHEET II



ENVIRONMENTAL CONTROL SYSTEM - BUILDING 50
FOR FLUID BED PROCESSORS (4) & PAN COATING PROCESSORS (2)

FLOW SHEET III

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

January 12, 1987

Mr. C.H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: APPLICATION FOR PERMIT TO CONSTRUCT 1 FLUIDIZED BED COATING UNIT.

Dear Mr. Fancy:

Attached please find an "Application to Construct Air Pollution Sources". The application attached is for the construction of 1 fluidized bed coating unit. This will bring the total number of fluidized bed coating units to 4 at this facility. As you are aware, Key has requested a permit for construction (Application #2) of an air pollution control system for the control of particulate, methylene chloride and methanol emissions. The emissions from this fluidized bed coating unit will be reduced by this control device.

Your cooperation in bringing this permitting about as expeditiously as possible is greatly appreciated. Should you have any questions or comments, please do not hesitate to call me at (305) 654-2240.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

attachment

cc: S. Brooks (S.E. Florida District)
P. Wong (DERM Office)

AC13-129893

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

SOUTHEAST FLORIDA DISTRICT
3301 GUN CLUB ROAD
P.O. BOX 3858
WEST PALM BEACH, FLORIDA 33402

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

ROY DUKE
DISTRICT MANAGER

APPLICATION TO OPERATE/CONSTRUCT AIR POLLUTION SOURCES

SOURCE TYPE: AIR POLLUTION [x] New[1] [ ] Existing[1]

APPLICATION TYPE: [X] Construction [ ] Operation [ ] Modification

COMPANY NAME: KEY PHARMACEUTICALS, INC. COUNTY: DADE

Identify the specific emission point source(s) addressed in this application (i.e. Lime Kiln No. 4 with Venturi Scrubber; Peaking Unit No. 2, Gas Fired) 1 FLUID BED PROCESSOR w/ CARBON ADSORPTION/SOLVENT RECOVERY

SOURCE LOCATION: Street 50 N.W. 176TH STREET City MIAMI

UTM: East 57987 North 7868445

Latitude 25 ° 56 ' 03 "N Longitude 80 ° 11 ' 42 "W

APPLICANT NAME AND TITLE: JAMES R. CONFROY, VICE PRESIDENT OPERATIONS

APPLICANT ADDRESS: 50 N.W. 176TH STREET, MIAMI 33169

SECTION I: STATEMENTS BY APPLICANT AND ENGINEER

A. APPLICANT

I am the undersigned owner or authorized representative* of KEY PHARMACEUTICALS, INC.

I certify that the statements made in this application for a CONSTRUCTION permit are true, correct and complete to the best of my knowledge and belief. Further, I agree to maintain and operate the pollution control source and pollution control facilities in such a manner as to comply with the provision of Chapter 403, Florida Statutes, and all the rules and regulations of the department and revisions thereof. I also understand that a permit, if granted by the department, will be non-transferable and I will promptly notify the department upon sale or legal transfer of the permitted establishment.

*Attach letter of authorization

Signed: James R Confroy

JAMES R. CONFROY, VICE PRESIDENT OPERATIONS
Name and Title (Please Type)

Date: 1/16/87 Telephone No. 305-654-2200

B. PROFESSIONAL ENGINEER REGISTERED IN FLORIDA (where required by Chapter 471, F.S.)

This is to certify that the engineering features of this pollution control project have been designed/examined by me and found to be in conformity with modern engineering principles applicable to the treatment and disposal of pollutants characterized in the permit application. There is reasonable assurance, in my professional judgment, that

[1] See Florida Administrative Code Rule 17-2.100(57) and (104)

* SEE NOTE PAGE 2

I HAVE REVIEWED THE CALCULATIONS USED TO DETERMINE THE STATED LEVELS OF PARTICULATE AND VOC EMISSIONS AND FIND THEM TO BE ACCURATE BASED ON PROJECTED MANUFACTURING LEVELS OF THE PRODUCT.

the pollution control facilities, when properly maintained and operated, will discharge an effluent that complies with all applicable statutes of the State of Florida and the rules and regulations of the department. It is also agreed that the undersigned will furnish, if authorized by the owner, the applicant a set of instructions for the proper maintenance and operation of the pollution control facilities and, if applicable, pollution sources.

Signed John N. Wells, P.E.

JOHN N. WELLS, P.E.
Name (Please Type)

KEY PHARMACEUTICALS, INC.
Company Name (Please Type)

50 N.W. 176TH STREET, MIAMI, FLORIDA 33169
Mailing Address (Please Type)

JOHN N. WELLS REGISTERED No. 33917 STATE OF FLORIDA

Florida Registration No. 33917 Date: 1/16/87 Telephone No. 305-654-2200

SECTION II: GENERAL PROJECT INFORMATION

A. Describe the nature and extent of the project. Refer to pollution control equipment, and expected improvements in source performance as a result of installation. State whether the project will result in full compliance. Attach additional sheet if necessary.

B. Schedule of project covered in this application (Construction Permit Application Only)

Start of Construction JUNE, 1987 Completion of Construction DECEMBER, 1987

C. Costs of pollution control system(s): (Note: Show breakdown of estimated costs only for individual components/units of the project serving pollution control purposes. Information on actual costs shall be furnished with the application for operation permit.)

$2,000,000.00 (SEE PERMIT APPLICATION #2)

D. Indicate any previous DER permits, orders and notices associated with the emission point, including permit issuance and expiration dates.

(1) CONSENT ORDER NO. 83-0373

(2) PERMIT TO CONSTRUCT FOR MFG GUANIDINE & QUINORA AC 13-115383

(3) PERMIT TO CONSTRUCT FOR MFG OF K-DUR AC 13-100437

E. Requested permitted equipment operating time: hrs/day 24 ; days/wk 7 ; wks/yr 52 ;

if power plant, hrs/yr_____; if seasonal, deacribe:_____

F. If this is a new source or major modification, anawer the following queationa. (Yea or No)

1. Is this source in a non-attainment area for a particular pollutant? YES

   a. If yea, has "offaet" been applied? NO

   b. If yes, haa "Lowest Achievable Emission Rate" been applied? NO

   c. If yea, list non-attainment pollutants. OZONE

2. Does beat available control technology (BACT) apply to this source? If yea, see Section VI. NO

3. Does the State "Prevention of Significant Deterioriation" (PSD) requirement apply to this source? If yes, see Sections VI and VII. NO

4. Do "Standarda of Performance for New Stationary Sourcea" (NSPS) apply to this source? NO

5. Do "National Emission Standarda for Hazardous Air Pollutants" (NESHAP) apply to this source? NO

H. Do "Reasonably Available Control Technology" (RACT) requirements apply to this source? NO

   a. If yes, for what pollutants?_____

   b. If yes, in addition to the information required in this form, any information requested in Rule 17-2.650 must be submitted.

Attach all supportive information related to any answer of "Yes". Attach any justification for any answer of "No" that might be considered questionable.

SECTION III: AIR POLLUTION SOURCES & CONTROL DEVICES (Other than Incinerators)

A. Raw Materials and Chemicals Used in your Process, if applicable:

Description	Contaminants		Utilization Rate - lbs/hr	Relate to Flow Diagram
	Type	% Wt		
METHANOL	VOC	10	18	"A"
METHYLENE CHLORIDE	VOC	90	194	"A"

B. Process Rate, if applicable: (See Section V, Item 1)

1. Total Process Input Rate (lbs/hr): 272 LB/HR

2. Product Weight (lbs/hr): 60 LB/HR

C. Airborne Contaminants Emitted: (Information in this table must be submitted for each emission point, use additional sheets as necessary)

Name of Contaminant	Emission[1]		Allowed[2] Emission Rate per Rule 17-2	Allowable[3] Emission lbs/hr	Potential[4] Emission		Relate to Flow Diagram
	Maximum lbs/hr	Actual T/yr			lbs/yr	T/yr	
VOC	2.5	7.9				78.8	"A"
PARTICULATE	0.02	0.05				5.3	"A"
METHYLENE CHLORIDE	26.7	85.1				851	"A"

[1]See Section V, Item 2.

[2]Reference applicable emission standards and units (e.g. Rule 17-2.600(5)(b)2. Table II, E. (1) - 0.1 pounds per million BTU heat input)

[3]Calculated from operating rate and applicable standard.

[4]Emission, if source operated without control (See Section V, Item 3).

D. Control Devices: (See Section V, Item 4)

Name and Type (Model & Serial No.)	Contaminant	Efficiency	Range of Particles Size Collected (in microns) (If applicable)	Basis for Efficiency (Section V Item 5)
CARBON ADSORBER	VOC	90%	N/A	SUPPLIER'S DESIGN
DUST COLLECTOR TORIT 3DF60	PARTICULATE	99.0%	2 MICRON OR LARGER	SUPPLIER'S DESIGN

E. Fuels

Type (Be Specific)	Consumption*		Maximum Heat Input (MMBTU/hr)
	avg/hr	max./hr	

*Units: Natural Gas--MMCF/hr; Fuel Oils--gallons/hr; Coal, wood, refuse, other--lbs/hr.

Fuel Analysis:

Percent Sulfur:_____ Percent Ash:_____

Density: _____ lbs/gal Typical Percent Nitrogen:_____

Heat Capacity: _____ BTU/lb _____ BTU/gal

Other Fuel Contaminants (which may cause air pollution):_____

F. If applicable, indicate the percent of fuel used for space heating.

Annual Average _____ Maximum _____

G. Indicate liquid or solid wastes generated and method of disposal.

10,000 LB/YR PARTICULATES FROM FILTER EQUIVALENT TO ABOUT 25 DRUMS/YEAR TO OFF-SITE DISPOSAL.

H. Emission Stack Geometry and Flow Characteristics (Provide data for each stack):

Stack Height: SEE APPLICATION #2 ft. Stack Diameter: _____ ft.

Gas Flow Rate: _____ ACFM _____ DSCFM Gas Exit Temperature: _____ °F.

Water Vapor Content: _____ % Velocity: _____ FPS

SECTION IV: INCINERATOR INFORMATION

Type of Waste	Type 0 (Plastics)	Type I (Rubbish)	Type II (Refuse)	Type III (Garbage)	Type IV (Pathological)	Type V (Liq.& Gas By-prod.)	Type VI (Solid By-prod.)
Actual lb/hr Incinerated							
Uncontrolled (lbs/hr)							

Description of Waste _____

Total Weight Incinerated (lbs/hr) _____ Design Capacity (lbs/hr) _____

Approximate Number of Hours of Operation per day _____ day/wk _____ wks/yr. _____

Manufacturer _____

Date Constructed _____ Model No. _____

	Volume $(ft)^3$	Heat Release (BTU/hr)	Fuel		Temperature (°F)
			Type	BTU/hr	
Primary Chamber					
Secondary Chamber					

Stack Height: _____ ft. Stack Diamter: _____ Stack Temp. _____

Gas Flow Rate: _____ ACFM _____ DSCFM* Velocity: _____ FPS

*If 50 or more tons per day design capacity, submit the emissions rate in grains per standard cubic foot dry gas corrected to 50% excess air.

Type of pollution control device: [ ] Cyclone [ ] Wet Scrubber [ ] Afterburner

[ ] Other (specify) _____

Brief description of operating characteristics of control devices: _____

_____

_____

_____

_____

Ultimate disposal of any effluent other than that emitted from the stack (scrubber water, ash, etc.):

_____

_____

_____

_____

NOTE: Items 2, 3, 4, 6, 7, 8, and 10 in Section V must be included where applicable.

SECTION V: SUPPLEMENTAL REQUIREMENTS

Please provide the following supplements where required for this application.

1. Total process input rate and product weight -- show derivation [Rule 17-2.100(127)]

2. To a construction application, attach basis of emission estimate (e.g., design calculations, design drawings, pertinent manufacturer's test data, etc.) and attach proposed methods (e.g., FR Part 60 Methods 1, 2, 3, 4, 5) to show proof of compliance with applicable standards. To an operation application, attach test results or methods used to show proof of compliance. Information provided when applying for an operation permit from a construction permit shall be indicative of the time at which the test was made.

3. Attach basis of potential discharge (e.g., emission factor, that is, AP42 test).

4. With construction permit application, include design details for all air pollution control systems (e.g., for baghouse include cloth to air ratio; for scrubber include cross-section sketch, design pressure drop, etc.)

5. With construction permit application, attach derivation of control device(s) efficiency. Include test or design data. Items 2, 3 and 5 should be consistent: actual emissions = potential (1-efficiency).

6. An 8 1/2" x 11" flow diagram which will, without revealing trade secrets, identify the individual operations and/or processes. Indicate where raw materials enter, where solid and liquid waste exit, where gaseous emissions and/or airborne particles are evolved and where finished products are obtained.

7. An 8 1/2" x 11" plot plan showing the location of the establishment, and points of airborne emissions, in relation to the surrounding area, residences and other permanent structures and roadways (Example: Copy of relevant portion of USGS topographic map).

8. An 8 1/2" x 11" plot plan of facility showing the location of manufacturing processes and outlets for airborne emissions. Relate all flows to the flow diagram.

9. The appropriate application fee in accordance with Rule 17-4.05. The check should be made payable to the Department of Environmental Regulation.

10. With an application for operation permit, attach a Certificate of Completion of Construction indicating that the source was constructed as shown in the construction permit.

SECTION VI: BEST AVAILABLE CONTROL TECHNOLOGY

A. Are standards of performance for new stationary sources pursuant to 40 C.F.R. Part 60 applicable to the source?

[ ] Yes [ ] No

Contaminant	Rate or Concentration

B. Has EPA declared the best available control technology for this class of sources (If yes, attach copy)

[ ] Yes [ ] No

Contaminant	Rate or Concentration

C. What emission levels do you propose as best available control technology?

Contaminant	Rate or Concentration

D. Describe the existing control and treatment technology (if any).

1. Control Device/System:
2. Operating Principles:
3. Efficiency:*
4. Capital Costs:

*Explain method of determining

5. Useful Life:

6. Operating Costs:

7. Energy:

8. Maintenance Cost:

9. Emissions:

Contaminant	Rate or Concentration

10. Stack Parameters

a. Height: ft.

b. Diameter: ft.

c. Flow Rate: ACFM

d. Temperature: °F.

e. Velocity: FPS

E. Describe the control and treatment technology available (As many types as applicable, use additional pages if necessary).

1.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

2.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

3.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to conetruct with control device, install in available space, and operate within proposed levels:

4.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Costs:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

F. Describe the control technology selected:

1. Control Device:

2. Efficiency:[1]

3. Capital Cost:

4. Useful Life:

5. Operating Cost:

6. Energy:[2]

7. Maintenance Cost:

8. Manufacturer:

9. Other locations where employed on similar processes:

a. (1) Company:

(2) Mailing Address:

(3) City:

(4) State:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

b. (1) Company:

(2) Mailing Address:

(3) City: (4) State:

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

10. Reason for selection and description of systems:

[1]Applicant must provide this information when available. Should this information not be available, applicant must state the reason(s) why.

SECTION VII - PREVENTION OF SIGNIFICANT DETERIORATION

A. Company Monitored Data

1. _____no. sites _____ TSP _____( ) SO^2* _____ Wind spd/dir

Period of Monitoring _____/____/_____ to _____/____/_____
month day year month day year

Other data recorded _____

Attach all data or statistical summaries to this application.

*Specify bubbler (B) or continuous (C).

2. Instrumentation, Field and Laboratory

a. Was instrumentation EPA referenced or its equivalent? [ ] Yes [ ] No

b. Was instrumentation calibrated in accordance with Department procedures?

[ ] Yes [ ] No [ ] Unknown

B. Meteorological Data Used for Air Quality Modeling

1. _____ Year(s) of data from _____/_____/_____ to _____/_____/_____
month day year month day year

2. Surface data obtained from (location)_____

3. Upper air (mixing height) data obtained from (location)_____

4. Stability wind rose (STAR) data obtained from (location)_____

C. Computer Models Used

1. _____ Modified? If yes, attach description.

2. _____ Modified? If yes, attach description.

3. _____ Modified? If yes, attach description.

4. _____ Modified? If yes, attach description.

Attach copies of all final model runs showing input data, receptor locations, and principle output tables.

D. Applicants Maximum Allowable Emission Data

Pollutant	Emission Rate	
TSP	_____	grams/sec
SO^2	_____	grams/sec

E. Emission Data Used in Modeling

Attach list of emission sources. Emission data required is source name, description of point source (on NEDS point number), UTM coordinates, stack data, allowable emissions, and normal operating time.

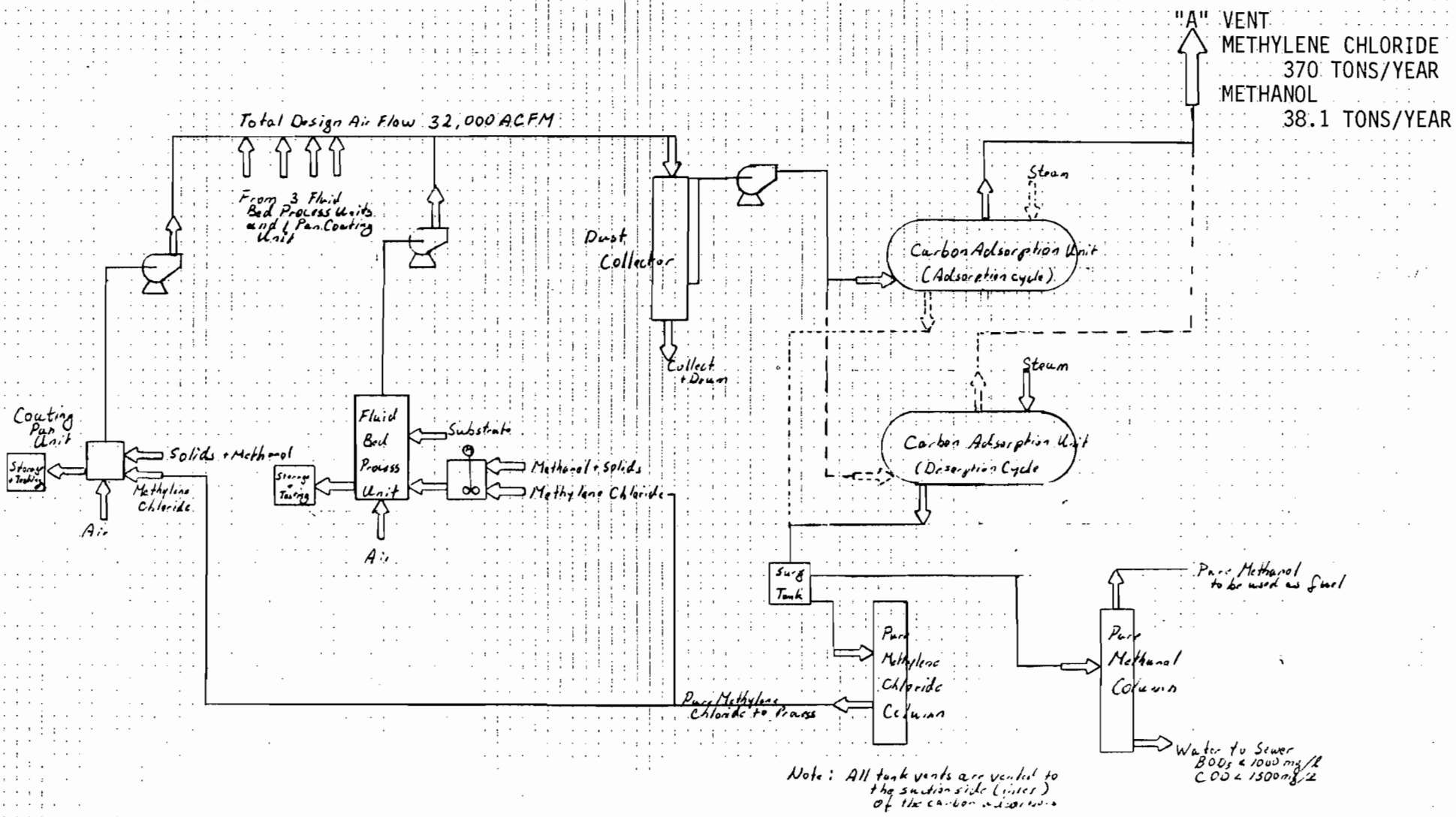
F. Attach all other information supportive to the PSD review.

G. Discuss the social and economic impact of the selected technology versus other applicable technologies (i.e., jobs, payroll, production, taxes, energy, etc.). Include assessment of the environmental impact of the sources.

H. Attach scientific, engineering, and technical material, reports, publications, journals, and other competent relevant information describing the theory and application of the requested best available control technology.

GENERAL ARRANGEMENT

PROCESS FLOW DIAGRAM
(FOUR FLUID BED PROCESS UNITS & TWO PAN COATING PROCESS UNITS)



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

C E R T I F I C A T E

To Whom It May Concern:

This is to certify that Robert A. Franke, Director of Engineering of Key Pharmaceuticals, Inc., is duly authorized to represent Key Pharmaceuticals, Inc., along with his designate, Thomas W. Flachmeyer, Manager Environmental Engineering and Waste Management; for the purposes of making Application for Permit to Construct or Operate Pollution Control Facilities for said company.

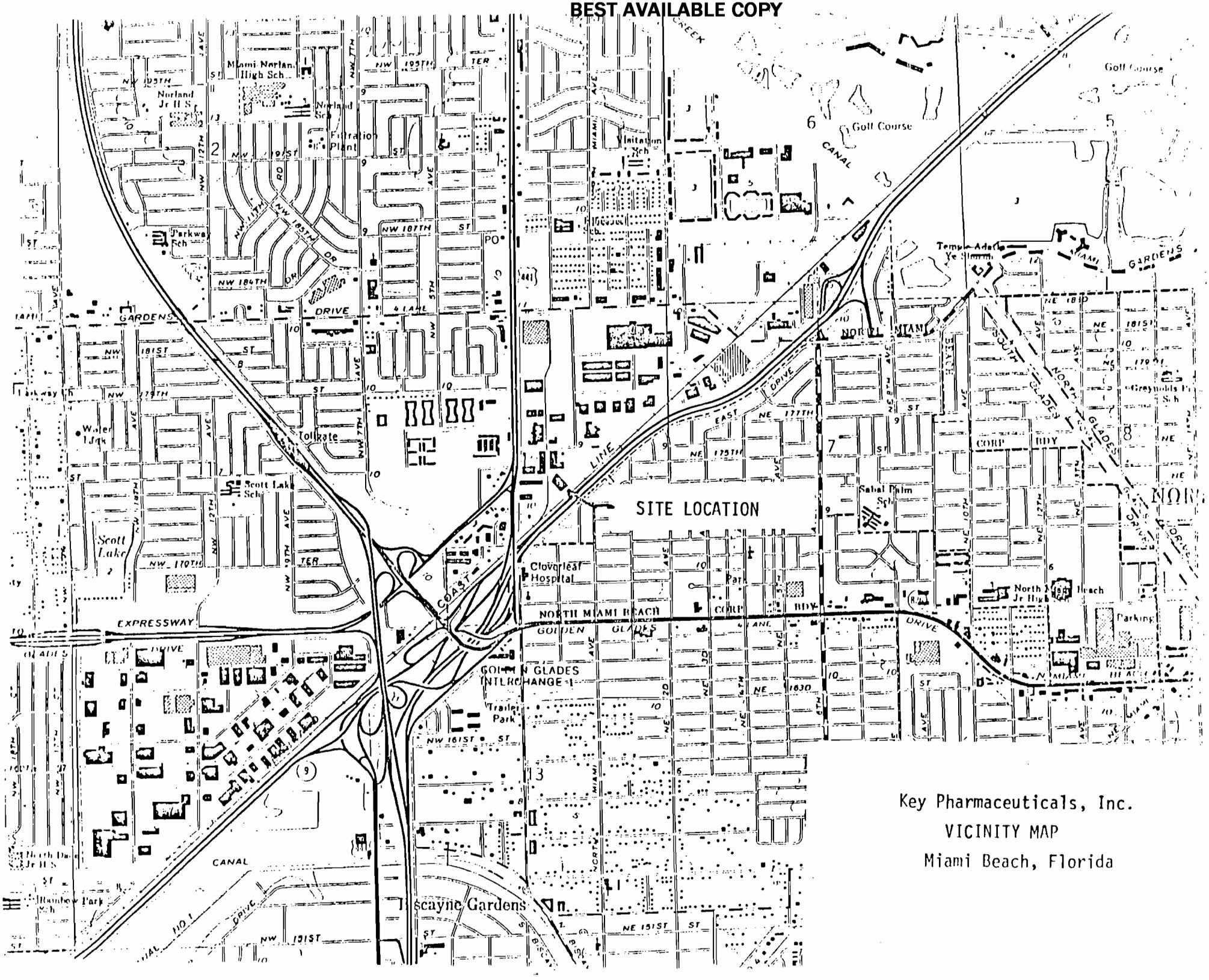
Key Pharmaceuticals, Inc.

James R. Confrey, Vice President
Miami and Puerto Rico Operations
JRC/db

STATE OF FLORIDA
COUNTY OF DADE
Sworn to and subscribed before me
this 21st day of October A.D. 1986.

NOTARY PUBLIC STATE OF FLORIDA
MY COMMISSION EXP. DEC 18,1989
BONDED THRU GENERAL INS. UND.

BEST AVAILABLE COPY



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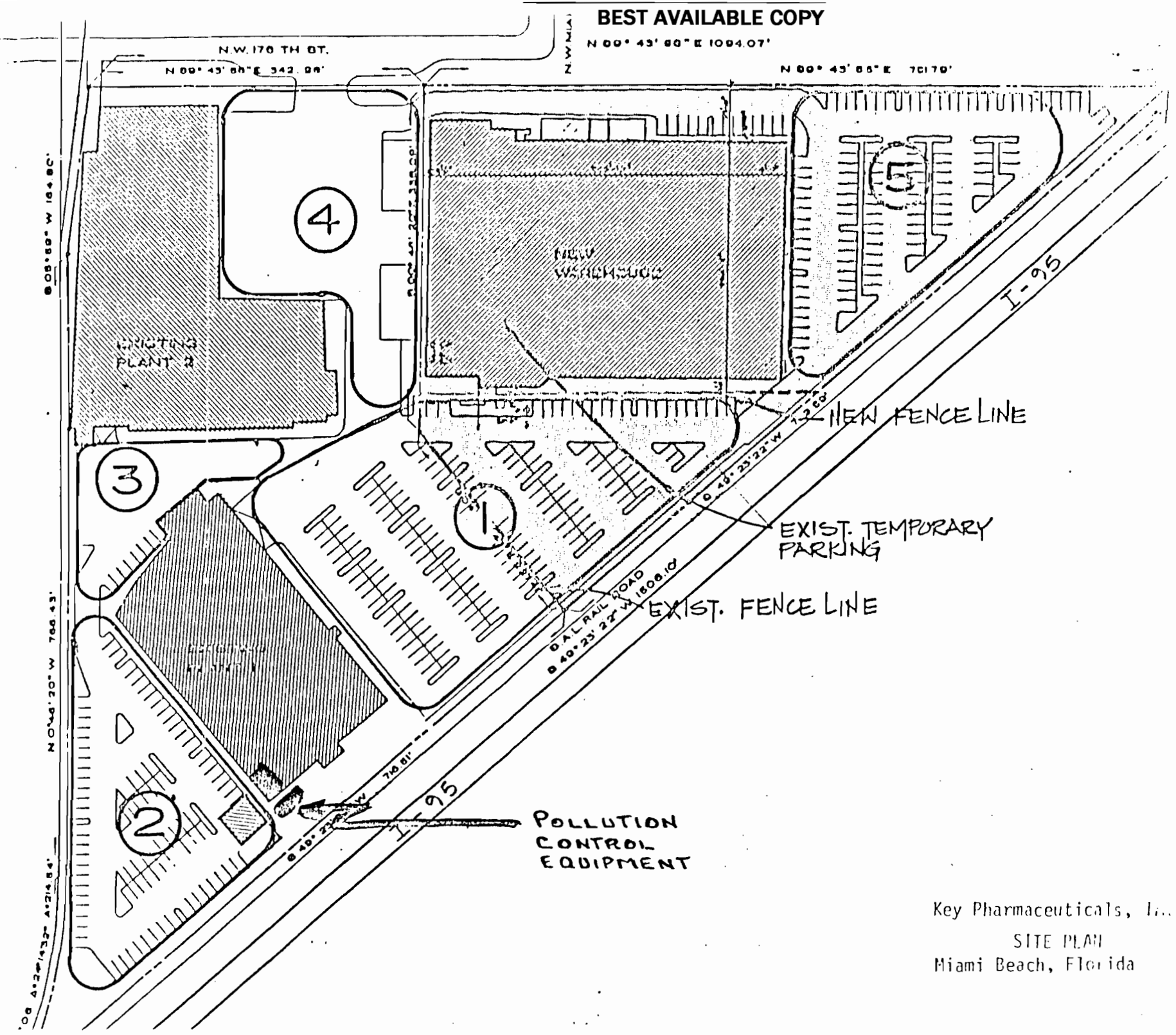
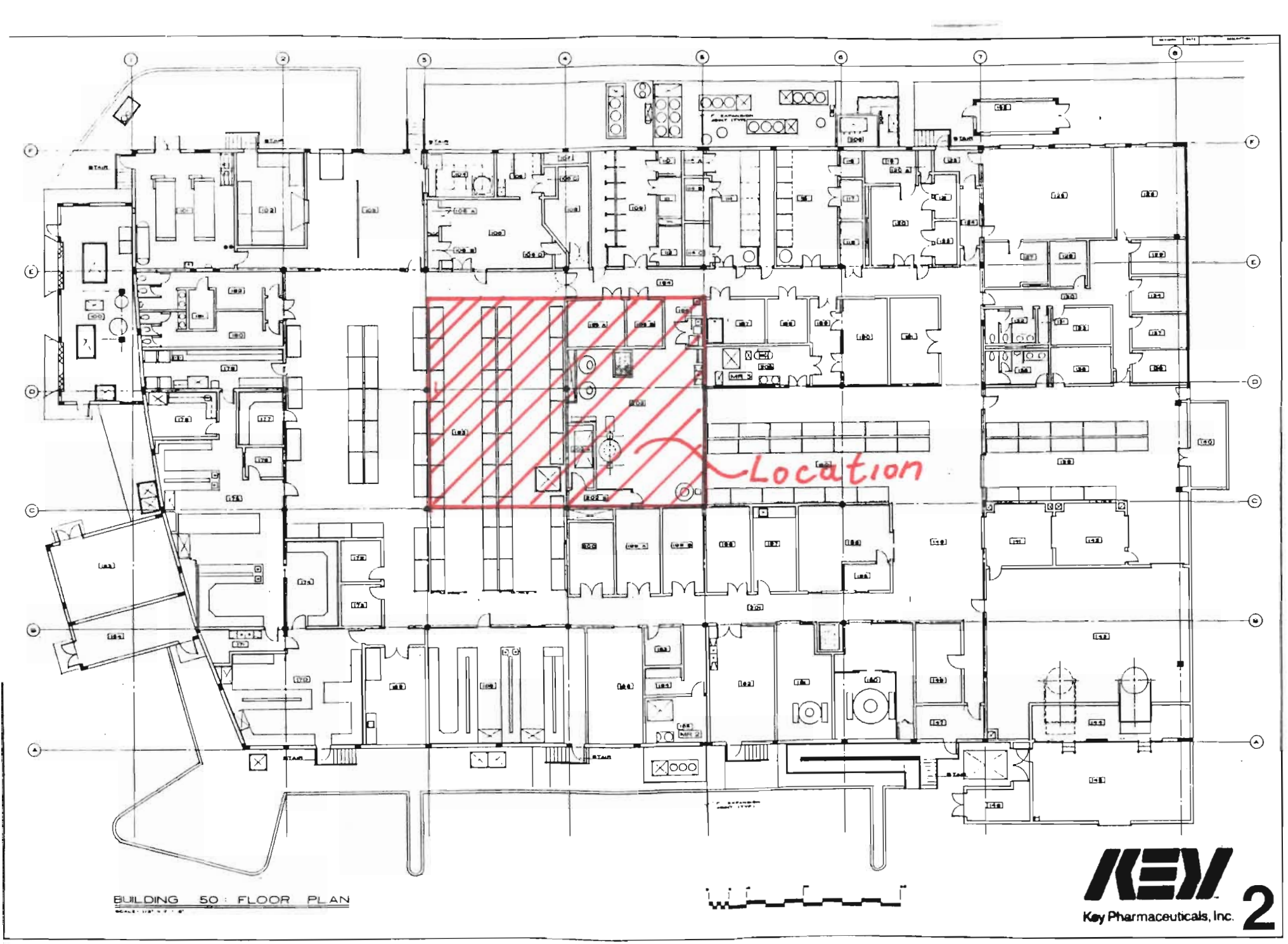


Key Pharmaceuticals, I...

SITE PLAN

Miami Beach, Florida



BUILDING 50 : FLOOR PLAN

Key Pharmaceuticals, Inc.

CHARGE K - Dar Environmental DATE 1-15-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 1 of 3 FILE NO. 0410

SUBJECT Process Emission Calculations for Fluid Bed Processor (Glatt) unit #4

Basis

Manufacturing Capacity

Unit # 4 - 796 lots per year

Lot Specifications

Methylene Chloride	2139 #
Methanol	198 #
Solids (Excipients)	665 #

A. Methylene Chloride Emissions

(i) Maximum Instantaneous Emission Potential 267 #/Hr

(ii) Max Instantaneous Emissions

Control System design - 90% removal eff.

∴ Max Instantaneous Emissions 26.7 #/Hr

(iii) Annual Emission Potential ~~88.6~~

851 Tons/year -
194 #/Hr

(iv) Annual Emissions

Control System design 90% removal eff.

∴ Average Annual Emissions 85.1 T/y
19.4 #/Hr

CHARGE K-Dar Environmental DATE 1-15-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 2 of 3 FILE NO. 0410

SUBJECT _____

B Methanol Emissions

(i) Max. Instantaneous Emission Potential 24.8 #/Hr

(ii) Max Instantaneous Emissions

Control System Design - 90% removal eff.

∴ Max Instantaneous Emissions 2.5 #/Hr

(iii) Annual Emission Potential

78.8 Tons/year
18.0 #/Hr

(iv) Annual Emissions

Control System Design - 90% removal eff.

∴ Average Annual Emissions 7.9 T/y

1.8 #/Hr

CHARGE K-Dar Environmental DATE 1-15-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 3 of 3 FILE NO. 0410

SUBJECT _____

C. Particulate Emissions

(i) Max Instantaneous Emission Potential

Emission Potential from Glatt is 2% of Solids

∴ 1.7 #/Hr

(ii) Max. Instantaneous Emissions

Dust Collector - 99% removal eff.

∴ Max Instantaneous Emissions 0.02 #/Hr

(iii) Annual Emission Potential

5.3 Tons/year
1.2 lb/Hr

(iv) Annual Emissions

Dust Collector - 99% removal eff.

∴ Average Annual Emissions 0.05 T/y
0.01 #/Hr

KEY PHARMACEUTICALS, INC.
APPLICATION #3

I. PRODUCTION

A. Accela-Cota (see Flow Sheet I - attached)

B. Solvents Involved:

Methylene Chloride
Methanol

C. Process Description (see Flow Sheet I - attached)

D. Process Quantities
Basis - 2190 lots of product for two pan coating units (Accela-Cota 1 & 2)
Methanol - 98.6 tons/year total all units
Methylene Chloride - 328.5 tons/year total all units
Solids - 657 tons/year total all units

E. Overall plant loadings for product

Stage 1 - one pan coating process unit by OCT'87
Stage 2 - second pan coating process unit by JUN'88

II. CONTROL SYSTEM

Carbon adsorption and solvent recovery (permitted separately, Permit Application #2). See Flow Sheet II - attached.

Process air containing methylene chloride, methanol, and particulates is delivered from the process to the suction side of the dust collector. The dust collector removes 99% of all particulates, solids are collected in drums and disposed of off-site by thermal oxidation and landfill. The solvent ladened air is then passed through one of three carbon adsorbers, the adsorbers operate in a configuration of 2 on line and 1 regenerating/stand-by. The carbon adsorbers are designed for a 90% + removal efficiency of both methylene chloride and methanol. The adsorbers are operated on a timed cycle with a breakthrough override mode, thereby guaranteeing the 90% removal efficiency. During the regeneration cycle the solvents are stripped from the carbon utilizing live steam. The stripped material is then condensed. Once all solvent materials have been stripped from the carbon, the carbon is dried and the unit is placed on stand-by. The liquid portion from the stripping operation then goes through various separation, distillation, and purification steps. The final products delivered are pure methylene chloride for re-use in the process, fuel grade methanol for use in the boilers to generate steam and a water discharge to sewer that contains less than 1000 milligrams per liter of 5-day Biological Oxygen Demand (BOD's) and less than 1500 milligrams per liter of Chemical Oxygen Demand (COD). This discharge is permitted separately by the Department of Environmental Regulations Metro Dade.

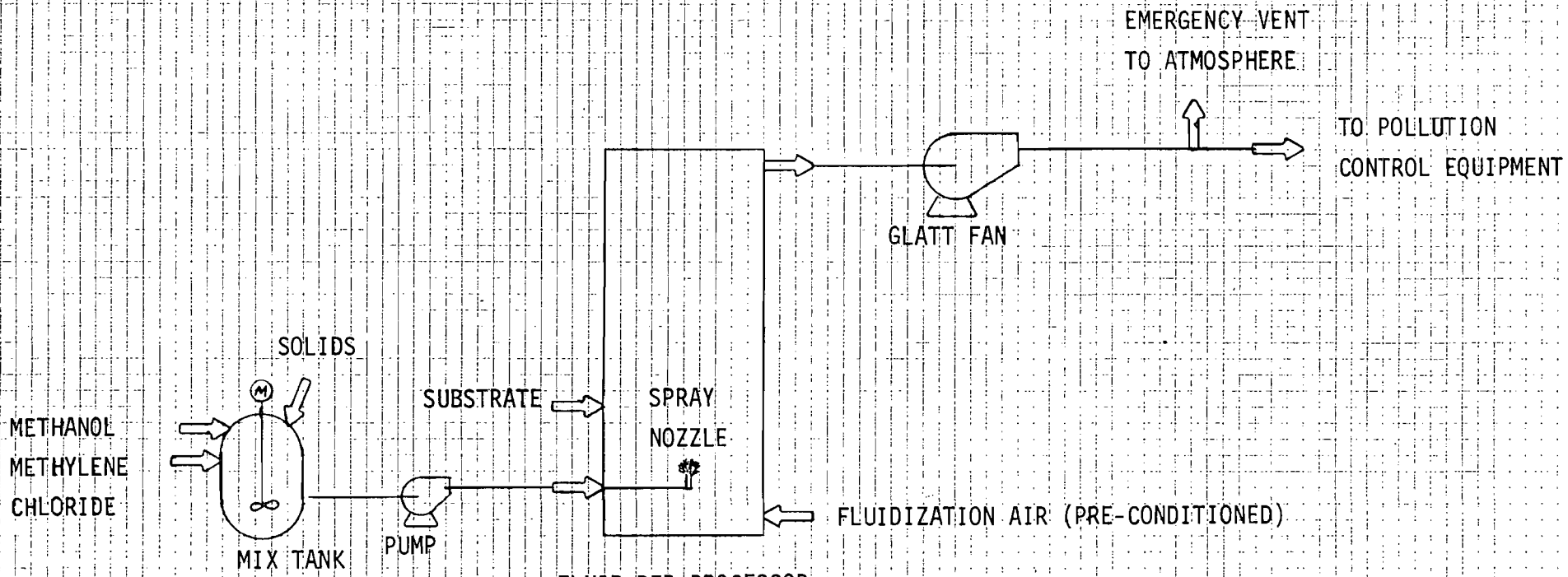
APPLICATION #3

III. SUMMARY

Based on the above presented information Key Pharmaceuticals, Inc. should be allowed to add two pan coating process units to manufacture K-DUR at its 50 N.W. 176 Street location. The increased loading to the Pollution Control Device is as follows:

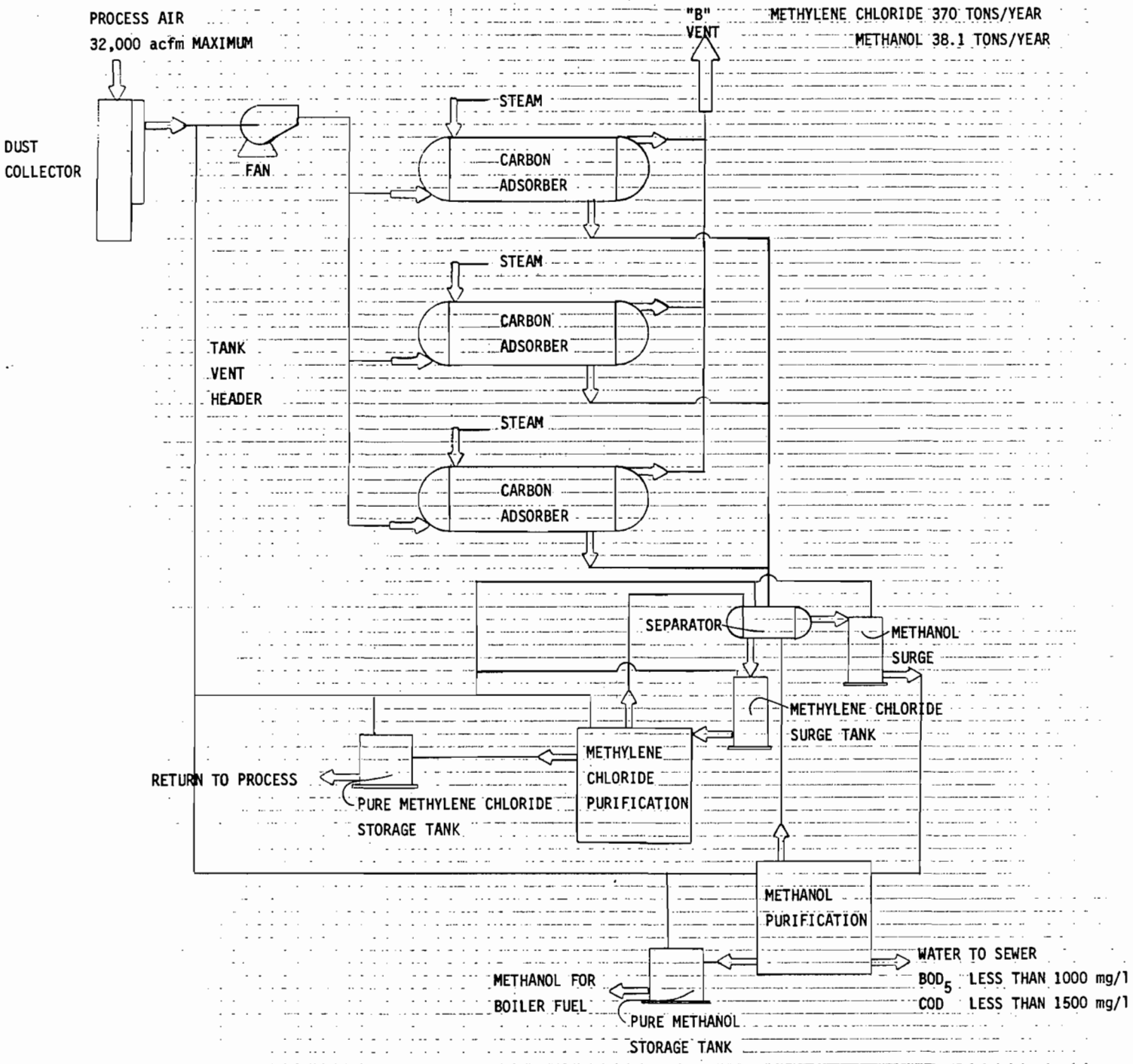
	PROPOSED CURRENT	INCREASE	NEW TOTAL	SYSTEM DESIGN
AIR FLOW (acfm)	24,000	5,000	29,000	32,000
METHANOL (T/Y)	282	98.6	380.6	1,086
METHYLENE CHLORIDE (T/Y)	3,046	328.5	3,374.5	5,326
PARTICULATES (T/Y)	19	4.4	23.4	38

The control technology proposed is considered state of the art for this application and the increase is well within design and permitting of the system. Therefore a permit should be issued.



TYPICAL FLOW DIAGRAM
FLUID BED PROCESS

FLOW SHEET 1



ENVIRONMENTAL CONTROL SYSTEM - BUILDING 50
FOR FLUID BED PROCESSORS (4) & PAN COATING PROCESSORS (2)

FLOW SHEET II

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

January 12, 1987

Mr. C.H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: APPLICATION TO CONSTRUCT TWO (2) PAN COATING PROCESS UNITS.

Dear Mr. Fancy:

Attached please find an "Application to Construct Air Pollution Sources". The application attached is for the construction of 2 Pan Coating Process units (Accela-Cota) at Key Pharmaceuticals, Inc 50 N.W. 176 Street, Miami location. The two units will be utilized to process prescription and over-the-counter medication. The installation of this equipment will allow Key to be placed strategically within the manufacturing market place. As you are aware, Key has requested a permit for construction (Application #2) of an air pollution control system for the control of particulate, methylene chloride, and methanol emissions. The emissions from these two pan coating units will be reduced by this control device.

Your cooperation in this matter is greatly appreciated. Should you have any questions please do not hesitate to call me at 305-654-2240.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

attachment

cc: S. Brooks (S.E. Florida District)
P. Wong (DERM Office)

AC 13-129893

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

SOUTHEAST FLORIDA DISTRICT
3301 GUN CLUB ROAD
P.O. BOX 3858
WEST PALM BEACH, FLORIDA 33402

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

ROY DUKE
DISTRICT MANAGER

APPLICATION TO OPERATE/CONSTRUCT AIR POLLUTION SOURCES

SOURCE TYPE: AIR POLLUTION [X] New[1] [ ] Existing[1]

APPLICATION TYPE: [X] Construction [ ] Operation [ ] Modification

COMPANY NAME: KEY PHARMACEUTICALS, INC. COUNTY: DADE

Identify the specific emission point source(s) addressed in this application (i.e. Lime Kiln No. 4 with Venturi Scrubber; Peaking Unit No. 2, Gas Fired) 2 PAN COATING UNITS

SOURCE LOCATION: Street 50 N.W. 176TH STREET City MIAMI

UTM: East 57987 North 2868445

Latitude 25 ° 56 ' 03 "N Longitude 80 ° 11 ' 42 "W

APPLICANT NAME AND TITLE: JAMES R. CONFROY, VICE PRESIDENT OPERATIONS

APPLICANT ADDRESS: 50 N.W. 176TH STREET, MIAMI, FL 33169

SECTION I: STATEMENTS BY APPLICANT AND ENGINEER

A. APPLICANT

I am the undersigned owner or authorized representative* of KEY PHARMACEUTICALS, INC

I certify that the statements made in this application for a CONSTRUCTION permit are true, correct and complete to the best of my knowledge and belief. Further, I agree to maintain and operate the pollution control source and pollution control facilities in such a manner as to comply with the provision of Chapter 403, Florida Statutes, and all the rules and regulations of the department and revisions thereof. I also understand that a permit, if granted by the department, will be non-transferable and I will promptly notify the department upon sale or legal transfer of the permitted establishment.

*Attach letter of authorization

Signed: James R Confroy

JAMES R. CONFROY, VICE PRESIDENT OPERATIONS
Name and Title (Please Type)

Date: 1/12/87 Telephone No. 305-654-2200

B. PROFESSIONAL ENGINEER REGISTERED IN FLORIDA (where required by Chapter 471, F.S.)*

This is to certify that the engineering features of this pollution control project have been designed/examined by me and found to be in conformity with modern engineering principles applicable to the treatment and disposal of pollutants characterized in the permit application. There is reasonable assurance, in my professional judgment, that

[1] See Florida Administrative Code Rule 17-2.100(57) and (104)

* SEE EXPLANATION PAGE 2

I HAVE REVIEWED THE CALCULATIONS USED TO DETERMINE THE STATED LEVELS OF PARTICULATE AND VOC EMISSIONS AND FIND THEM TO BE ACCURATE BASED ON PROJECTED MANUFACTURING LEVELS OF THE PRODUCT.

the pollution control facilities, when properly maintained and operated, will discharge an effluent that complies with all applicable statutes of the State of Florida and the rules and regulations of the department. It is also agreed that the undersigned will furnish, if authorized by the owner, the applicant a set of instructions for the proper maintenance and operation of the pollution control facilities and, if applicable, pollution sources.

Signed John N. Wells, P.E.

JOHN N. WELLS, P.E.
Name (Please Type)

KEY PHARMACEUTICALS, INC.
Company Name (Please Type)

50 N.W. 176TH STREET, MIAMI, FL 33169
Mailing Address (Please Type)

Florida Registration No. 33917 Date: 1/12/87 Telephone No. 305-654-2200

SECTION II: GENERAL PROJECT INFORMATION

A. **Describe the nature and extent of the project. Refer to pollution control equipment, and expected improvements in source performance as a result of installation. State whether the project will result in full compliance. Attach additional sheet if necessary.**

THE PROJECT ENTAILS THE INSTALLATION OF TWO PAN COATING UNITS (ACCELA COTA'S) PLUS ANCILLARY EQUIPMENT. THE COATING UNITS WILL BE UTILIZED TO MANUFACTURE VARIOUS PRESCRIPTION DRUG PRODUCTS.

B. **Schedule of project covered in this application (Construction Permit Application Only)**

Start of Construction JUN'87 Completion of Construction SEP'88

C. **Costs of pollution control system(s): (Note: Show breakdown of estimated costs only for individual components/units of the project serving pollution control purposes. Information on actual costs shall be furnished with the application for operation permit.)**

$2,000,000.00 (SEE PERMIT APPLICATION #2).

D. **Indicate any previous DER permits, orders and notices associated with the emission point, including permit issuance and expiration dates.**

(1) CONSENT ORDER NO. 83-0373

(2) PERMIT TO CONSTRUCT FOR MFG GUANIDINE & QUINORA AC 13-115383

(3) PERMIT TO CONSTRUCT FOR MFG OF K-DUR AC 13-100437

E. Requested permitted equipment operating time: hrs/day 24 ; days/wk 7 ; wks/yr 52 ;

if power plant, hrs/yr_____; if seasonal, describe:_____

F. If this is a new source or major modification, answer the following questions. (Yes or No)

1. Is this source in a non-attainment area for a particular pollutant?	YES
a. If yes, has "offset" been applied?	NO
b. If yes, has "Lowest Achievable Emission Rate" been applied?	NO
c. If yes, list non-attainment pollutants.	OZONE
2. Does best available control technology (BACT) apply to this source? If yes, see Section VI.	NO
3. Does the State "Prevention of Significant Deterioriation" (PSD) requirement apply to this source? If yes, see Sections VI and VII.	NO
4. Do "Standards of Performance for New Stationary Sources" (NSPS) apply to this source?	NO
5. Do "National Emission Standards for Hazardous Air Pollutants" (NESHAP) apply to this source?	NO
H. Do "Reasonably Available Control Technology" (RACT) requirements apply to this source?	NO

a. If yes, for what pollutants?_____

b. If yes, in addition to the information required in this form, any information requested in Rule 17-2.650 must be submitted.

Attach all supportive information related to any answer of "Yes". Attach any justification for any answer of "No" that might be considered questionable.

SECTION III: AIR POLLUTION SOURCES & CONTROL DEVICES (Other than Incinerators)

A. Raw Materials and Chemicals Used in your Process, if applicable:

Description	Contaminants		Utilization Rate - lbs/hr	Relate to Flow Diagram
	Type	% Wt		
METHANOL	VOC	13	60 LB/HR *	FLOW SHEET I
METHYLENE CHLORIDE	VOC	87	400 LB/HR *	FLOW SHEET I

* BASED ON ALL SOLVENTS USED IN 3 HOURS (TOTAL FOR TWO UNITS).

B. Process Rate, if applicable: (See Section V, Item 1)

1. Total Process Input Rate (lbs/hr): 272.5 LB/HR

2. Product Weight (lbs/hr): 50 LB/HR

C. Airborne Contaminants Emitted: (Information in this table must be submitted for each emission point, use additional sheets as necessary)

Name of Contaminant	Emission[1]		Allowed[2] Emission Rate per Rule 17-2	Allowable[3] Emission lbs/hr	Potential[4] Emission		Relate to Flow Diagram
	Maximum lbs/hr	Actual T/yr			lbs/yr	T/yr	
METHANOL	6	99				98.6	II"A"
METHYLENE CHLORIDE	40	657				657	II"A"
PARTICULATE	0.03	0.04				4.4	II"A"

[1]See Section V, Item 2.

[2]Reference applicable emission standards and units (e.g. Rule 17-2.600(5)(b)2. Table II, E. (1) - 0.1 pounds per million BTU heat input)

[3]Calculated from operating rate and applicable standard.

[4]Emission, if source operated without control (See Section V, Item 3).

D. Control Devices: (See Section V, Item 4)

Name and Type (Model & Serial No.)	Contaminant	Efficiency	Range of Particles Size Collected (in microns) (If applicable)	Basis for Efficiency (Section V Item 5)
CARBON ADSORPTION	VOC	90%		DESIGN
DUST COLLECTOR TORIT 3DF60	PARTICULATE	99%		DESIGN

E. Fuels

Type (Be Specific)	Consumption*		Maximum Heat Input (MMBTU/hr)
	avg/hr	max./hr	

*Units: Natural Gas--MMCF/hr; Fuel Oils--gallons/hr; Coal, wood, refuse, other--lbs/hr.

Fuel Analysis:

Percent Sulfur: _____ Percent Ash: _____

Density: _____ lbs/gal Typical Percent Nitrogen: _____

Heat Capacity: _____ BTU/lb _____ BTU/gal

Other Fuel Contaminants (which may cause air pollution): _____

F. If applicable, indicate the percent of fuel used for space heating.

Annual Average _____ Maximum _____

G. Indicate liquid or solid wastes generated and method of disposal.

4,400 LB/YR PARTICULATE FROM FILTER. EQUIVALENT TO ABOUT 12 DRUMS/YEAR TO OFF-SITE DISPOSAL.

H. Emission Stack Geometry and Flow Characteristics (Provide data for each stack):

Stack Height: SEE PERMIT APPLICATION #2 ft. Stack Diameter: _____ ft.

Gas Flow Rate: _____ ACFM _____ DSCFM Gas Exit Temperature: _____ °F.

Water Vapor Content: _____ % Velocity: _____ FPS

SECTION IV: INCINERATOR INFORMATION

Type of Waste	Type 0 (Plastics)	Type I (Rubbish)	Type II (Refuse)	Type III (Garbage)	Type IV (Pathological)	Type V (Liq.& Gas By-prod.)	Type VI (Solid By-prod.)
Actual lb/hr Incinerated							
Uncontrolled (lbs/hr)							

Description of Waste _____

Total Weight Incinerated (lbs/hr) _____ Design Capacity (lbs/hr) _____

Approximate Number of Hours of Operation per day _____ day/wk _____ wks/yr. _____

Manufacturer _____

Date Constructed _____ Model No. _____

	Volume $(ft)^3$	Heat Release (BTU/hr)	Fuel		Temperature (°F)
			Type	BTU/hr	
Primary Chamber					
Secondary Chamber					

Stack Height: _____ ft. Stack Diamter: _____ Stack Temp. _____

Gas Flow Rate: _____ ACFM _____ DSCFM* Velocity: _____ FPS

*If 50 or more tons per day design capacity, submit the emissions rate in grains per standard cubic foot dry gas corrected to 50% excess air.

Type of pollution control device: [ ] Cyclone [ ] Wet Scrubber [ ] Afterburner

[ ] Other (specify) _____

Brief description of operating characteristics of control devices: _____

_____

_____

_____

_____

Ultimate disposal of any effluent other than that emitted from the stack (scrubber water, ash, etc.):

_____

_____

_____

_____

NOTE: Items 2, 3, 4, 6, 7, 8, and 10 in Section V must be included where applicable.

SECTION V: SUPPLEMENTAL REQUIREMENTS

Please provide the following supplements where required for this application.

1. Total process input rate and product weight -- show derivation [Rule 17-2.100(127)]

2. To a construction application, attach basis of emission estimate (e.g., design calculations, design drawings, pertinent manufacturer's test data, etc.) and attach proposed methods (e.g., FR Part 60 Methods 1, 2, 3, 4, 5) to show proof of compliance with applicable standards. To an operation application, attach test results or methods used to show proof of compliance. Information provided when applying for an operation permit from a construction permit shall be indicative of the time at which the test was made.

3. Attach basis of potential discharge (e.g., emission factor, that is, AP42 test).

4. With construction permit application, include design details for all air pollution control systems (e.g., for baghouse include cloth to air ratio; for scrubber include cross-section sketch, design preasure drop, etc.)

5. With construction permit application, attach derivation of control device(s) efficiency. Include test or design data. Items 2, 3 and 5 should be consistent: actual emissions = potential (1-efficiency).

6. An 8 1/2" x 11" flow diagram which will, without revealing trade secrets, identify the individual operations and/or processes. Indicate where raw materials enter, where solid and liquid waste exit, where gaseous emissions and/or airborne particles are evolved and where finished products are obtained.

7. An 8 1/2" x 11" plot plan showing the location of the establishment, and points of airborne emissions, in relation to the surrounding area, residences and other permanent structures and roadways (Example: Copy of relevant portion of USGS topographic map).

8. An 8 1/2" x 11" plot plan of facility showing the location of manufacturing processes and outlets for airborne emissions. Relate all flows to the flow diagram.

9. The appropriate application fee in accordance with Rule 17-4.05. The check should be made payable to the Department of Environmental Regulation.

10. With an application for operation permit, attach a Certificate of Completion of Construction indicating that the source was constructed as shown in the construction permit.

SECTION VI: BEST AVAILABLE CONTROL TECHNOLOGY

A. Are standards of performance for new stationary sources pursuant to 40 C.F.R. Part 60 applicable to the source?

[ ] Yes [ ] No

Contaminant	Rate or Concentration

B. Has EPA declared the best available control technology for this class of sources (If yes, attach copy)

[ ] Yes [ ] No

Contaminant	Rate or Concentration

C. What emission levels do you propose as best available control technology?

Contaminant	Rate or Concentration

D. Describe the existing control and treatment technology (if any).

1. Control Device/System:
2. Operating Principles:
3. Efficiency:*
4. Capital Costs:

*Explain method of determining

5. Useful Life:

6. Operating Costs:

7. Energy:

8. Maintenance Cost:

9. Emissions:

Contaminant	Rate or Concentration

10. Stack Parameters

a. Height: ft.

b. Diameter: ft.

c. Flow Rate: ACFM

d. Temperature: °F.

e. Velocity: FPS

E. Describe the control and treatment technology available (As many types as applicable, use additional pages if necessary).

1.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

2.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

3.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

4.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Costs:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

F. Describe the control technology selected:

1. Control Device:

2. Efficiency:[1]

3. Capital Cost:

4. Useful Life:

5. Operating Cost:

6. Energy:[2]

7. Maintenance Cost:

8. Manufacturer:

9. Other locations where employed on similar processes:

a. (1) Company:

(2) Mailing Address:

(3) City:

(4) State:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

b. (1) Company:

(2) Mailing Address:

(3) City: (4) State:

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

10. Reason for selection and description of systems:

[1]Applicant must provide this information when available. Should this information not be available, applicant must state the reason(s) why.

SECTION VII - PREVENTION OF SIGNIFICANT DETERIORATION

A. Company Monitored Data

1. _____no. sites _____ TSP _____( ) SO^2* _____ Wind spd/dir

Period of Monitoring _____/_____/_____ to _____/_____/_____
month day year month day year

Other data recorded _____

Attach all data or statistical summaries to this application.

*Specify bubbler (B) or continuous (C).

2. Instrumentation, Field and Laboratory

a. Was instrumentation EPA referenced or its equivalent? [ ] Yes [ ] No

b. Was instrumentation calibrated in accordance with Department procedures?

[ ] Yes [ ] No [ ] Unknown

B. Meteorological Data Used for Air Quality Modeling

1. _____ Year(s) of data from ____/____/____ to ____/____/____
month day year month day year

2. Surface data obtained from (location)_____

3. Upper air (mixing height) data obtained from (location)_____

4. Stability wind rose (STAR) data obtained from (location)_____

C. Computer Models Used

1. _____ Modified? If yes, attach description.

2. _____ Modified? If yes, attach description.

3. _____ Modified? If yes, attach description.

4. _____ Modified? If yes, attach description.

Attach copies of all final model runs showing input data, receptor locations, and principle output tables.

D. Applicants Maximum Allowable Emission Data

Pollutant	Emission Rate	
TSP	_____	grams/sec
SO^2	_____	grams/sec

E. Emission Data Used in Modeling

Attach list of emission sources. Emission data required is source name, description of point source (on NEDS point number), UTM coordinates, stack data, allowable emissions, and normal operating time.

F. Attach all other information supportive to the PSD review.

G. Discuss the social and economic impact of the selected technology versus other applicable technologies (i.e., jobs, payroll, production, taxes, energy, etc.). Include assessment of the environmental impact of the sources.

H. Attach scientific, engineering, and technical material, reports, publications, journals, and other competent relevant information describing the theory and application of the requested best available control technology.

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

C E R T I F I C A T E

To Whom It May Concern:

This is to certify that Robert A. Franke, Director of Engineering of Key Pharmaceuticals, Inc., is duly authorized to represent Key Pharmaceuticals, Inc., along with his designate, Thomas W. Flachmeyer, Manager Environmental Engineering and Waste Management; for the purposes of making Application for Permit to Construct or Operate Pollution Control Facilities for said company.

Key Pharmaceuticals, Inc.

James R. Confroy, Vice President
Miami and Puerto Rico Operations

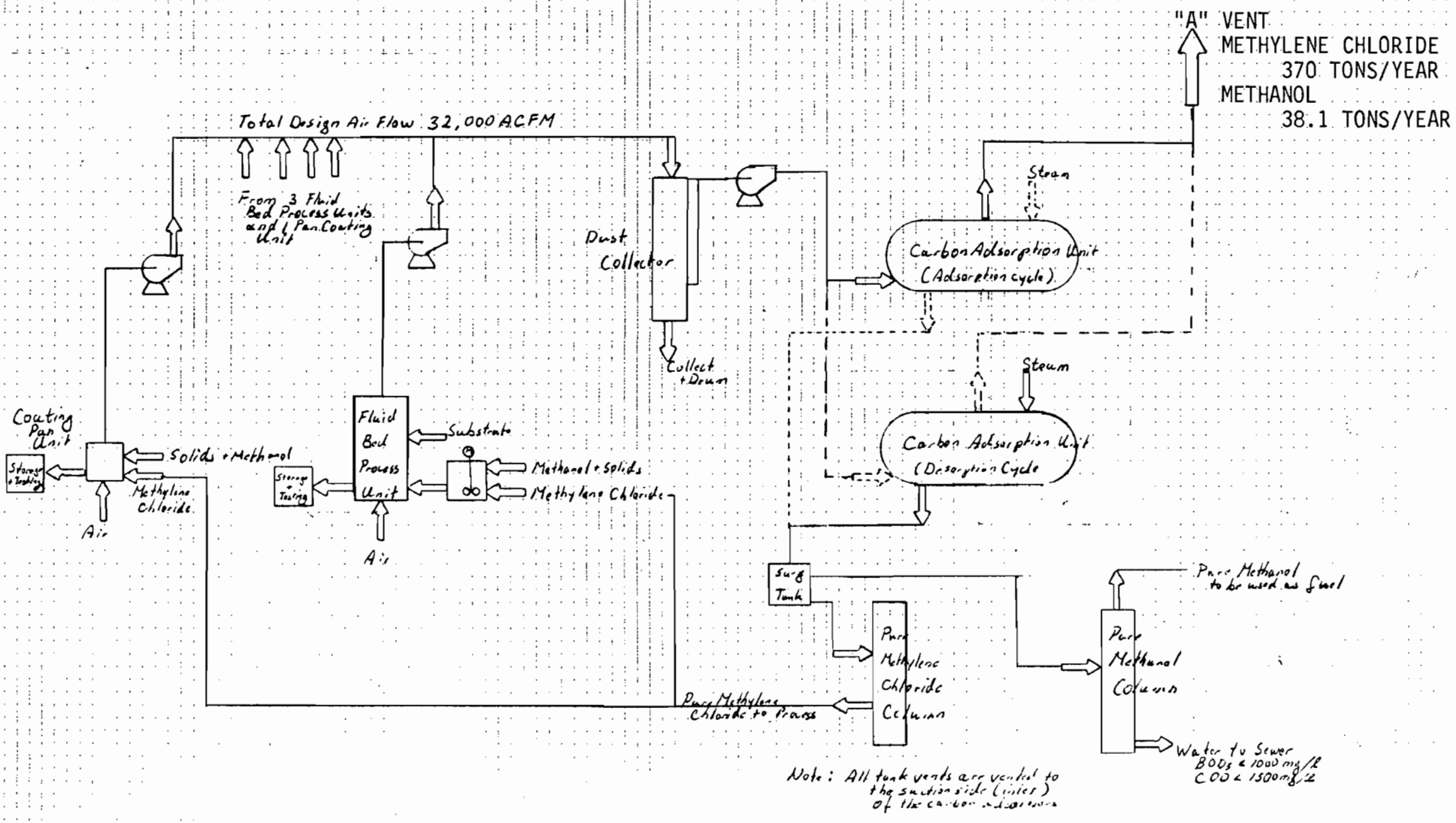
JRC/db

STATE OF FLORIDA
COUNTY OF DADE
Sworn to and subscribed before me
this 21st day of October A.D. 1986.

NOTARY PUBLIC STATE OF FLORIDA
MY COMMISSION EXP. DEC 18,1989
BONDED THRU GENERAL INS. UND.

GENERAL EQUIPMENT LAYOUT

PROCESS FLOW DIAGRAM
(FOUR FLUID BED PROCESS UNITS & TWO PAN COATING PROCESS UNITS)



FLOW SHEET II

CHARGE Accela-Cota - Environmental DATE 1-16-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 1 of 3 FILE NO. _____

SUBJECT Process Emission Calculations for two Pan Coating Process Units

Basis

Production Capacity 1095 lots per year each

Lot Specifications

Methanol	901b
Methylene chloride	6001b
Solids	4001b

A. Methanol Emissions

(i) Maximum Instantaneous Emissions Potential

30 lb/Hr per unit ∴ 60 lb/Hr

(ii) Maximum Instantaneous Emissions

Carbon Adsorber Design - 90% removal eff.

∴ Maximum Instantaneous Emissions 6 lb/Hr

(iii) Annual Emission Potential

49.3 Tons/year per unit	98.6 Tons/year Total
11.3 lb/Hr per unit	22.6 lb/Hr Total

(iv) Annual Emissions

Carbon Adsorber Design - 90% removal eff.

∴ Average Annual Emissions 9.9 T/y

2.3 lb/Hr

CHARGE Accola - Cota - Environmental DATE 1-16-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 2 of 3 FILE NO. _____

SUBJECT _____

B Methylene Chloride Emissions.

(i) Maximum Instantaneous Emission Potential

200 lb/Hr per Unit ∴ 400 lb/Hr

(ii) Maximum Instantaneous Emissions

Carbon Adsorber Design - 90% removal eff.

∴ Maximum Instantaneous Emissions 40 lb/Hr

(iii) Annual Emission Potential

328.5 Tons/year per unit 657 Tons/year Total
75.0 lb/Hr per unit 150 lb/Hr Total

(iv) Annual Emissions

Carbon Adsorber Design - 90% removal eff.

∴ Average Annual Emissions 65.7 T/y
15 lb/Hr

CHARGE Accla Cota - Environmental DATE 1-16-87

PREPARED BY JWF CHECKED BY _____ SHEET NO. 3 of 3 FILE NO. _____

SUBJECT _____

C. Particulate Emissions

(i) Max Instantaneous Emission Potential

Emission Potential from Accla Cota is 1% of Solids

∴ Max Instantaneous Emission Potential

1.3 lb/Hr per unit 2.6 lb/Hr Total

(ii) Max Instantaneous Emissions

Dust Collector Design - 99% removal eff.

∴ Max Instantaneous Emissions 0.03 lb/Hr

(iii) Annual Emission Potential

2.19 Tons/year per unit 4.4 Tons/year Total
0.5 lb/Hr per unit. 1 lb/Hr Total

(iv) Annual Emissions

Dust collector Design - 99% removal eff.

∴ Average Annual Emissions 0.04 T/y

0.01 lb/Hr

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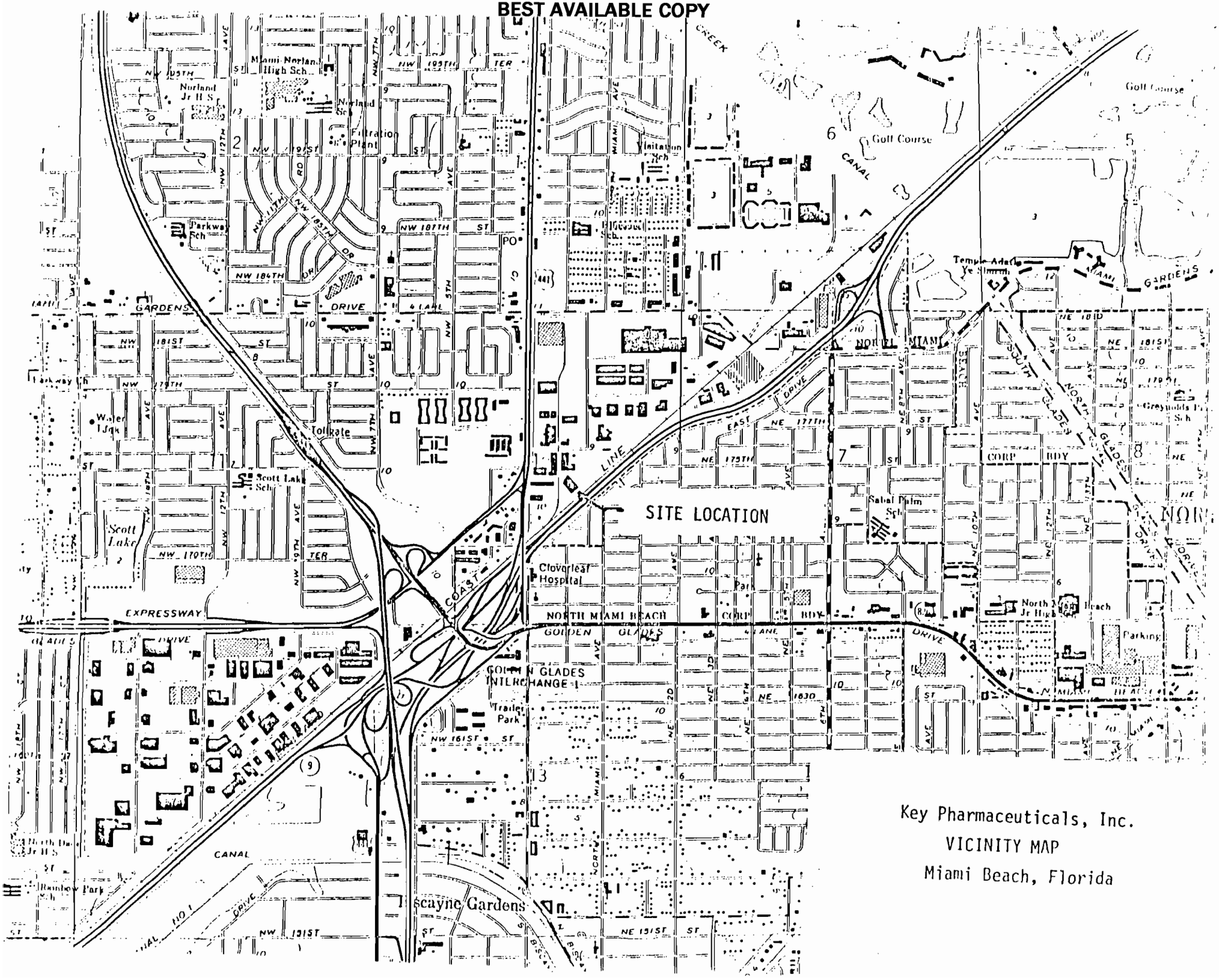

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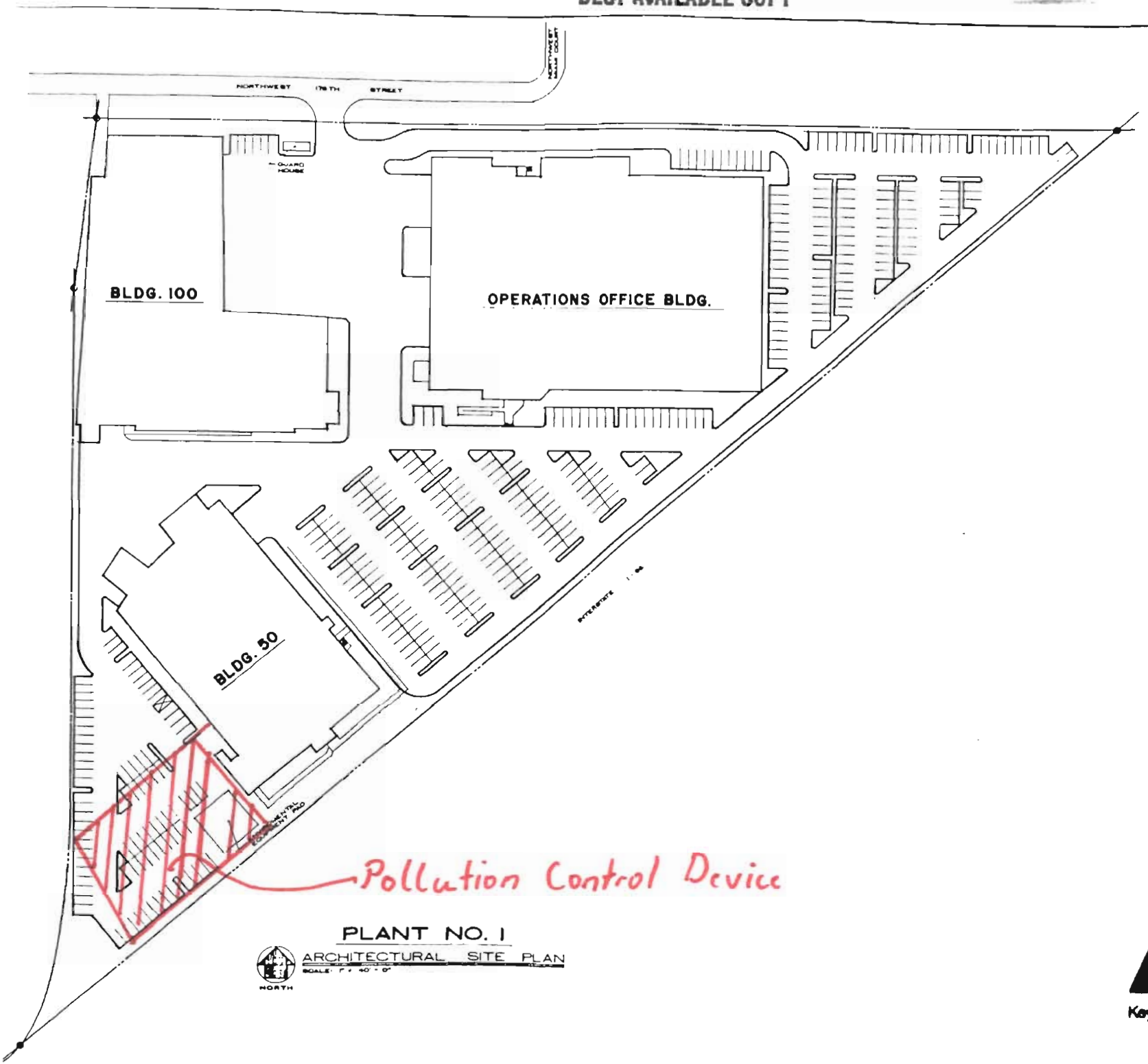


PLANT NO. 1

ARCHITECTURAL SITE PLAN

SCALE: 1" = 40'-0"

Key Pharmaceuticals, Inc.

BUILDING 50 · FLOOR PLAN

KEY

Key Pharmaceuticals, Inc.

KEY PHARMACEUTICALS, INC.
NEW PROCESS REVIEW

I. PRODUCTION

A. Accela-Cota (see Flow Sheet I - attached)

B. Solvents Involved:

Methylene Chloride
Methanol

C. Process Description (see Flow Sheet I - attached)

D. Process Quantities
Basis - 2190 lots of product for two pan coating units (Accela-Cota 1 & 2)
Methanol - 98.6 tons/year total all units
Methylene Chloride - 328.5 tons/year total all units
Solids - 657 tons/year total all units

E. Overall plant loadings for product

Stage 1 - one pan coating process unit by OCT'87
Stage 2 - second pan coating process unit by JUN'88

II. CONTROL SYSTEM

Carbon adsorption and solvent recovery (permitted separately, Permit Application #2). See Flow Sheet II - attached.

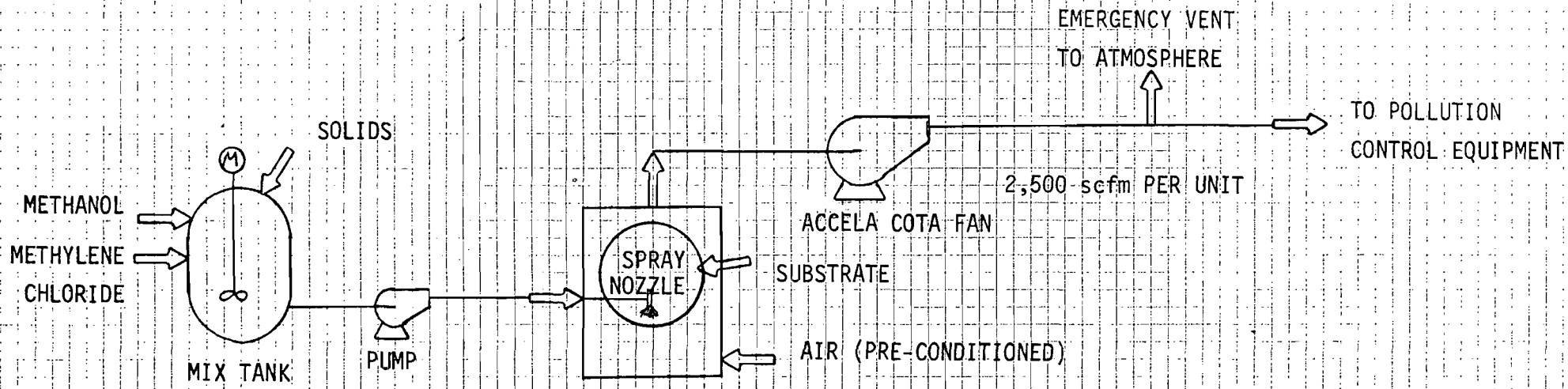
Process air containing methylene chloride, methanol, and particulates is delivered from the process to the suction side of the dust collector. The dust collector removes 99% of all particulates, solids are collected in drums and disposed of off-site by thermal oxidation and landfill. The solvent ladened air is then passed through one of three carbon adsorbers, the adsorbers operate in a configuration of 2 on line and 1 regenerating/stand-by. The carbon adsorbers are designed for a 90% + removal efficiency of both methylene chloride and methanol. The adsorbers are operated on a timed cycle with a breakthrough override mode, thereby guaranteeing the 90% removal efficiency. During the regeneration cycle the solvents are stripped from the carbon utilizing live steam. The stripped material is then condensed. Once all solvent materials have been stripped from the carbon, the carbon is dried and the unit is placed on stand-by. The liquid portion from the stripping operation then goes through various separation, distillation, and purification steps. The final products delivered are pure methylene chloride for re-use in the process, fuel grade methanol for use in the boilers to generate steam and a water discharge to sewer that contains less than 1000 milligrams per liter of 5-day Biological Oxygen Demand (BOD's) and less than 1500 milligrams per liter of Chemical Oxygen Demand (COD). This discharge is permitted separately by the Department of Environmental Regulations Metro Dade.

III. SUMMARY

Based on the above presented information Key Pharmaceuticals, Inc. should be allowed to add two pan coating process units to manufacture K-DUR at its 50 N.W. 176 Street location. The increased loading to the Pollution Control Device is as follows:

	PROPOSED CURRENT	INCREASE	NEW TOTAL	SYSTEM DESIGN
AIR FLOW (acfm)	24,000	5,000	29,000	32,000
METHANOL (T/Y)	282	98.6	380.6	1,086
METHYLENE CHLORIDE (T/Y)	3,046	328.5	3,374.5	5,326
PARTICULATES (T/Y)	19	4.4	23.4	38

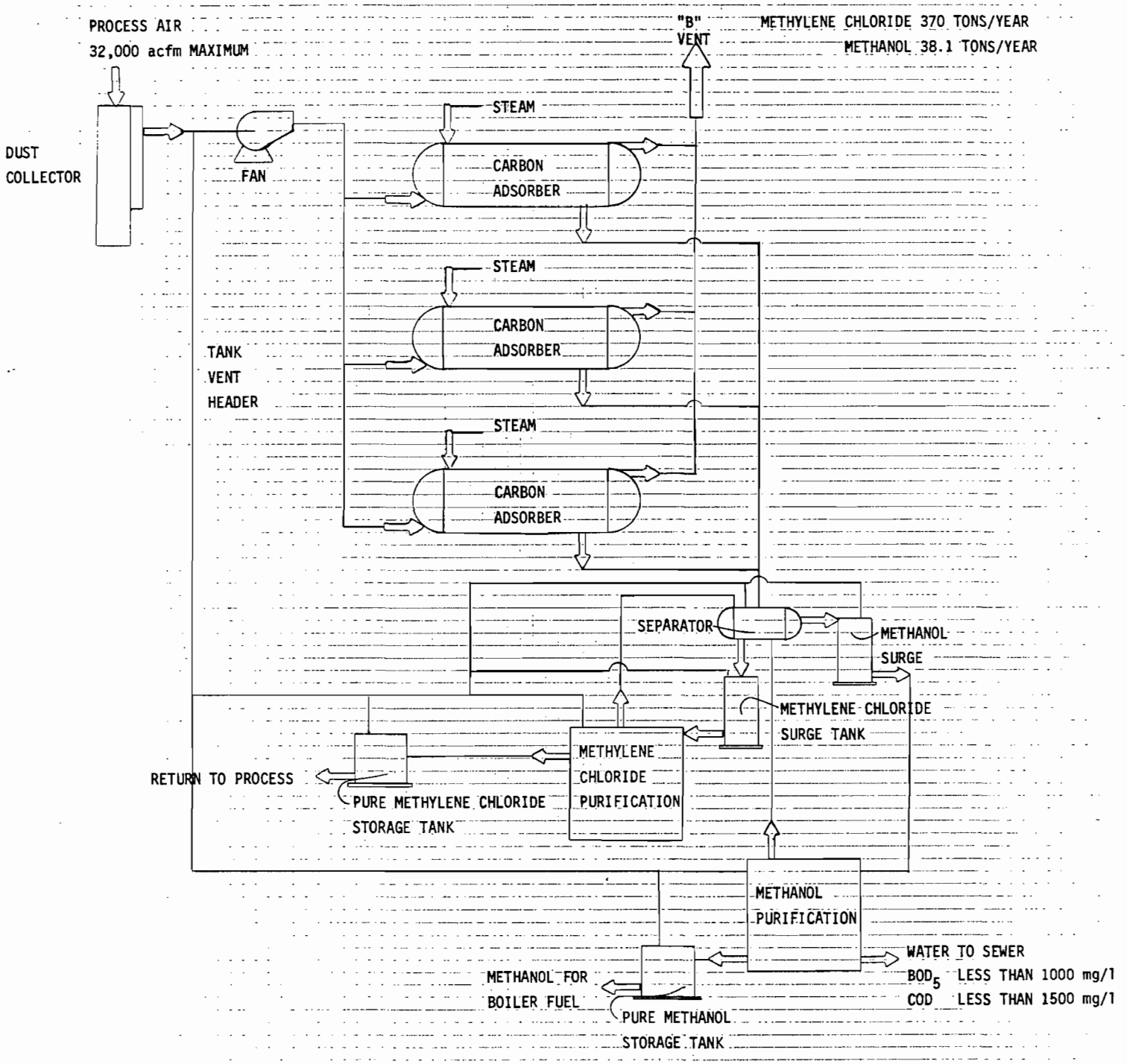
The control technology proposed is considered state of the art for this application and the increase is well within design and permitting of the system. Therefore a permit should be issued.



TYPICAL FLOW DIAGRAM

PAN COATING UNIT

FLOW SHEET I



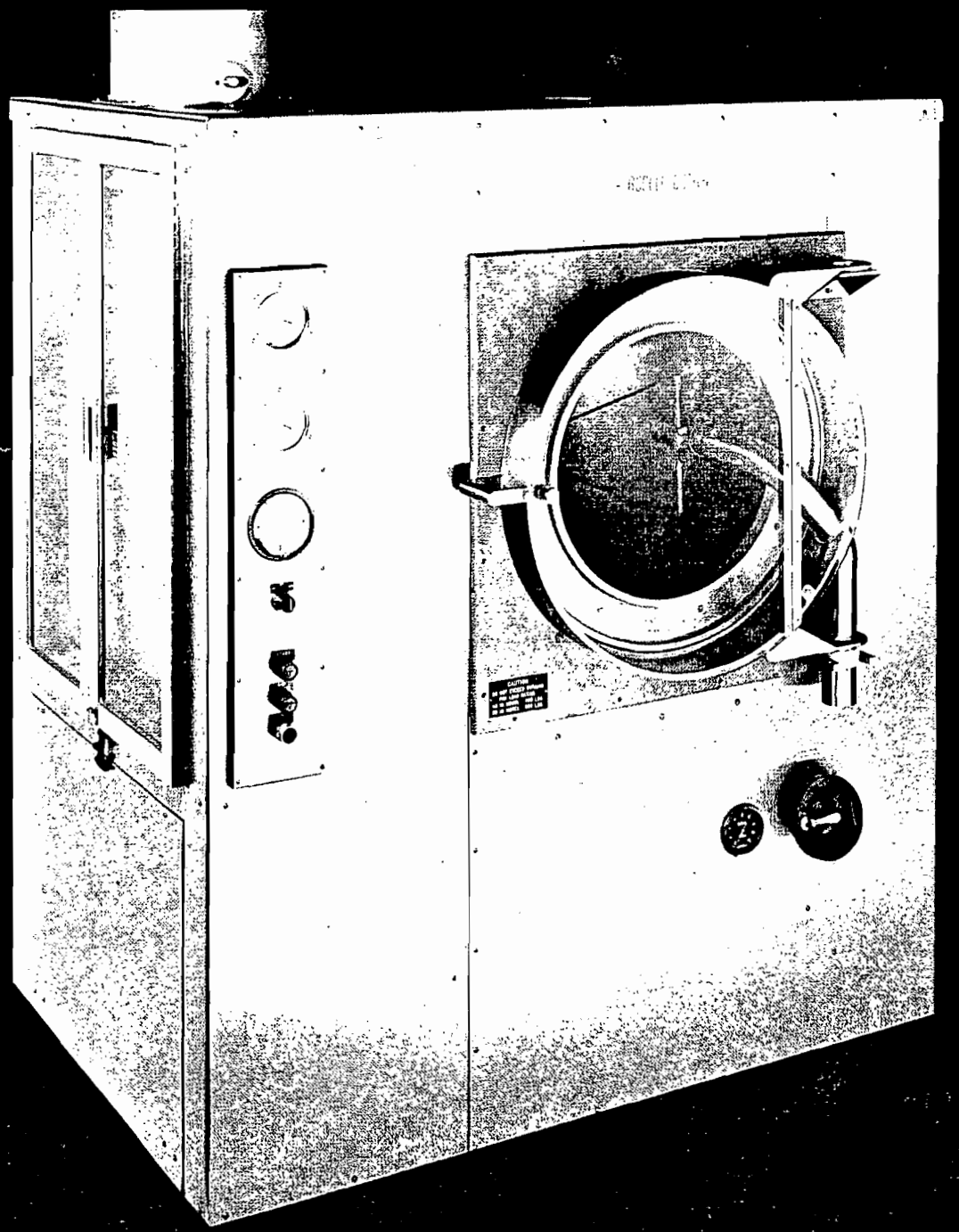
ENVIRONMENTAL CONTROL SYSTEM - BUILDING 50
FOR FLUID BED PROCESSORS (4) & PAN COATING PROCESSORS (2)

FLOW SHEET II

THOMAS ENGINEERING

ACCELA-COTA®

Now Available in Four Models



FEATURING

faster cycle time

precision, uniform coating

efficient use of material

lower labor costs

automatic tablet cleaning

great versatility

the patented, high performance concept in coating pan design that provides...

The unique side vented pan with controlled air flow pulls 100% of the drying air through the tumbling bed of tablets. All tablet surfaces are exposed to maximum volume of moving air.

Accelerated drying assures more uniform tablet coating. Small granules, dust, chips, broken tablets and flash are automatically removed.

By eliminating uncontrolled turbulence, dead air pockets and poor flow patterns the **ACCELA•COTA** eliminates the major reasons for coating material loss. This cuts waste by up to 30%!

ACCELA•COTA coats twice as fast as conventional pans.

Clean up takes only a fraction of the time and effort. For example: Pan cleaning is simply a matter of hosing down the pan. Water drains through the perforated pan into the Stainless Steel sink in the machine base, which is pitched to facilitate drainage.

Tablets are automatically cleaned and dedusted both before and during the coating operation, assuring a smooth, fault free tablet surface.

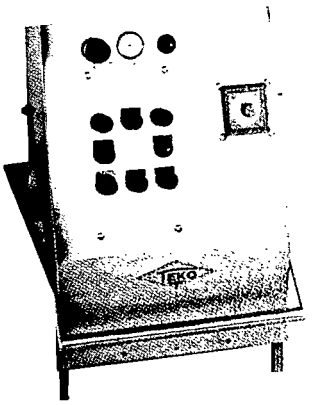
Whether spraying or ladling, either aqueous or solvent systems, film or sugar coating, the **ACCELA•COTA** Action/Air coating pan provides the ultimate in coating efficiency. Ideal for an almost unlimited variety of candy and tablet coating assignments.

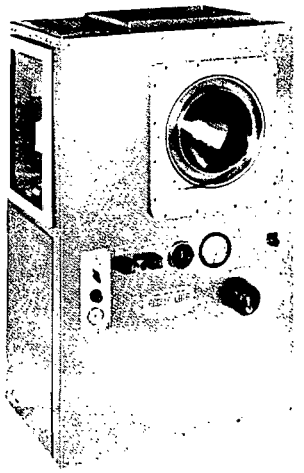
ACCELA•SPRAY II

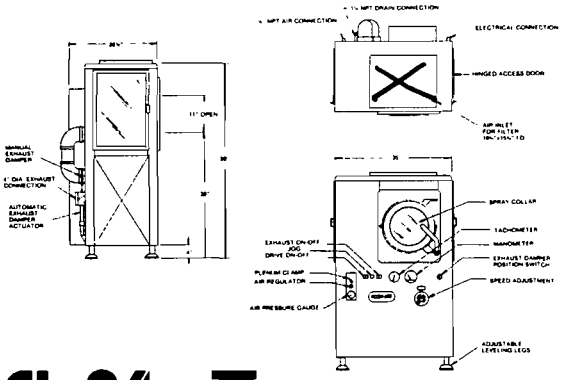
The Thomas **ACCELA • SPRAY II**, a new development in the technique of tablet coating, offers the following advantages:

- Intermittent or continuous spray cycle controls.
- Positive displacement rotary pump can be disassembled without tools. Sanitary construction meets the requirements of the U.S.D.A.
- Sanitary NEMA 3 drip proof construction for cleanability. Explosion proof NEMA 7 electrics for safety.
- Fail safe air atomizing spray system for one or two pan operation.

All of these features are in a portable compact stainless steel console, suitable for ***all*** pan coating installations.



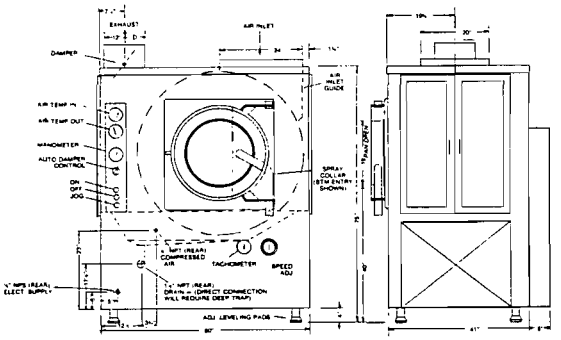


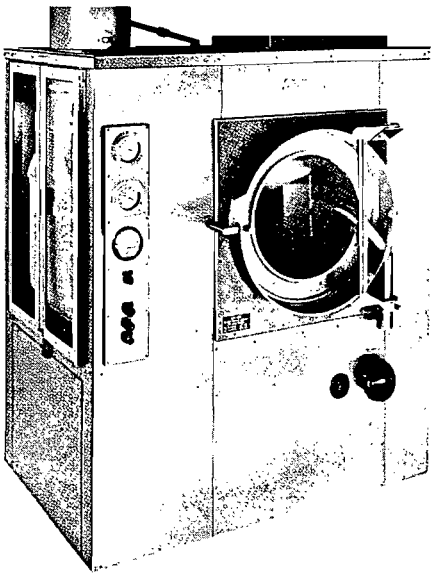


MODEL 24 - II

A semi-production model with an approximate working capacity of 40 pounds. Suitable for development work as well as small batch production.

Now Available in Four Models





MODEL 48 - V

A production model with an approximate working capacity of 400 pounds.

FEATURING

faster cycle time

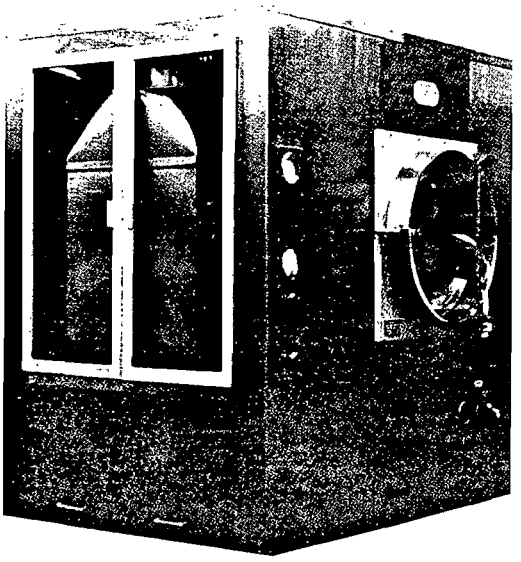
precision, uniform coating

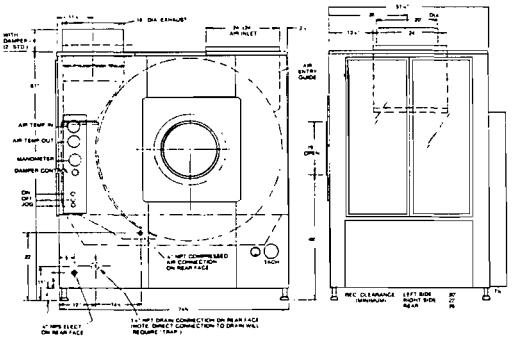
efficient use of material

lower labor costs

automatic tablet cleaning

great versatility





MODEL 60 - III

A high-capacity production model with an approximate working capacity of 900 pounds.

INFORMATION AVAILABLE ON THE **NEW** MODEL 66-I UPON REQUEST, SEE BACK PAGE FOR SPECIFICATIONS. SOME ILLUSTRATED FEATURES QUOTED AS OPTIONS.

SPECIFICATIONS (Some Features Quoted as Options)

	24-II	48-V	60-III	66-I	48" vs. 60" % Increase	60" vs. 66" % Increase
Floor Area (Sq. Ft.)	6.6	20	30.7	43.5	+54%	+42%
Machine Height	59"	77"	83"	89"	—	—
Net Weight	525#	1600#	2800#	3600#	—	—
Drive	¾ HP	2 HP	5 HP	10 HP	—	—
VariSpeed (RPM)	12-36	2-14	1¾-13	1¼-12	—	—
Pan Perimeter Velocity (FPM)	75/226	25/176	27/204	22/207	—	—
Pan Opening Dia.	11"	19"	19"	19"	—	—
Front/Pan Rear (I.D.)	20½	39½	49	62½	—	—
Pan Lip Height to Floor	38"	40"	40"	43"	—	—
Brim Volume (Cu. Ft.)	3/4	6 2/3	15	30	+125%	+100%
Max. Load Weight	45#	400#	900#	1800#	+125%	+100%
Tablet Bed Height (Static)	6½"	14½"	20½"	23½"	+41%	+14½%
Exhaust Plenum Area (Sq. In.)	77	400/490*	825/1037*	1451/1825*		
Exhaust Plenum Pos (Degrees)	24/65	37/102* or 37/90	20/108* or 20/90	20/108* or 20/90		
Exhaust Volume (CFM)	350	800/2200	1200/4700	1500/8300		
Air Velocity thru Tablet Bed (in/sec. @ max.)	130	130	130	130		
Exhaust Connection	4" Dia.	12" Dia.	18" Dia.	20" Dia.		
Static Pressure Max. " W.G.	6"	8"	11"	12"		
CFM/100# Prod. @ Max.	777	550	522	461		
Sink Depth	3½	8	10	10		
Vibration Leveling Pads	Yes	Yes	Yes	Yes		
Self-Contained Exhaust Blower	Yes (1 HP)	No	No	No		
Pan Unloader	No	Yes	Yes	Yes		
Baffles	2	4	6	6		

*Plenum supplied with closure panel to reduce opening when required.

U.S. Pat. Nos. 3573966 and 3601086, CAN. Pat. No. 883719

ACCELA•SCOOP

NO MORE SCOOPING!

- Unloads 900 lbs. of tablets in seconds.
- Gentle action.
- Available for 48" or 60" ACCELA•COTAS
- Construction is of stainless steel for easy, thorough cleaning.
- Saves time, saves money.
- Clamps quickly to pan.

The ACCELA•SCOOP fastens to the pan simply and conveniently. Jog the pan for 3-4 revolutions and *all* of the tablets are unloaded.

THOMAS ENGINEERING INC.

CENTRAL AND ELA ROADS, P.O. BOX 198 • HOFFMAN ESTATES, ILLINOIS 60195
312/358-5800 • TELEX 28-1054

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PRINTED IN USA FORM NO. AC-79

ACCELA-COTA REVISED SPECIFICATIONS

		24-III	48-V	60-III	66-I
PAN DIAMETER	(IN)	24	48	60	66
MACHINE WIDTH	(IN)	35	60	74-3/4	83
MACHINE DEPTH	(IN)	26½	47	58-3/4	76
MACHINE HEIGHT	(IN)	59	75	81	86
NET WEIGHT	(LBS.)	525	1600	2800	3600
DRIVE MOTOR		3/4 HP	2 HP	5 HP	10 HP
EXPLOSION PROOF ELECTRICS		YES	YES	YES	YES
VARI-SPEED	(RPM)	12 to 36	2 to 14	1-3/4 to 13	1-3/4 to 12
PAN OPENING DIAMETER	(IN)	11	19	19	19
PAN LIP HEIGHT TO FLOOR	(IN)	38	40	40	43
PAN DEPTH	(IN)	20½	39½	49	62½
BRIM VOLUME	(LITERS)	21	189	425	850
MAXIMUM RECOMMENDED LOAD WEIGHT	(KG)	20	185	400	815
EXHAUST PLENUM AREA*	(SQ. IN)	77	270-490	737-1037	1250-1835
TYPICAL AIR VOLUME**	(CFM)	350	1000-2500	1200-3500	1500-5000
AIR INLET OPENING	(IN)	10½ x 12-1/8	19½ x 20	24 x 25	14 x 36
AIR EXHAUST DUCT DIAMETER	(IN)	4	12	18	20
SINK DEPTH	(IN)	3½	8	10	10
VIBRATION LEVELING PADS		YES	YES	YES	YES
SELF CONTAINED EXHAUST BLOWER		YES	NO	NO	NO
TURN KEY SYSTEM		YES	YES	YES	YES
PAN UNLOADER		NO	YES	YES	YES
BAFFLES		2	4	6	6

Note *: Plenum can be supplied with optional reduction closure panels to reduce opening when required.

Note**: In general, drying time can be reduced by increase air volume through the pan. Accela-Cota is designed to accommodate large volumes of air on a non-fluctuating basis.

Note: Electrical power: 230V/460V/3PH/60HZ. Other voltages available upon request.

R/062885/shw

ACCELA-COTA MODEL 48-V HOODED

MAXIMUM OPERATING SPECIFICATIONS

Pan Size	48"
Approximate Working Capacity	400 lbs./ 6.7 cu. ft. Brim
Pan Speed	Variable 2-14 RPM
Perforated Pan Section	.117" diameter hole; 51% Open Area
Exhaust Fan Capacity	1000 to 2500 CFM
Exhaust Duct	12" Diameter
Supply Air Opening	20" x 19½"

MACHINE SPECIFICATIONS

1. 2 HP, 230/460/3, 1800 RPM Motor Drive, 110 Volt Control Circuit.
2. Positive drive transmission system.
3. Type 304 stainless steel pan, exhaust plenum, sink, hood and exterior finish.
4. Mild steel base frame with epoxy finish, stainless clad.
5. Hinged access doors on left and right sides of hood enclosure.
6. Pan ball bearing supported at both ends.
7. Stainless sink includes stand pipe and 1½" NPT drain connection.
8. Removable mixing baffles [four (4)].
9. Air inlet guide.
10. Leveling mounts.
11. Pan Opening - 19".
12. Floor to pan opening - 40".
13. Floor space - 60" x 47".
14. Overall Height - 75" (plus air connections).
15. Net Weight - 1625 lbs.

ACCESSORY EQUIPMENT:

a) Class I, Group D and Class II, Group F & G explosion proof motor, push-button controls (start, stop & jog) and wiring (disconnect by customer).
b) Variable speed drive 2 to 14 rpm
c) Exhaust balancing damper - butterfly type - manual
d) Exhaust balancing damper with automatic remote control - three (3) positions
e) Mechanical tachometer
f) Manometer
g) Anti-slide baffles (factory installed only)
h) Accela-Unloading Baffles (factory installed)
i) Exhaust air temperature indicator
j) Inlet air temperature indicator
k) Accela Scoop
l) Spray collar attachment including door adjustable nozzle support rod (customer to advise top or bottom entry)
m) Exhaust plenum reduction baffles (4",8",12")
n) Wired 208V/3PH/60 HZ

R/081584/shw

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

January 12, 1987

Mr. C.H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: APPLICATION TO CONSTRUCT FOUR (4) TABLET PRESSES.

Dear Mr. Fancy:

Attached please find an "Application to Construct Air Pollution Sources". The application attached is for the construction of 4 Tablet Presses at Key Pharmaceuticals, Inc 50 N.W. 176 Street, Miami location. These Tablet Presses have been permitted under the K-DUR, GUANIDINE, QUINORA, AND DRUG 0420 manufacturing permits. This application is for the units themselves, separate from any specific product consideration. This fall in line with your department guidance to permit equipment rather that products. As you can see these units are serviced by two dust collectors with a design removal efficiency of 99%. This makes the total emissions negligible (0.2 tons/year).

Your cooperation in this matter is greatly appreciated. Should you have any questions please do not hesitate to call me at 305-654-2240.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

attachment

cc: S. Brooks (S.E. Florida District)
P. Wong (DERM Office)

AC 13-129894
AC 13-129895

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

SOUTHEAST FLORIDA DISTRICT
3301 GUN CLUB ROAD
P.O. BOX 3858
WEST PALM BEACH, FLORIDA 33402

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

ROY DUKE
DISTRICT MANAGER

APPLICATION TO OPERATE/CONSTRUCT AIR POLLUTION SOURCES

SOURCE TYPE: AIR POLLUTION [ ] New[1] [X] Existing[1]

APPLICATION TYPE: [X] Construction [ ] Operation [ ] Modification

COMPANY NAME: KEY PHARMACEUTICALS, INC. COUNTY: DADE

Identify the specific emission point source(s) addressed in this application (i.e. Lime Kiln No. 4 with Venturi Scrubber; Peaking Unit No. 2, Gas Fired) 4 TABLET PRESSES

SOURCE LOCATION: Street 50 N.W. 176TH STREET City MIAMI

UTM: East 57987 North 7868445

Latitude 25 ° 56 ' 03 "N Longitude 80 ° 11 ' 42 "W

APPLICANT NAME AND TITLE: JAMES R. CONFROY, VICE PRESIDENT OPERATIONS

APPLICANT ADDRESS: 50 N.W. 176TH STREET, MIAMI, FL 33169

SECTION I: STATEMENTS BY APPLICANT AND ENGINEER

A. APPLICANT

I am the undersigned owner or authorized representative* of KEY PHARMACEUTICALS, INC.

I certify that the statements made in this application for a CONSTRUCTION permit are true, correct and complete to the best of my knowledge and belief. Further, I agree to maintain and operate the pollution control source and pollution control facilities in such a manner as to comply with the provision of Chapter 403, Florida Statutes, and all the rules and regulations of the department and revisions thereof. I also understand that a permit, if granted by the department, will be non-transferable and I will promptly notify the department upon sale or legal transfer of the permitted establishment.

*Attach letter of authorization

Signed: James R Confroy

JAMES R. CONFROY, VICE PRESIDENT OPERATIONS
Name and Title (Please Type)

Date: 1/12/87 Telephone No. 305-654-2200

B. PROFESSIONAL ENGINEER REGISTERED IN FLORIDA (where required by Chapter 471, F.S.) *

This is to certify that the engineering features of this pollution control project have been designed/examined by me and found to be in conformity with modern engineering principles applicable to the treatment and disposal of pollutants characterized in the permit application. There is reasonable assurance, in my professional judgment, that

[1] See Florida Administrative Code Rule 17-2.100(57) and (104)

* SEE NOTE PAGE 2

I HAVE REVIEWED THE CALCULATIONS USED TO DETERMINE THE STATED LEVELS OF PARTICULATE AND VOC EMISSIONS AND FIND THEM TO BE ACCURATE BASED ON PROJECTED MANUFACTURING LEVELS OF THE PRODUCT.

the pollution control facilities, when properly maintained and operated, will discharge an effluent that complies with all applicable statutes of the State of Florida and the rules and regulations of the department. It is also agreed that the undersigned will furnish, if authorized by the owner, the applicant a set of instructions for the proper maintenance and operation of the pollution control facilities and, if applicable, pollution sources.

Signed J.C. Wells P.E.

JOHN N. WELLS, P.E.
Name (Please Type)

KEY PHARMACEUTICALS, INC.
Company Name (Please Type)

50 N.W. 176TH STREET, MIAMI, FL 33169
Mailing Address (Please Type)

Florida Registration No. 33917 Date: 1/12/87 Telephone No. 305-654-2200

SECTION II: GENERAL PROJECT INFORMATION

A. Describe the nature and extent of the project. Refer to pollution control equipment, and expected improvements in source performance as a result of installation. State whether the project will result in full compliance. Attach additional sheet if necessary.

TABLET PROCESSES ARE UTILIZED DURING THE MANUFACTURING OF VARIOUS SOLID DOSE (TABLET OR CAPSULE) PHARMACEUTICAL PRODUCTS. ROOM DUST CONTROL AND TABLET DEDUSTING IS PROVIDED FOR TABLET PRESS. DUE TO CONSTRAINTS A LOSS OF PRODUCT OF LESS THAN ½ OF 1% CAN ONLY BE TOLERATED.

B. Schedule of project covered in this application (Construction Permit Application Only)

Start of Construction MAR'87 Completion of Construction SEP'87

C. Costs of pollution control system(s): (Note: Show breakdown of estimated costs only for individual components/units of the project serving pollution control purposes. Information on actual costs shall be furnished with the application for operation permit.)

$50,000.00

D. Indicate any previous DER permits, orders and notices associated with the emission point, including permit issuance and expiration dates.

(1) CONSENT ORDER NO. 83-0373 (CLOSED)

(2) PERMIT TO CONSTRUCT FOR MFG GUANIDINE & QUINORA AC 13-115383

(3) PERMIT TO CONSTRUCT FOR MFG K-DUR AC 13-100437

E. Requested permitted equipment operating time: hrs/day 24 ; days/wk 7 ; wks/yr 52 ;

if power plant, hrs/yr_____; if seasonal, describe:_____

F. If this is a new source or major modification, answer the following questions. (Yes or No)

1. Is this source in a non-attainment area for a particular pollutant?	YES
a. If yes, has "offset" been applied?	NO
b. If yes, has "Lowest Achievable Emission Rate" been applied?	NO
c. If yes, list non-attainment pollutants.	OZONE
2. Does best available control technology (BACT) apply to this source? If yes, see Section VI.	NO
3. Does the State "Prevention of Significant Deterioriation" (PSD) requirement apply to this source? If yes, see Sections VI and VII.	NO
4. Do "Standards of Performance for New Stationary Sources" (NSPS) apply to this source?	NO
5. Do "National Emission Standards for Hazardous Air Pollutants" (NESHAP) apply to this source?	NO
H. Do "Reasonably Available Control Technology" (RACT) requirements apply to this source?	NO

a. If yes, for what pollutants?_____

b. If yes, in addition to the information required in this form, any information requested in Rule 17-2.650 must be submitted.

Attach all supportive information related to any answer of "Yes". Attach any justification for any answer of "No" that might be considered questionable.

SECTION III: AIR POLLUTION SOURCES & CONTROL DEVICES (Other than Incinerators)

A. Raw Materials and Chemicals Used in your Process, if applicable:

Description	Contaminants		Utilization Rate - lbs/hr	Relate to Flow Diagram
	Type	% Wt		
SOLIDS	PARTICULATE	100	80	"A"
			(PER UNIT)	

B. Process Rate, if applicable: (See Section V, Item 1)

1. Total Process Input Rate (lbs/hr): 321.1 LB/HR

2. Product Weight (lbs/hr): 320 LB/HR

C. Airborne Contaminants Emitted: (Information in this table must be submitted for each emission point, use additional sheets as necessary)

Name of Contaminant	Emission[1]		Allowed[2] Emission Rate per Rule 17-2	Allowable[3] Emission lbs/hr	Potential[4] Emission		Relate to Flow Diagram
	Maximum lbs/hr	Actual T/yr			lbs/yr	T/yr	
PARTICULATE	0.05	0.2	N/A	N/A		20.8	"A"

[1]See Section V, Item 2.

[2]Reference applicable emission standards and units (e.g. Rule 17-2.600(5)(b)2. Table II, E. (1) - 0.1 pounds per million BTU heat input)

[3]Calculated from operating rate and applicable standard.

[4]Emission, if source operated without control (See Section V, Item 3).

D. Control Devices: (See Section V, Item 4)

Name and Type (Model & Serial No.)	Contaminant	Efficiency	Range of Particles Size Collected (in microns) (If applicable)	Basis for Efficiency (Section V Item 5)
TORIT DUST COLLECTOR	PARTICULATE	99%	2 MICRON OR LARGER	SUPPLIER'S DESIGN

E. Fuels

Type (Be Specific)	Consumption*		Maximum Heat Input (MMBTU/hr)
	avg/hr	max./hr	

*Units: Natural Gas--MMCF/hr; Fuel Oils--gallons/hr; Coal, wood, refuse, other--lbs/hr.

Fuel Analysis:

Percent Sulfur:_____ Percent Ash:_____

Density: _____ lbs/gal Typical Percent Nitrogen:_____

Heat Capacity: _____ BTU/lb _____ BTU/gal

Other Fuel Contaminants (which may cause air pollution):_____

F. If applicable, indicate the percent of fuel used for space heating.

Annual Average _____ Maximum _____

G. Indicate liquid or solid wastes generated and method of disposal.

20.6 TONS PER YEAR OF SOLIDS ARE COLLECTED IN APPROXIMATELY 120 DRUMS. ALL SOLID WASTE IS DISPOSED OF OFF-SITE AT AN APPROVED FACILITY.

H. Emission Stack Geometry and Flow Characteristics (Provide data for each stack):

Stack Height: OFF ROOF 11 ft. Stack Diameter: 12" x 12" ft.

Gas Flow Rate: 4000 ACFM _____ DSCFM Gas Exit Temperature: 70 °F.

Water Vapor Content: 50-60% % Velocity: 67 FPS

SECTION IV: INCINERATOR INFORMATION

Type of Waste	Type 0 (Plastics)	Type I (Rubbish)	Type II (Refuse)	Type III (Garbage)	Type IV (Pathological)	Type V (Liq.& Gas By-prod.)	Type VI (Solid By-prod.)
Actual lb/hr Incinerated							
Uncontrolled (lbs/hr)							

Description of Waste _____

Total Weight Incinerated (lbs/hr) _____ Design Capacity (lbs/hr) _____

Approximate Number of Hours of Operation per day _____ day/wk _____ wks/yr. _____

Manufacturer _____

Date Constructed _____ Model No. _____

	Volume $(ft)^3$	Heat Release (BTU/hr)	Fuel		Temperature (°F)
			Type	BTU/hr	
Primary Chamber					
Secondary Chamber					

Stack Height: _____ ft. Stack Diamter: _____ Stack Temp. _____

Gas Flow Rate: _____ ACFM _____ DSCFM* Velocity: _____ FPS

*If 50 or more tons per day design capacity, submit the emissions rate in grains per standard cubic foot dry gas corrected to 50% excess air.

Type of pollution control device: [ ] Cyclone [ ] Wet Scrubber [ ] Afterburner

[ ] Other (specify) _____

Brief description of operating characteristics of control devices: _____

_____

_____

_____

_____

Ultimate disposal of any effluent other than that emitted from the stack (scrubber water, ash, etc.):

_____

_____

_____

_____

NOTE: Items 2, 3, 4, 6, 7, 8, and 10 in Section V must be included where applicable.

SECTION V: SUPPLEMENTAL REQUIREMENTS

Please provide the following supplements where required for this application.

1. Total process input rate and product weight -- show derivation [Rule 17-2.100(127)]

2. To a construction application, attach basis of emission estimate (e.g., design calculations, design drawings, pertinent manufacturer's test data, etc.) and attach proposed methods (e.g., FR Part 60 Methods 1, 2, 3, 4, 5) to show proof of compliance with applicable standards. To an operation application, attach test results or methods used to show proof of compliance. Information provided when applying for an operation permit from a construction permit shall be indicative of the time at which the test was made.

3. Attach basis of potential discharge (e.g., emission factor, that is, AP42 test).

4. With construction permit application, include design details for all air pollution control systems (e.g., for baghouse include cloth to air ratio; for scrubber include cross-section sketch, design pressure drop, etc.)

5. With construction permit application, attach derivation of control device(s) efficiency. Include test or design data. Items 2, 3 and 5 should be consistent: actual emissions = potential (1-efficiency).

6. An 8 1/2" x 11" flow diagram which will, without revealing trade secrets, identify the individual operations and/or processes. Indicate where raw materials enter, where solid and liquid waste exit, where gaseous emissions and/or airborne particles are evolved and where finished products are obtained.

7. An 8 1/2" x 11" plot plan showing the location of the establishment, and points of airborne emissions, in relation to the surrounding area, residences and other permanent structures and roadways (Example: Copy of relevant portion of USGS topographic map).

8. An 8 1/2" x 11" plot plan of facility showing the location of manufacturing processes and outlets for airborne emissions. Relate all flows to the flow diagram.

9. The appropriate application fee in accordance with Rule 17-4.05. The check should be made payable to the Department of Environmental Regulation.

10. With an application for operation permit, attach a Certificate of Completion of Construction indicating that the source was constructed as shown in the construction permit.

SECTION VI: BEST AVAILABLE CONTROL TECHNOLOGY

A. Are standards of performance for new stationary sources pursuant to 40 C.F.R. Part 60 applicable to the source?

[ ] Yes [ ] No

Contaminant	Rate or Concentration

B. Has EPA declared the best available control technology for this class of sources (If yes, attach copy)

[ ] Yes [ ] No

Contaminant	Rate or Concentration

C. What emission levels do you propose as best available control technology?

Contaminant	Rate or Concentration

D. Describe the existing control and treatment technology (if any).

1. Control Device/System:
2. Operating Principles:
3. Efficiency:*
4. Capital Costs:

*Explain method of determining

5. Useful Life:

6. Operating Costs:

7. Energy:

8. Maintenance Cost:

9. Emissions:

Contaminant	Rate or Concentration

10. Stack Parameters

a. Height: ft.

b. Diameter: ft.

c. Flow Rate: ACFM

d. Temperature: °F.

e. Velocity: FPS

E. Describe the control and treatment technology available (As many types as applicable, use additional pages if necessary).

1.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

2.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

3.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

4.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Costs:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

F. Describe the control technology selected:

1. Control Device:

2. Efficiency:[1]

3. Capital Cost:

4. Useful Life:

5. Operating Cost:

6. Energy:[2]

7. Maintenance Cost:

8. Manufacturer:

9. Other locations where employed on similar processes:

a. (1) Company:

(2) Mailing Address:

(3) City:

(4) State:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

b. (1) Company:

(2) Mailing Address:

(3) City: (4) State:

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

10. Reason for selection and description of systems:

[1]Applicant must provide this information when available. Should this information not be available, applicant must state the reason(s) why.

SECTION VII - PREVENTION OF SIGNIFICANT DETERIORATION

A. Company Monitored Data

1. _____no. sites _____ TSP _____( ) SO^2* _____ Wind spd/dir

Period of Monitoring _____/_____/_____ to _____/_____/_____
month day year month day year

Other data recorded _____

Attach all data or statistical summaries to this application.

*Specify bubbler (B) or continuous (C).

2. Instrumentation, Field and Laboratory

a. Was instrumentation EPA referenced or its equivalent? [ ] Yes [ ] No

b. Was instrumentation calibrated in accordance with Department procedures?

[ ] Yes [ ] No [ ] Unknown

B. Meteorological Data Used for Air Quality Modeling

1. _____ Year(s) of data from _____/_____/_____ to _____/_____/_____
month day year month day year

2. Surface data obtained from (location)_____

3. Upper air (mixing height) data obtained from (location)_____

4. Stability wind rose (STAR) data obtained from (location)_____

C. Computer Models Used

1. _____ Modified? If yes, attach description.

2. _____ Modified? If yes, attach description.

3. _____ Modified? If yes, attach description.

4. _____ Modified? If yes, attach description.

Attach copies of all final model runs showing input data, receptor locations, and principle output tables.

D. Applicants Maximum Allowable Emission Data

Pollutant	Emission Rate	
TSP	_____	grams/sec
SO^2	_____	grams/sec

E. Emission Data Used in Modeling

Attach list of emission sources. Emission data required is source name, description of point source (on NEDS point number), UTM coordinates, stack data, allowable emissions, and normal operating time.

F. Attach all other information supportive to the PSD review.

G. Discuss the social and economic impact of the selected technology versus other applicable technologies (i.e., jobs, payroll, production, taxes, energy, etc.). Include assessment of the environmental impact of the sources.

H. Attach scientific, engineering, and technical material, reports, publications, journals, and other competent relevant information describing the theory and application of the requested best available control technology.

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

C E R T I F I C A T E

To Whom It May Concern:

This is to certify that Robert A. Franke, Director of Engineering of Key Pharmaceuticals, Inc., is duly authorized to represent Key Pharmaceuticals, Inc., along with his designate, Thomas W. Flachmeyer, Manager Environmental Engineering and Waste Management; for the purposes of making Application for Permit to Construct or Operate Pollution Control Facilities for said company.

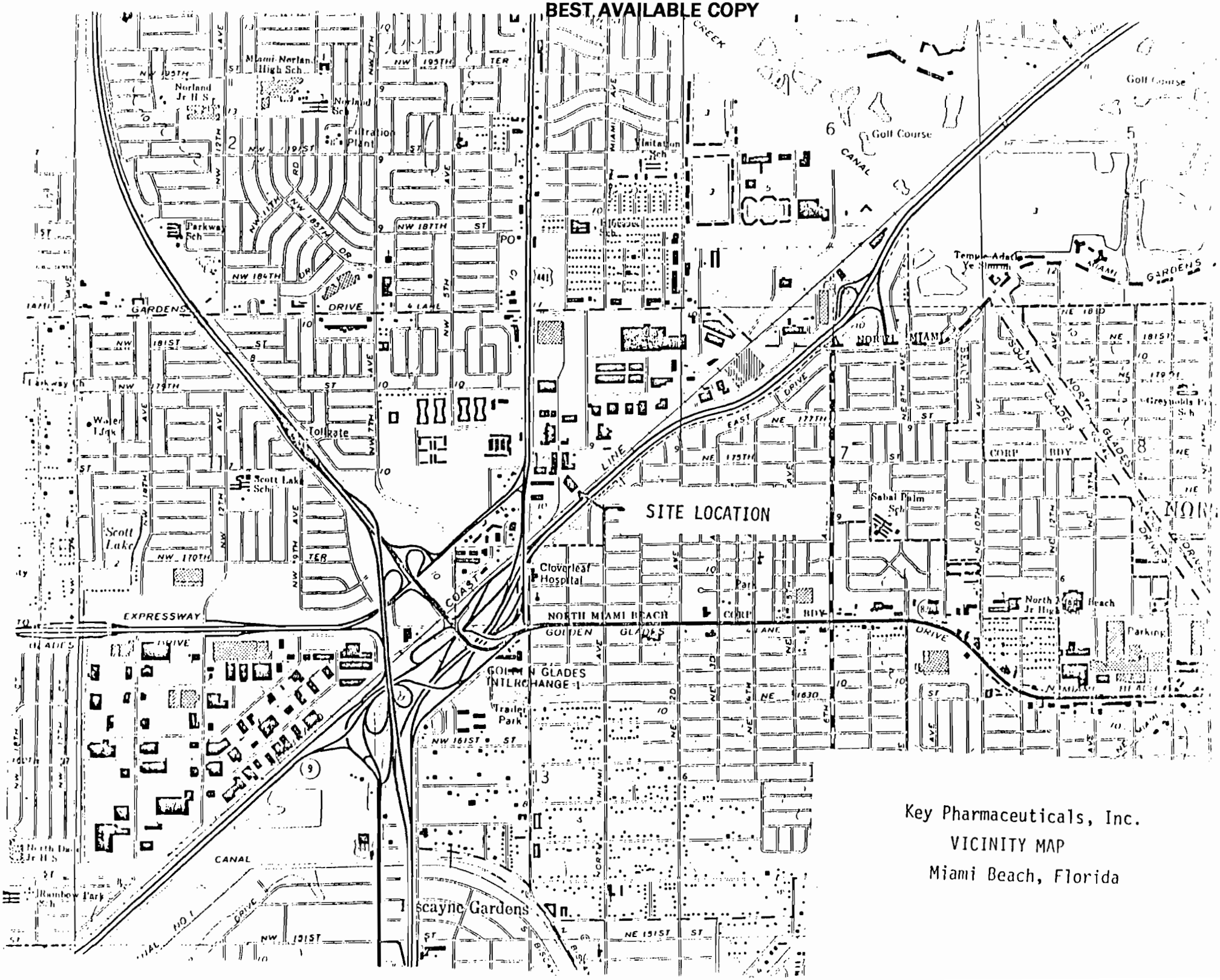
Key Pharmaceuticals, Inc.

James R. Confroy, Vice President
Miami and Puerto Rico Operations
JRC/db

STATE OF FLORIDA
COUNTY OF DADE
Sworn to and subscribed before me
this 21st day of October A.D. 1986.

NOTARY PUBLIC STATE OF FLORIDA
MY COMMISSION EXP. DEC 18,1989
BONDED THRU GENERAL INS. UND.

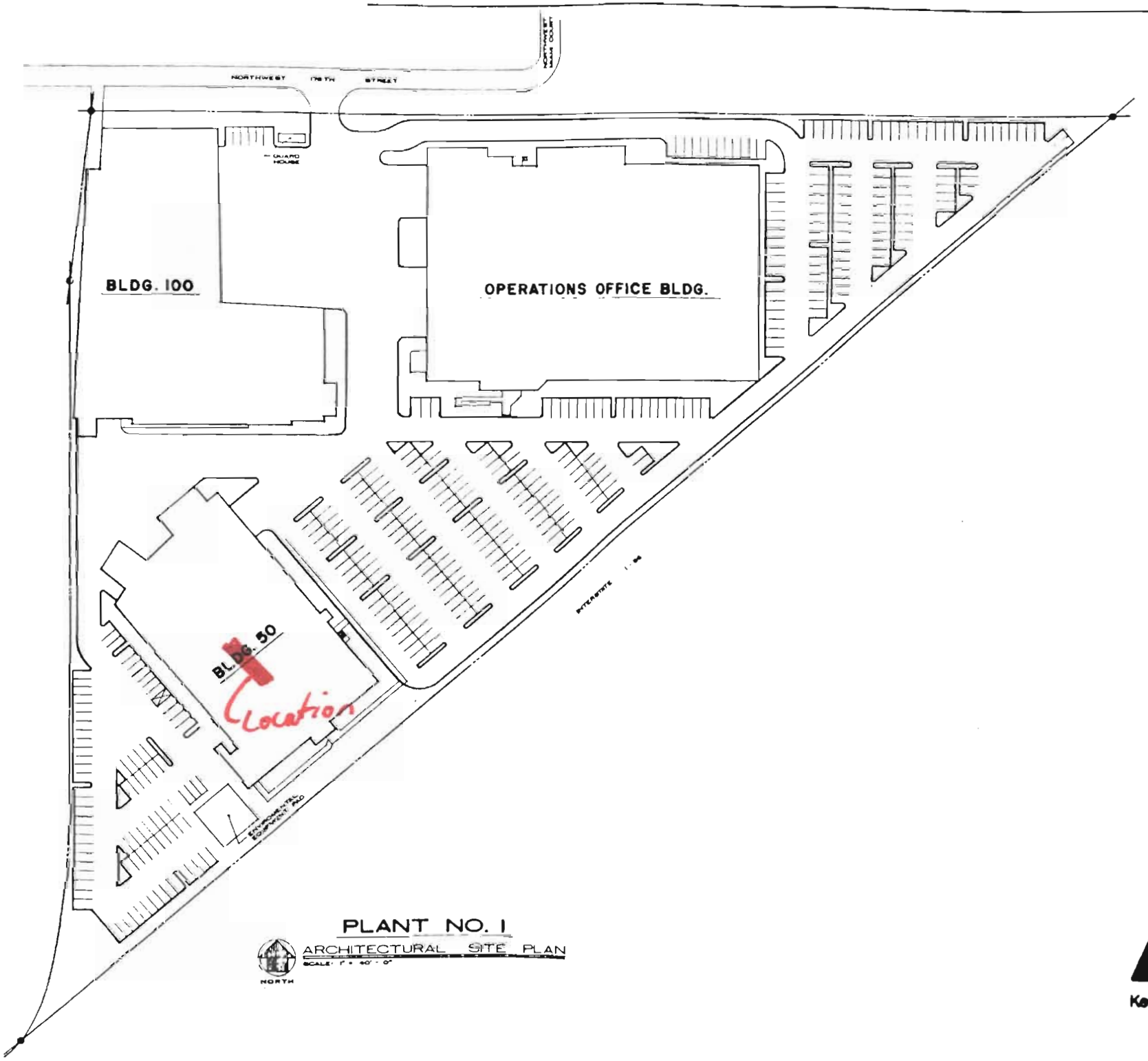
BEST AVAILABLE COPY



Key Pharmaceuticals, Inc.

VICINITY MAP

Miami Beach, Florida

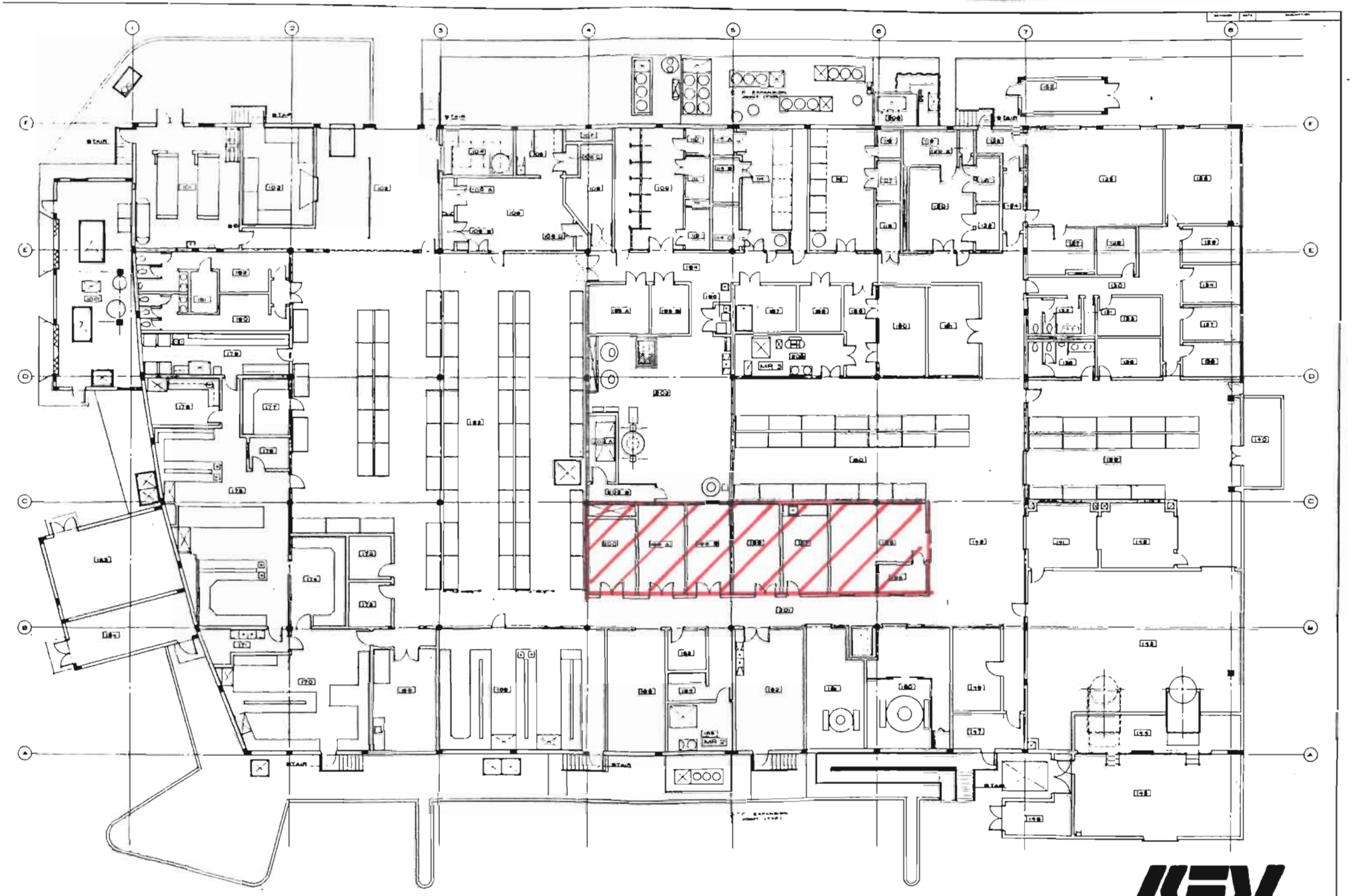


PLANT NO. 1

ARCHITECTURAL SITE PLAN

SCALE: 1" = 40'-0"

Key Pharmaceuticals, Inc.



BUILDING 50 : FLOOR PLAN

Key Pharmaceuticals, Inc.

2

CHARGE Tablet Press DATE 1-18-87

PREPARED BY JWF CHECKED BY _____ SHEET NO. 1 of 1 FILE NO. _____

SUBJECT

Emission Calculations for Tablet Presses

Basis

Machine maximum thruput - 1,500 tablets per minute

maximum tablet weight - 1.2 grams

$\therefore 1{,}500 \times 1.2 \times 2.205 \times 10^{-3} \times 60 = 238$ lb/Hr

maximum product loss ½ of 1%

$\therefore$ maximum emission potential

$4 \times 238 \times 0.005 = 4.76$ lb/Hr

Dust Collector Design; 99% removal efficiency

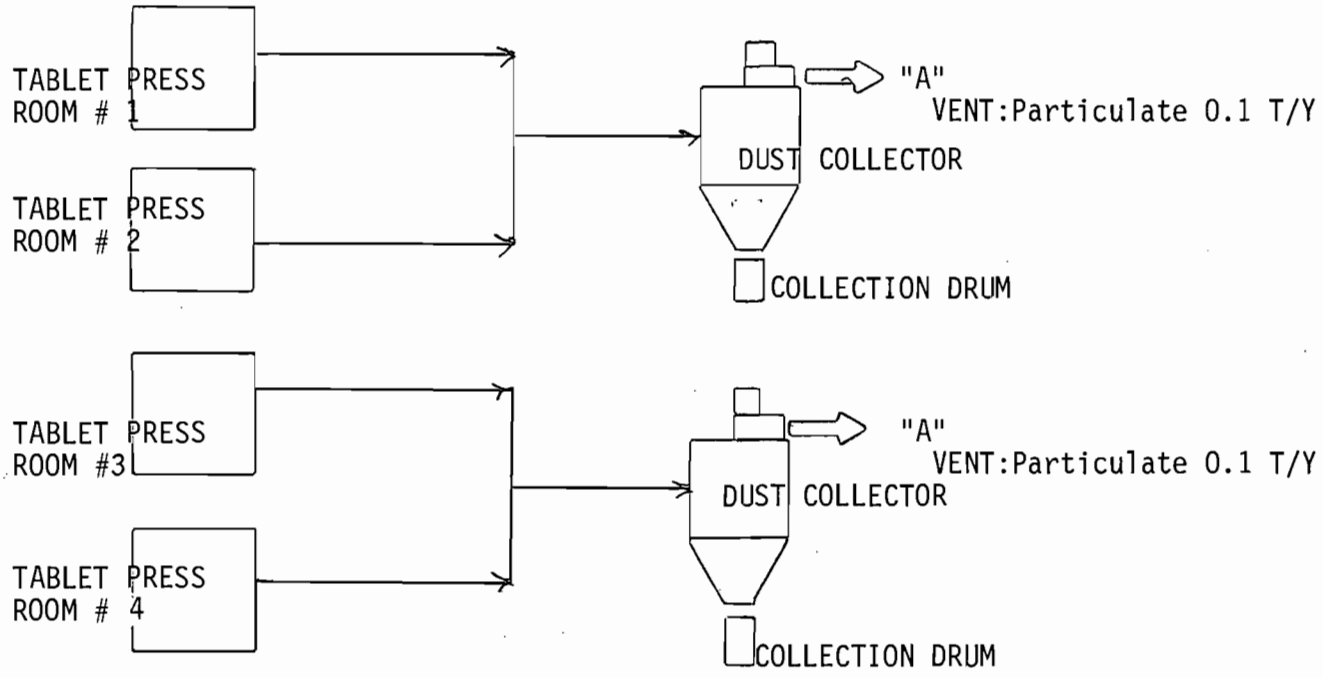
$\therefore$ maximum emissions 0.2 Tons/year

0.05 lb/Hr

CHARGE Tablet Press DATE 1-18-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 1 of 1 FILE NO. _____

SUBJECT Process Flow Diagram



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

January 12, 1987

Mr. C.H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: APPLICATION TO CONSTRUCT TWO (2) GRANULATORS.

Dear Mr. Fancy:

Attached please find an "Application to Construct Air Pollution Sources". The application attached is for the construction of 2 Granulation Machines at Key Pharmaceuticals, Inc 50 N.W. 176 Street, Miami location. These Granulators have been permitted under the GUANIDINE and QUINORA Manufacturing Permit. This application is for the units themselves, separate from any specific product considerations. This falls in line with your department's guidance to permit equipment rather than products. This permit application specifically states that it is only for aqueous (i.e. non-solvent) granulations. As you can see these units are serviced by a dust collector with a designed removal efficiency of 99%. This makes the total emissions from these units negligible (0.02 tons/year).

Your cooperation in this matter is greatly appreciated. Should you have any questions please do not hesitate to call me at 305-654-2240.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

attachment

cc: S. Brooks (S.E. Florida District)
P. Wong (DERM Office)

AC 13-129897

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

SOUTHEAST FLORIDA DISTRICT
3301 GUN CLUB ROAD
P.O. BOX 3858
WEST PALM BEACH, FLORIDA 33402

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

ROY DUKE
DISTRICT MANAGER

APPLICATION TO OPERATE/CONSTRUCT AIR POLLUTION SOURCES

SOURCE TYPE: AIR POLLUTION [ ] New[1] [X] Existing[1]

APPLICATION TYPE: [X] Construction [ ] Operation [ ] Modification

COMPANY NAME: KEY PHARMACEUTICALS, INC. COUNTY: DADE

Identify the specific emission point source(s) addressed in this application (i.e. Lime Kiln No. 4 with Venturi Scrubber; Peaking Unit No. 2, Gas Fired) 2 GRANULATORS

SOURCE LOCATION: Street 50 N.W. 176TH STREET City MIAMI

UTM: East 57987 North 7868445

Latitude 25 ° 56 ' 03 "N Longitude 80 ° 11 ' 42 "W

APPLICANT NAME AND TITLE: JAMES R. CONFROY, VICE PRESIDENT OPERATIONS

APPLICANT ADDRESS: 50 N.W. 176TH STREET, MIAMI, FL 33169

SECTION I: STATEMENTS BY APPLICANT AND ENGINEER

A. APPLICANT

I am the undersigned owner or authorized representative* of KEY PHARMACEUTICALS, INC.

I certify that the statements made in this application for a CONSTRUCTION permit are true, correct and complete to the best of my knowledge and belief. Further, I agree to maintain and operate the pollution control source and pollution control facilities in such a manner as to comply with the provision of Chapter 403, Florida Statutes, and all the rules and regulations of the department and revisions thereof. I also understand that a permit, if granted by the department, will be non-transferable and I will promptly notify the department upon sale or legal transfer of the permitted establishment.

*Attach letter of authorization

Signed: James R Confroy

JAMES R. CONFROY, VICE PRESIDENT OPERATIONS
Name and Title (Please Type)

Date: 1/12/87 Telephone No. 305-654-2200

B. PROFESSIONAL ENGINEER REGISTERED IN FLORIDA (where required by Chapter 471, F.S.) *

This is to certify that the engineering features of this pollution control project have been designed/examined by me and found to be in conformity with modern engineering principles applicable to the treatment and disposal of pollutants characterized in the permit application. There is reasonable assurance, in my professional judgment, that

[1] See Florida Administrative Code Rule 17-2.100(57) and (104)

* SEE NOTE PAGE 2

I HAVE REVIEWED THE CALCULATIONS USED TO DETERMINE THE STATED LEVELS OF PARTICULATE AND VOC EMISSIONS AND FIND THEM TO BE ACCURATE BASED ON PROJECTED MANUFACTURING LEVELS OF THE PRODUCT.

the pollution control facilities, when properly maintained and operated, will discharge an effluent that complies with all applicable statutes of the State of Florida and the rules and regulations of the department. It is also agreed that the undersigned will furnish, if authorized by the owner, the applicant a set of instructions for the proper maintenance and operation of the pollution control facilities and, if applicable, pollution sources.

Signed J.N. Wells P.E.

JOHN N. WELLS, P.E.
Name (Please Type)

KEY PHARMACEUTICALS, INC.
Company Name (Please Type)

50 N.W. 176TH STREET, MIAMI, FL. 33169
Mailing Address (Please Type)

Florida Registration No. 33917 **Date:** 1/12/87 **Telephone No.** 305-654-2200

SECTION II: GENERAL PROJECT INFORMATION

A. Describe the nature and extent of the project. Refer to pollution control equipment, and expected improvements in source performance as a result of installation. State whether the project will result in full compliance. Attach additional sheet if necessary.

THE TWO GRANULATORS WILL BE UTILIZED DURING THE MANUFACTURING OF VARIOUS SOLID DOSE (TABLET) PHARMACEUTICAL PRODUCTS. ROOM DUST CONTROL IS PROVIDED FOR IN THE ROOM. DUE TO COST CONSTRAINTS A LOSS OF PRODUCT OF LESS THAN ½ OF 1% CAN ONLY BE TOLERATED.

B. Schedule of project covered in this application (Construction Permit Application Only)

Start of Construction MAR'87 **Completion of Construction** SEP'87

C. Costs of pollution control system(s): (Note: Show breakdown of estimated costs only for individual components/units of the project serving pollution control purposes. Information on actual costs shall be furnished with the application for operation permit.)

$25,000.00

D. Indicate any previous DER permits, orders and notices associated with the emission point, including permit issuance and expiration dates.

(1) CONSENT ORDER NO. 83-0373 (CLOSED)

(2) PERMIT TO CONSTRUCT FOR MFG GUANIDINE & QUINORA AC 13-115383

(3) PERMIT TO CONSTRUCT FOR MFG OF K-DUR AC 13-100437

E. Requested permitted equipment operating time: hrs/day 24 ; days/wk 7 ; wks/yr 52 ;

if power plant, hrs/yr_____; if seasonal, describe:_____

F. If this is a new source or major modification, answer the following questions. (Yes or No)

1. Is this source in a non-attainment area for a particular pollutant? YES

   a. If yes, has "offset" been applied? NO

   b. If yes, has "Lowest Achievable Emission Rate" been applied? NO

   c. If yes, list non-attainment pollutants. OZONE

2. Does best available control technology (BACT) apply to this source? If yes, see Section VI. NO

3. Does the State "Prevention of Significant Deterioriation" (PSD) requirement apply to this source? If yes, see Sections VI and VII. NO

4. Do "Standards of Performance for New Stationary Sources" (NSPS) apply to this source? NO

5. Do "National Emission Standards for Hazardous Air Pollutants" (NESHAP) apply to this source? NO

H. Do "Reasonably Available Control Technology" (RACT) requirements apply to this source? NO

   a. If yes, for what pollutants?_____

   b. If yes, in addition to the information required in this form, any information requested in Rule 17-2.650 must be submitted.

Attach all supportive information related to any answer of "Yes". Attach any justification for any answer of "No" that might be considered questionable.

SECTION III: AIR POLLUTION SOURCES & CONTROL DEVICES (Other than Incinerators)

A. Raw Materials and Chemicals Used in your Process, if applicable:

Description	Contaminants		Utilization Rate - lbs/hr	Relate to Flow Diagram
	Type	% Wt		
SOLIDS	PARTICULATE	100	41 (PER UNIT)	"A"

B. Process Rate, if applicable: (See Section V, Item 1)

1. Total Process Input Rate (lbs/hr): 123.6 LB/HR

2. Product Weight (lbs/hr): 82 LB/HR

C. Airborne Contaminants Emitted: (Information in this table must be submitted for each emission point, use additional sheets as necessary)

Name of Contaminant	Emission[1]		Allowed[2] Emission Rate per Rule 17-2	Allowable[3] Emission lbs/hr	Potential[4] Emission		Relate to Flow Diagram
	Maximum lbs/hr	Actual T/yr			lbs/yr	T/yr	
PARTICULATE	0.004	0.02	N/A	N/A		1.8	"A"

[1]See Section V, Item 2.

[2]Reference applicable emission standards and units (e.g. Rule 17-2.600(5)(b)2. Table II, E. (1) - 0.1 pounds per million BTU heat input)

[3]Calculated from operating rate and applicable standard.

[4]Emission, if source operated without control (See Section V, Item 3).

D. Control Devices: (See Section V, Item 4)

Name and Type (Model & Serial No.)	Contaminant	Efficiency	Range of Particles Size Collected (in microns) (If applicable)	Basis for Efficiency (Section V Item 5)
TORIT DUST COLLECTOR	PARTICULATE	99%	2 MICRON OR LARGER	SUPPLIER'S DESIGN

E. Fuels

Type (Be Specific)	Consumption*		Maximum Heat Input (MMBTU/hr)
	avg/hr	max./hr	

*Units: Natural Gas--MMCF/hr; Fuel Oils--gallons/hr; Coal, wood, refuse, other--lbs/hr.

Fuel Analysis:

Percent Sulfur: _____ Percent Ash: _____

Density: _____ lbs/gal Typical Percent Nitrogen: _____

Heat Capacity: _____ BTU/lb _____ BTU/gal

Other Fuel Contaminants (which may cause air pollution): _____

F. If spplicable, indicate the percent of fuel used for space heating.

Annual Average _____ Maximum _____

G. Indicate liquid or solid wastes generated and method of disposal.

7.8 TONS PER YEAR OF SOLIDS ARE COLLECTED IN APPROXIMATELY 10 DRUMS. ALL SOLID WASTE IS DISPOSED OF OFF-SITE AT AN APPROVED FACILITY.

H. Emission Stack Geometry and Flow Characteristics (Provide data for each stack):

Stack Height: OFF ROOF 11 FT. ft. Stack Diameter: 12" x 12" ft.

Gas Flow Rate: 4000 ACFM _____ DSCFM Gas Exit Temperature: 70 °F.

Water Vapor Content: 50% to 60% RH % Velocity: 67 FPS

SECTION IV: INCINERATOR INFORMATION

Type of Waste	Type 0 (Plastics)	Type I (Rubbish)	Type II (Refuse)	Type III (Garbage)	Type IV (Pathological)	Type V (Liq.& Gas By-prod.)	Type VI (Solid By-prod.)
Actual lb/hr Incinerated							
Uncontrolled (lbs/hr)							

Description of Waste _____

Total Weight Incinerated (lbs/hr) _____ Design Capacity (lbs/hr) _____

Approximate Number of Hours of Operation per dey _____ day/wk _____ wks/yr. _____

Manufacturer _____

Date Conatructed _____ Model No. _____

	Volume $(ft)^3$	Heat Release (BTU/hr)	Fuel		Temperature (°F)
			Type	BTU/hr	
Primary Chamber					
Secondary Chamber					

Stack Height: _____ ft. Steck Diamter: _____ Steck Temp. _____

Gas Flow Rate: _____ ACFM _____ DSCFM* Velocity: _____ FPS

*If 50 or more tons per day design capacity, submit the emissions rate in grains per standard cubic foot dry gas corrected to 50% excess air.

Type of pollution control device: [ ] Cyclone [ ] Wet Scrubber [ ] Afterburner

[ ] Other (specify) _____

Brief description of operating characteristics of control devices: _____

_____

_____

_____

_____

Ultimate disposal of any effluent other than that emitted from the stack (scrubber water, ash, etc.):

_____

_____

_____

_____

NOTE: Items 2, 3, 4, 6, 7, 8, and 10 in Section V must be included where applicable.

SECTION V: SUPPLEMENTAL REQUIREMENTS

Please provide the following supplements where required for this application.

1. Total process input rate and product weight -- show derivation [Rule 17-2.100(127)]

2. To a construction application, attach basis of emission estimate (e.g., design calculations, design drawings, pertinent manufacturer's test data, etc.) and attach proposed methods (e.g., FR Part 60 Methods 1, 2, 3, 4, 5) to show proof of compliance with applicable standards. To an operation application, attach test results or methods used to show proof of compliance. Information provided when applying for an operation permit from a construction permit shall be indicative of the time at which the test was made.

3. Attach basis of potential discharge (e.g., emission factor, that is, AP42 test).

4. With construction permit application, include design details for all air pollution control systems (e.g., for baghouse include cloth to air ratio; for scrubber include cross-section sketch, design pressure drop, etc.)

5. With construction permit application, attach derivation of control device(s) efficiency. Include test or design data. Items 2, 3 and 5 should be consistent: actual emissions = potential (1-efficiency).

6. An 8 1/2" x 11" flow diagram which will, without revealing trade secrets, identify the individual operations and/or processes. Indicate where raw materials enter, where solid and liquid waste exit, where gaseous emissions and/or airborne particles are evolved and where finished products are obtained.

7. An 8 1/2" x 11" plot plan showing the location of the establishment, and points of airborne emissions, in relation to the surrounding area, residences and other permanent structures and roadways (Example: Copy of relevant portion of USGS topographic map).

8. An 8 1/2" x 11" plot plan of facility showing the location of manufacturing processes and outlets for airborne emissions. Relate all flows to the flow diagram.

9. The appropriate application fee in accordance with Rule 17-4.05. The check should be made payable to the Department of Environmental Regulation.

10. With an application for operation permit, attach a Certificate of Completion of Construction indicating that the source was constructed as shown in the construction permit.

SECTION VI: BEST AVAILABLE CONTROL TECHNOLOGY

A. Are standards of performance for new stationary sources pursuant to 40 C.F.R. Part 60 applicable to the source?

[ ] Yes [ ] No

Contaminant	Rate or Concentration

B. Has EPA declared the best available control technology for this class of sources (If yes, attach copy)

[ ] Yes [ ] No

Contaminant	Rate or Concentration

C. What emission levels do you propose as best available control technology?

Contaminant	Rate or Concentration

D. Describe the existing control and treatment technology (if any).

1. Control Device/System:
2. Operating Principles:
3. Efficiency:*
4. Capital Costs:

*Explain method of determining

5. Useful Life:

6. Operating Costs:

7. Energy:

8. Maintenance Cost:

9. Emissions:

Contaminant	Rate or Concentration

10. Stack Parameters

a. Height: ft.

b. Diameter: ft.

c. Flow Rate: ACFM

d. Temperature: °F.

e. Velocity: FPS

E. Describe the control and treatment technology available (As many types as applicable, use additional pages if necessary).

1.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

2.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

3.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

4.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Costs:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

F. Describe the control technology selected:

1. Control Device:

2. Efficiency:[1]

3. Capital Cost:

4. Useful Life:

5. Operating Cost:

6. Energy:[2]

7. Maintenance Cost:

8. Manufacturer:

9. Other locations where employed on similar processes:

a. (1) Company:

(2) Mailing Address:

(3) City:

(4) State:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

b. (1) Company:

(2) Mailing Address:

(3) City: (4) State:

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

10. Reason for selection and description of systems:

[1]Applicant must provide this information when available. Should this information not be available, applicant must state the reason(s) why.

SECTION VII - PREVENTION OF SIGNIFICANT DETERIORATION

A. Company Monitored Data

1. _____no. sites _____ TSP _____( ) SO^{2}* _____ Wind spd/dir

Period of Monitoring _____/_____/_____ to _____/_____/_____
month day year month day year

Other data recorded _____

Attach all data or statistical summaries to this application.

*Specify bubbler (B) or continuous (C).

2. Instrumentation, Field and Laboratory

a. Was instrumentation EPA referenced or its equivalent? [ ] Yes [ ] No

b. Was instrumentation calibrated in accordance with Department procedures?

[ ] Yes [ ] No [ ] Unknown

B. Meteorological Data Used for Air Quality Modeling

1. _____ Year(s) of data from ____/____/____ to ____/____/____
month day year month day year

2. Surface data obtained from (location)_____

3. Upper air (mixing height) data obtained from (location)_____

4. Stability wind rose (STAR) data obtained from (location)_____

C. Computer Models Used

1. _____ Modified? If yes, attach description.

2. _____ Modified? If yes, attach description.

3. _____ Modified? If yes, attach description.

4. _____ Modified? If yes, attach description.

Attach copies of all final model runs showing input data, receptor locations, and principle output tables.

D. Applicants Maximum Allowable Emission Data

Pollutant	Emission Rate	
TSP	_____	grams/sec
SO^2	_____	grams/sec

E. Emission Data Used in Modeling

Attach list of emission sources. Emission data required is source name, description of point source (on NEDS point number), UTM coordinates, stack data, allowable emissions, and normal operating time.

F. Attach all other information supportive to the PSD review.

G. Discuss the social and economic impact of the selected technology versus other applicable technologies (i.e., jobs, payroll, production, taxes, energy, etc.). Include assessment of the environmental impact of the sources.

H. Attach scientific, engineering, and technical material, reports, publications, journals, and other competent relevant information describing the theory and application of the requested best available control technology.

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

C E R T I F I C A T E

To Whom It May Concern:

This is to certify that Robert A. Franke, Director of Engineering of Key Pharmaceuticals, Inc., is duly authorized to represent Key Pharmaceuticals, Inc., along with his designate, Thomas W. Flachmeyer, Manager Environmental Engineering and Waste Management; for the purposes of making Application for Permit to Construct or Operate Pollution Control Facilities for said company.

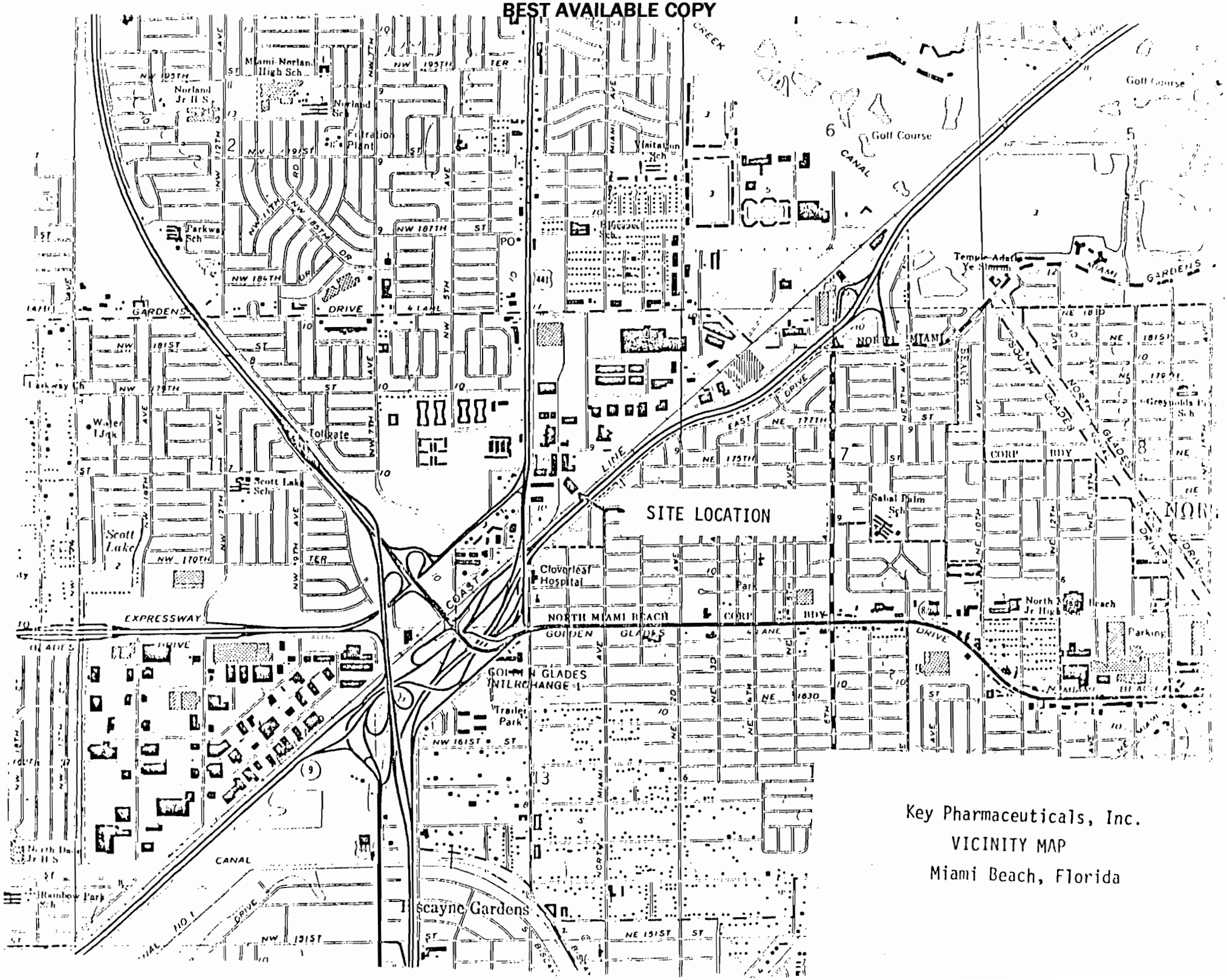
Key Pharmaceuticals, Inc.

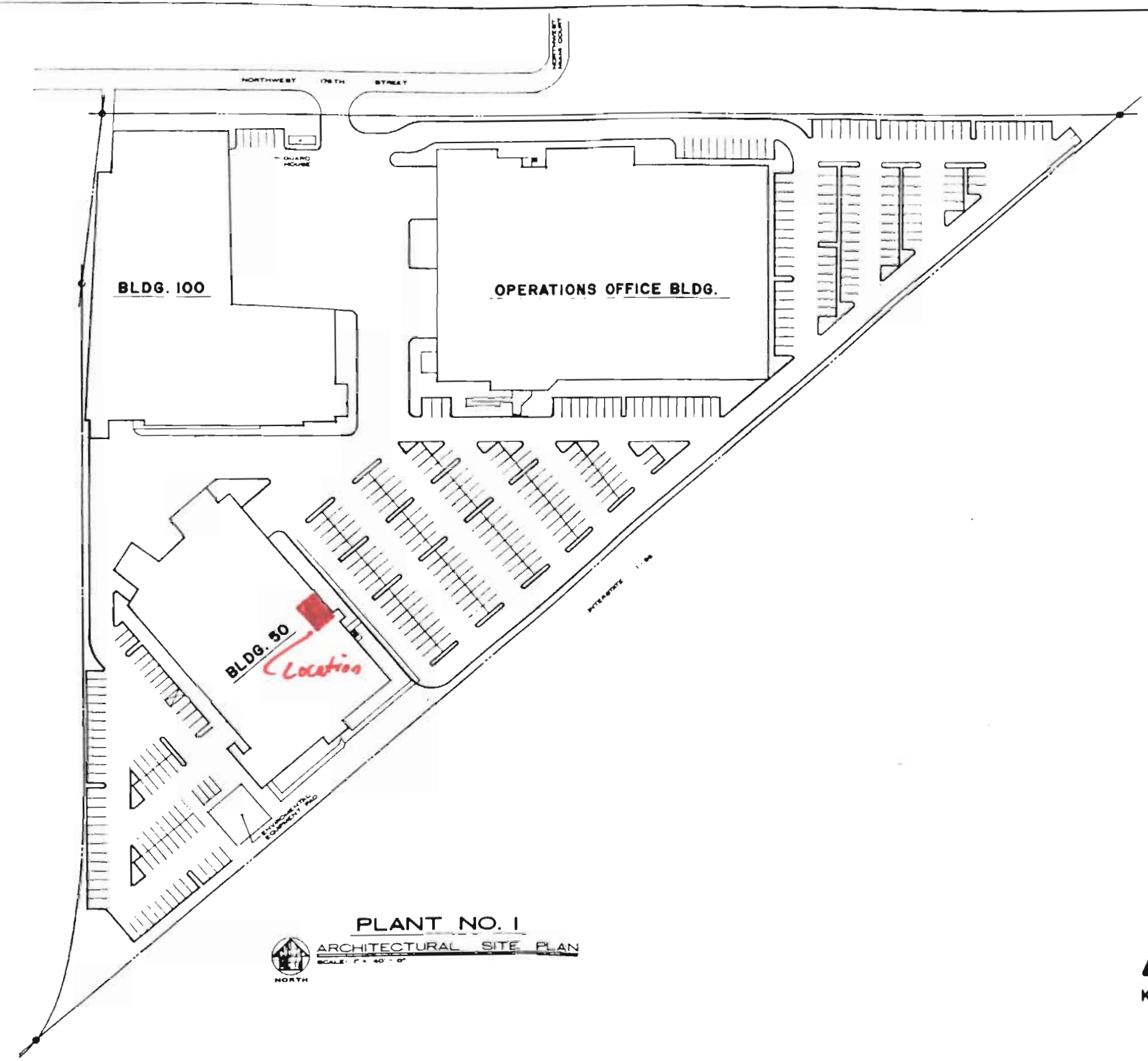
James R. Confroy, Vice President
Miami and Puerto Rico Operations
JRC/db

STATE OF FLORIDA
COUNTY OF DADE
Sworn to and subscribed before me
this 21st day of October A.D. 1986.

NOTARY PUBLIC STATE OF FLORIDA
MY COMMISSION EXP. DEC 18,1989
BONDED THRU GENERAL INS. UND.

BEST AVAILABLE COPY





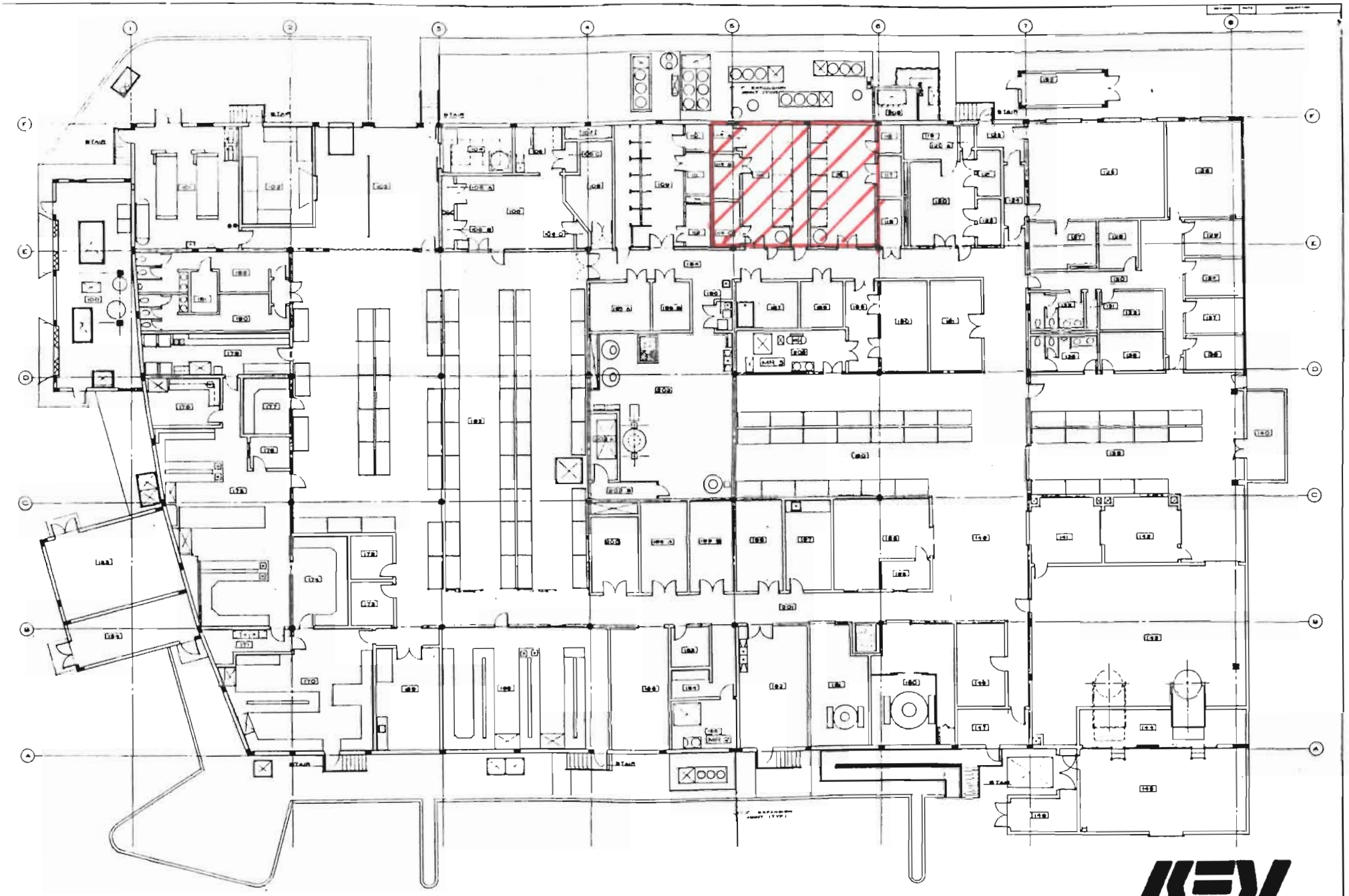
PLANT NO. 1

ARCHITECTURAL SITE PLAN

SCALE: 1" = 40'-0"

NORTH

Key Pharmaceuticals, Inc.



BUILDING 50 FLOOR PLAN

Key Pharmaceuticals, Inc.

CHARGE Granulation - Aqueous DATE 1-18-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 1 of 1 FILE NO. _____

SUBJECT Emission Calculation for Aqueous Granulations

Basis:

Machine maximum capacity : 450 kg Solids

2 Granulation machines

lot cycle is 24 hours

Lot Specifications

450 kg Solids (max)

Water as needed

Maximum thruput 362 Tons per year

Maximum product loss due to dusting 1/2 of 1%

∴ Maximum emission potential 1.8 T/y

0.41 lb/Hr

Dust Collector Design - 99% removal efficiency

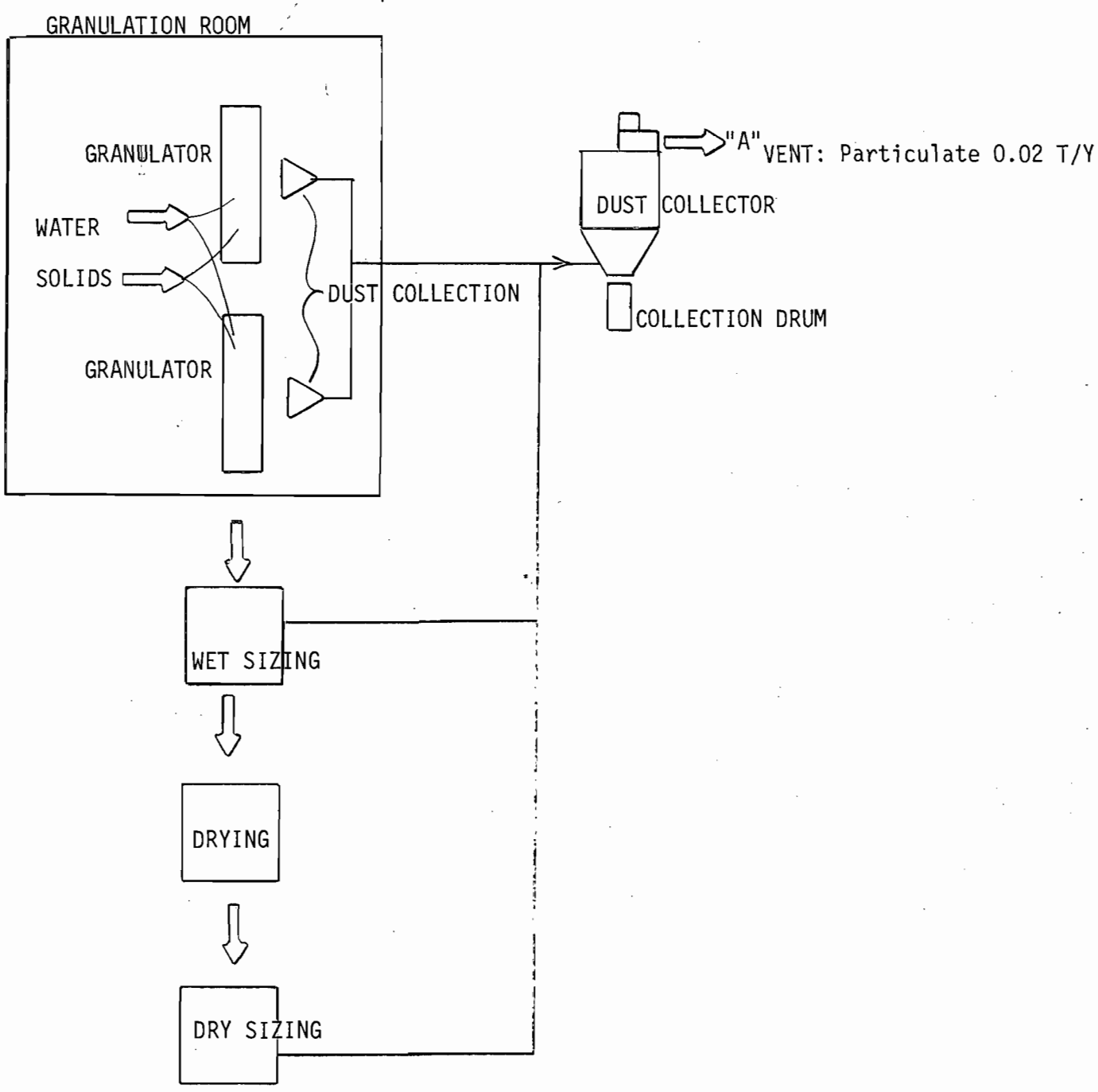
∴ Maximum emissions 0.02 T/y

0.004 lb/Hr

CHARGE Aqueous Granulation DATE 1-18-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 1 of 1 FILE NO. _____

SUBJECT Process Flow - Aqueous Granulation



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 654-2200

Telex: 808235

January 12, 1987

Mr. C.H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality Management
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: APPLICATION TO CONSTRUCT ONE (1) GRANULATOR.

Dear Mr. Fancy:

Attached please find an "Application to Construct Air Pollution Sources". The application attached is for the construction of 1 Granulator for solvent granulation at Key Pharmaceuticals, Inc 50 N.W. 176 Street, Miami location. This piece of equipment is one of the two units permitted in Application #6. The reasoning for permitting the unit twice is due to the fact that the aqueous process and the solvent process for granulation differ from one another. Key is committed to try to manufacture as many products as possible using aqueous formulation. This application will allow Key to manufacture a small quantity of products that could not be granulated utilizing the aqueous formulations. The two solvents utilized will be isopropyl alcohol and 3-A alcohol. This application supercedes and replaces the permit to manufacture GUANIDINE and QUINORA (AC-13-115383).

Your cooperation in this matter is greatly appreciated. Should you have any questions please do not hesitate to call me at 305-654-2240.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

attachment

cc: S. Brooks (S.E. Florida District)
P. Wong (DERM Office)

AC 13-129897

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

SOUTHEAST FLORIDA DISTRICT
3301 GUN CLUB ROAD
P.O. BOX 3858
WEST PALM BEACH, FLORIDA 33402

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

ROY DUKE
DISTRICT MANAGER

APPLICATION TO OPERATE/CONSTRUCT AIR POLLUTION SOURCES

SOURCE TYPE: AIR POLLUTION [ ] New[1] [X] Existing[1]

APPLICATION TYPE: [X] Construction [ ] Operation [ ] Modification

COMPANY NAME: KEY PHARMACEUTICALS, INC. COUNTY: DADE

Identify the specific emission point source(s) addressed in this application (i.e. Lime Kiln No. 4 with Venturi Scrubber; Peaking Unit No. 2, Gas Fired) 1 GRANULATOR AND DRYER

SOURCE LOCATION: Street 50 N.W. 176TH STREET City MIAMI

UTM: East 57987 North 2868445

Latitude 25 ° 56 ' 03 "N Longitude 80 ° 11 ' 42 "W

APPLICANT NAME AND TITLE: JAMES R. CONFROY, VICE PRESIDENT OPERATIONS

APPLICANT ADDRESS: 50 N.W. 176TH STREET, MIAMI, FL 33169

SECTION I: STATEMENTS BY APPLICANT AND ENGINEER

A. APPLICANT

I am the undersigned owner or authorized representative* of KEY PHARMACEUTICALS, INC.

I certify that the statements made in this application for a CONSTRUCTION permit are true, correct and complete to the best of my knowledge and belief. Further, I agree to maintain and operate the pollution control source and pollution control facilities in such a manner as to comply with the provision of Chapter 403, Florida Statutes, and all the rules and regulations of the department and revisions thereof. I also understand that a permit, if granted by the department, will be non-transferable and I will promptly notify the department upon sale or legal transfer of the permitted establishment.

*Attach letter of authorization

Signed: James R Confroy

JAMES R. CONFROY, VICE PRESIDENT OPERATIONS
Name and Title (Please Type)

Date: 1/12/87 Telephone No. 305-654-2200

B. PROFESSIONAL ENGINEER REGISTERED IN FLORIDA (where required by Chapter 471, F.S.) *

This is to certify that the engineering features of this pollution control project have been designed/examined by me and found to be in conformity with modern engineering principles applicable to the treatment and disposal of pollutants characterized in the permit application. There is reasonable assurance, in my professional judgment, that

[1] See Florida Administrative Code Rule 17-2.100(57) and (104)

* SEE NOTE PAGE 2

I HAVE REVIEWED THE CALCULATIONS USED TO DETERMINE THE STATED LEVELS OF PARTICULATE AND VOC EMISSIONS AND FIND THEM TO BE ACCURATE BASED ON PROJECTED MANUFACTURING LEVELS OF THE PRODUCT.

the pollution control facilities, when properly maintained and operated, will discharge an effluent that complies with all applicable statutes of the State of Florida and the rules and regulations of the department. It is also agreed that the undersigned will furnish, if authorized by the owner, the applicant a set of instructions for the proper maintenance and operation of the pollution control facilities and, if applicable, pollution sources.

Signed John N. Wells, P.E.

JOHN N. WELLS, P.E.
Name (Please Type)

KEY PHARMACEUTICALS, INC.
Company Name (Please Type)

50 N.W. 176TH STREET, MIAMI, FL. 33169
Mailing Address (Please Type)

REGISTERED PROFESSIONAL ENGINEER NO. 33917 STATE OF FLORIDA

Florida Registration No. 33917 **Date:** 1/12/87 **Telephone No.** 305-654-2200

SECTION II: GENERAL PROJECT INFORMATION

A. Describe the nature and extent of the project. Refer to pollution control equipment, and expected improvements in source performance as a result of installation. State whether the project will result in full compliance. Attach additional sheet if necessary.

THE GRANULATOR WILL BE UTILIZED DURING THE MANUFACTURING OF VARIOUS SOLID DOSE (TABLET) PHARMACEUTICAL PRODUCTS. THE PRODUCTS ARE GRANULATED UTILIZING VARIOUS SOLVENTS AND THEN DRIED. DUST COLLECTION IS PROVIDED FOR. DUE TO COST CONSTRAINTS A LOSS OF PRODUCT OF LESS THAN ½ OF 1% CAN ONLY BE TOLERATED.

B. Schedule of project covered in this application (Construction Permit Application Only)

Start of Construction MAR'87 **Completion of Construction** SEP'87

C. Costs of pollution control system(s): (Note: Show breakdown of estimated costs only for individual components/units of the project serving pollution control purposes. Information on actual costs shall be furnished with the application for operation permit.)

$25,000.00

D. Indicate any previous DER permits, orders and notices associated with the emission point, including permit issuance and expiration dates.

(1) CONSENT ORDER 83-0373 (CLOSED)

(2) PERMIT TO CONSTRUCT FOR MFG GUANIDINE & QUINORA AC 13-115383

(3) PERMIT TO CONSTRUCT FOR MFG OF K-DUR AC 13-100437

E. Requested permitted equipment operating time: hrs/day 24 ; days/wk 7 ; wks/yr 52 ;

if power plant, hrs/yr_____; if seasonal, describe:_____

F. If this is a new source or major modification, answer the following questions. (Yes or No)

1. Is this source in a non-attainment area for a particular pollutant?	YES
a. If yes, has "offset" been applied?	NO
b. If yes, has "Lowest Achievable Emission Rate" been applied?	NO
c. If yes, list non-attainment pollutants.	OZONE
2. Does best available control technology (BACT) apply to this source? If yes, see Section VI.	NO
3. Does the State "Prevention of Significant Deterioriation" (PSD) requirement apply to this source? If yes, see Sections VI and VII.	NO
4. Do "Standards of Performance for New Stationary Sources" (NSPS) apply to this source?	NO
5. Do "National Emission Standards for Hazardous Air Pollutants" (NESHAP) apply to this source?	NO
H. Do "Reasonably Available Control Technology" (RACT) requirements apply to this source?	NO

a. If yes, for what pollutants?_____

b. If yes, in addition to the information required in this form, any information requested in Rule 17-2.650 must be submitted.

Attach all supportive information related to any answer of "Yes". Attach any justification for any answer of "No" that might be considered questionable.

SECTION III: AIR POLLUTION SOURCES & CONTROL DEVICES (Other than Incinerators)

A. Raw Materials and Chemicals Used in your Process, if applicable:

Description	Contaminants		Utilization Rate - lbs/hr *	Relate to Flow Diagram
	Type	% Wt		
VOC	VOC	100%	6.9	"A"
ISOPROPANOL OR				
3-A ALCOHOL				

* BASED ON SOLVENTS BEING USED IN 24 HOURS.

B. Process Rate, if applicable: (See Section V, Item 1)

1. Total Process Input Rate (lbs/hr): 34.4 LB/HR

2. Product Weight (lbs/hr): 27.5 LB/HR

C. Airborne Contaminants Emitted: (Information in this table must be submitted for each emission point, use additional sheets as necessary)

Name of Contaminant	Emission[1]		Allowed[2] Emission Rate per Rule 17-2	Allowable[3] Emission lbs/hr	Potential[4] Emission		Relate to Flow Diagram
	Maximum lbs/hr	Actual T/yr			lbs/yr	T/yr	
PARTICULATE	0.001	0.006				0.6	"A"
VOC	20.7 **	30.2				30.2	"A"

[1]See Section V, Item 2. ** BASED ON ALL SOLVENTS BEING USED IN 8 HOURS

[2]Reference applicable emission standards and units (e.g. Rule 17-2.600(5)(b)2. Table II, E. (1) - 0.1 pounds per million BTU heat input)

[3]Calculated from operating rate and applicable standard.

[4]Emission, if source operated without control (See Section V, Item 3).

D. Control Devices: (See Section V, Item 4)

Name and Type (Model & Serial No.)	Contaminant	Efficiency	Range of Particles Size Collected (in microns) (If applicable)	Basis for Efficiency (Section V Item 5)
TORIT DUST COLLECTOR	PARTICULATE	99%	2 MICRON OR LARGER	SUPPLIER'S DESIGN

E. Fuels

Type (Be Specific)	Consumption*		Maximum Heat Input (MMBTU/hr)
	avg/hr	max./hr	

*Units: Natural Gas--MMCF/hr; Fuel Oils--gallons/hr; Coal, wood, refuse, other--lbs/hr.

Fuel Analysis:

Percent Sulfur: _____ Percent Ash: _____

Density: _____ lbs/gal Typical Percent Nitrogen: _____

Heat Capacity: _____ BTU/lb _____ BTU/gal

Other Fuel Contaminants (which may cause air pollution): _____

F. If applicable, indicate the percent of fuel used for space heating.

Annual Average _____ Maximum _____

G. Indicate liquid or solid wastes generated and method of disposal.

1,200 LB/YEAR OF SOLIDS ARE COLLECTED IN APPROXIMATELY 4 DRUMS. ALL SOLID WASTE IS DISPOSED OF OFF-SITE AT AN APPROVED FACILITY.

H. Emission Stack Geometry and Flow Characteristics (Provide data for each stack):

Stack Height: OFF ROOF 11 FT. ft. Stack Diameter: 12" x 12" ft.

Gas Flow Rate: 4000 ACFM _____ DSCFM Gas Exit Temperature: 70 °F.

Water Vapor Content: 50% to 60% RH % Velocity: 67 FPS

SECTION IV: INCINERATOR INFORMATION

Type of Waste	Type 0 (Plastics)	Type I (Rubbish)	Type II (Refuse)	Type III (Garbage)	Type IV (Pathological)	Type V (Liq.& Gas By-prod.)	Type VI (Solid By-prod.)
Actual lb/hr Incinerated							
Uncontrolled (lbs/hr)							

Description of Waste _____

Total Weight Incinerated (lbs/hr) _____ Design Capacity (lbs/hr) _____

Approximate Number of Hours of Operation per day _____ day/wk _____ wks/yr. _____

Manufacturer _____

Date Constructed _____ Model No. _____

	Volume $(ft)^3$	Heat Release (BTU/hr)	Fuel		Temperature (°F)
			Type	BTU/hr	
Primary Chamber					
Secondary Chamber					

Stack Height: _____ ft. Stack Diamter: _____ Stack Temp. _____

Gas Flow Rate: _____ ACFM _____ DSCFM* Velocity: _____ FPS

*If 50 or more tons per day design capacity, submit the emissions rate in grains per standard cubic foot dry gas corrected to 50% excess air.

Type of pollution control device: [ ] Cyclone [ ] Wet Scrubber [ ] Afterburner

[ ] Other (specify) _____

Brief description of operating characteristics of control devices: _____

_____

_____

_____

_____

Ultimate disposal of any effluent other than that emitted from the stack (scrubber water, ash, etc.):

_____

_____

_____

_____

NOTE: Items 2, 3, 4, 6, 7, 8, and 10 in Section V must be included where applicable.

SECTION V: SUPPLEMENTAL REQUIREMENTS

Please provide the following supplements where required for this application.

1. Total process input rate and product weight -- show derivation [Rule 17-2.100(127)]

2. To a construction application, attach basis of emission estimate (e.g., design calculations, design drawings, pertinent manufacturer's test data, etc.) and attach proposed methods (e.g., FR Part 60 Methods 1, 2, 3, 4, 5) to show proof of compliance with applicable standards. To an operation application, attach test results or methods used to show proof of compliance. Information provided when applying for an operation permit from a construction permit shall be indicative of the time at which the test was made.

3. Attach basis of potential discharge (e.g., emission factor, that is, AP42 test).

4. With construction permit application, include design details for all air pollution control systems (e.g., for baghouse include cloth to air ratio; for scrubber include cross-section sketch, design pressure drop, etc.)

5. With construction permit application, attach derivation of control device(s) efficiency. Include test or design data. Items 2, 3 and 5 should be consistent: actual emissions = potential (1-efficiency).

6. An 8 1/2" x 11" flow diagram which will, without revealing trade secrets, identify the individual operations and/or processes. Indicate where raw materials enter, where solid and liquid waste exit, where gaseous emissions and/or airborne particles are evolved and where finished products are obtained.

7. An 8 1/2" x 11" plot plan showing the location of the establishment, and points of airborne emissions, in relation to the surrounding area, residences and other permanent structures and roadways (Example: Copy of relevant portion of USGS topographic map).

8. An 8 1/2" x 11" plot plan of facility showing the location of manufacturing processes and outlets for airborne emissions. Relate all flows to the flow diagram.

9. The appropriate application fee in accordance with Rule 17-4.05. The check should be made payable to the Department of Environmental Regulation.

10. With an application for operation permit, attach a Certificate of Completion of Construction indicating that the source was constructed as shown in the construction permit.

SECTION VI: BEST AVAILABLE CONTROL TECHNOLOGY

A. Are standards of performance for new stationary sources pursuant to 40 C.F.R. Part 60 applicable to the source?

[ ] Yes [ ] No

Contaminant	Rate or Concentration

B. Has EPA declared the best available control technology for this class of sources (If yes, attach copy)

[ ] Yes [ ] No

Contaminant	Rate or Concentration

C. What emission levels do you propose as best available control technology?

Contaminant	Rate or Concentration

D. Describe the existing control and treatment technology (if any).

1. Control Device/System:
2. Operating Principles:
3. Efficiency:*
4. Capital Costs:

*Explain method of determining

5. Useful Life:

6. Operating Costs:

7. Energy:

8. Maintenance Cost:

9. Emissions:

Contaminant	Rate or Concentration

10. Stack Parameters

a. Height: ft.

b. Diameter: ft.

c. Flow Rate: ACFM

d. Temperature: °F.

e. Velocity: FPS

E. Describe the control and treatment technology available (As many types as applicable, use additional pages if necessary).

1.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

2.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

3.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

4.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Costs:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

k. Ability to construct with control device, install in available space, and operate within proposed levels:

F. Describe the control technology selected:

1. Control Device:

2. Efficiency:[1]

3. Capital Cost:

4. Useful Life:

5. Operating Cost:

6. Energy:[2]

7. Maintenance Cost:

8. Manufacturer:

9. Other locations where employed on similar processes:

a. (1) Company:

(2) Mailing Address:

(3) City:

(4) State:

[1]Explain method of determining efficiency.
[2]Energy to be reported in units of electrical power - KWH design rate.

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

b. (1) Company:

(2) Mailing Address:

(3) City: (4) State:

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

10. Reason for selection and description of systems:

[1]Applicant must provide this information when available. Should this information not be available, applicant must state the reason(s) why.

SECTION VII - PREVENTION OF SIGNIFICANT DETERIORATION

A. Company Monitored Data

1. _____no. sites _____ TSP _____( ) SO^{2}* _____ Wind spd/dir

Period of Monitoring _____/_____/_____ to _____/_____/_____
month day year month day year

Other data recorded _____

Attach all data or statistical summaries to this application.

*Specify bubbler (B) or continuous (C).

2. Instrumentation, Field and Laboratory

a. Was instrumentation EPA referenced or its equivalent? [ ] Yes [ ] No

b. Was instrumentation calibrated in accordance with Department procedures?

[ ] Yes [ ] No [ ] Unknown

B. Meteorological Data Used for Air Quality Modeling

1. _____ Year(s) of data from _____/_____/_____ to _____/_____/_____
month day year month day year

2. Surface data obtained from (location)_____

3. Upper air (mixing height) data obtained from (location)_____

4. Stability wind rose (STAR) data obtained from (location)_____

C. Computer Models Used

1. _____ Modified? If yes, attach description.

2. _____ Modified? If yes, attach description.

3. _____ Modified? If yes, attach description.

4. _____ Modified? If yes, attach description.

Attach copies of all final model runs showing input data, receptor locations, and principle output tables.

D. Applicants Maximum Allowable Emission Data

Pollutant	Emission Rate	
TSP	_____	grams/sec
SO^2	_____	grams/sec

E. Emission Data Used in Modeling

Attach list of emission sources. Emission data required is source name, description of point source (on NEDS point number), UTM coordinates, stack data, allowable emissions, and normal operating time.

F. Attach all other information supportive to the PSD review.

G. Discuss the social and economic impact of the selected technology versus other applicable technologies (i.e., jobs, payroll, production, taxes, energy, etc.). Include assessment of the environmental impact of the sources.

H. Attach scientific, engineering, and technical material, reports, publications, journals, and other competent relevant information describing the theory and application of the requested best available control technology.

Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

C E R T I F I C A T E

To Whom It May Concern:

This is to certify that Robert A. Franke, Director of Engineering of Key Pharmaceuticals, Inc., is duly authorized to represent Key Pharmaceuticals, Inc., along with his designate, Thomas W. Flachmeyer, Manager Environmental Engineering and Waste Management; for the purposes of making Application for Permit to Construct or Operate Pollution Control Facilities for said company.

Key Pharmaceuticals, Inc.

James R. Confroy, Vice President

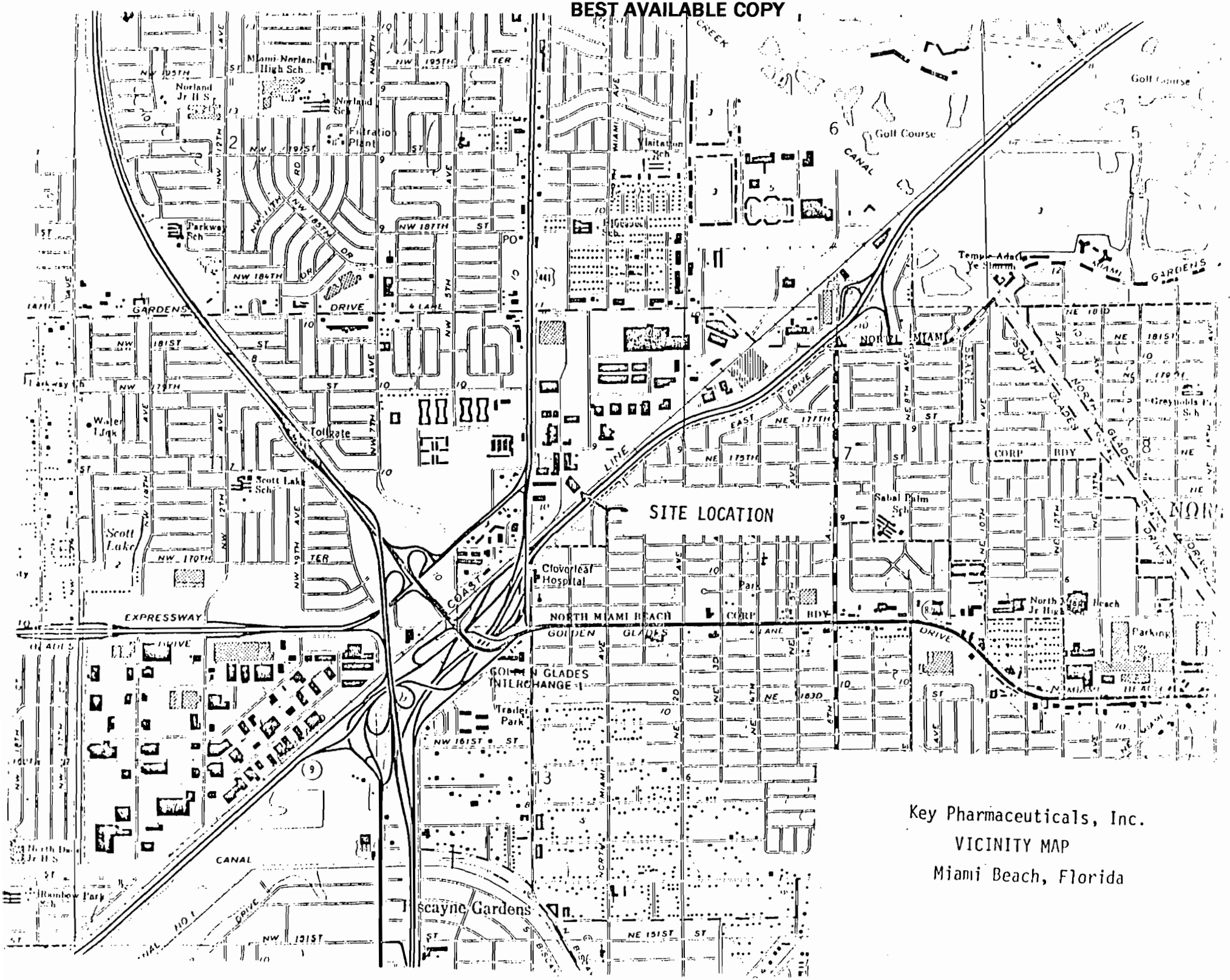
Miami and Puerto Rico Operations

JRC/db

STATE OF FLORIDA
COUNTY OF DADE
Sworn to and subscribed before me
this 21st day of October A.D. 1986.

NOTARY PUBLIC STATE OF FLORIDA
MY COMMISSION EXP. DEC 18,1989
BONDED THRU GENERAL INS. UND.

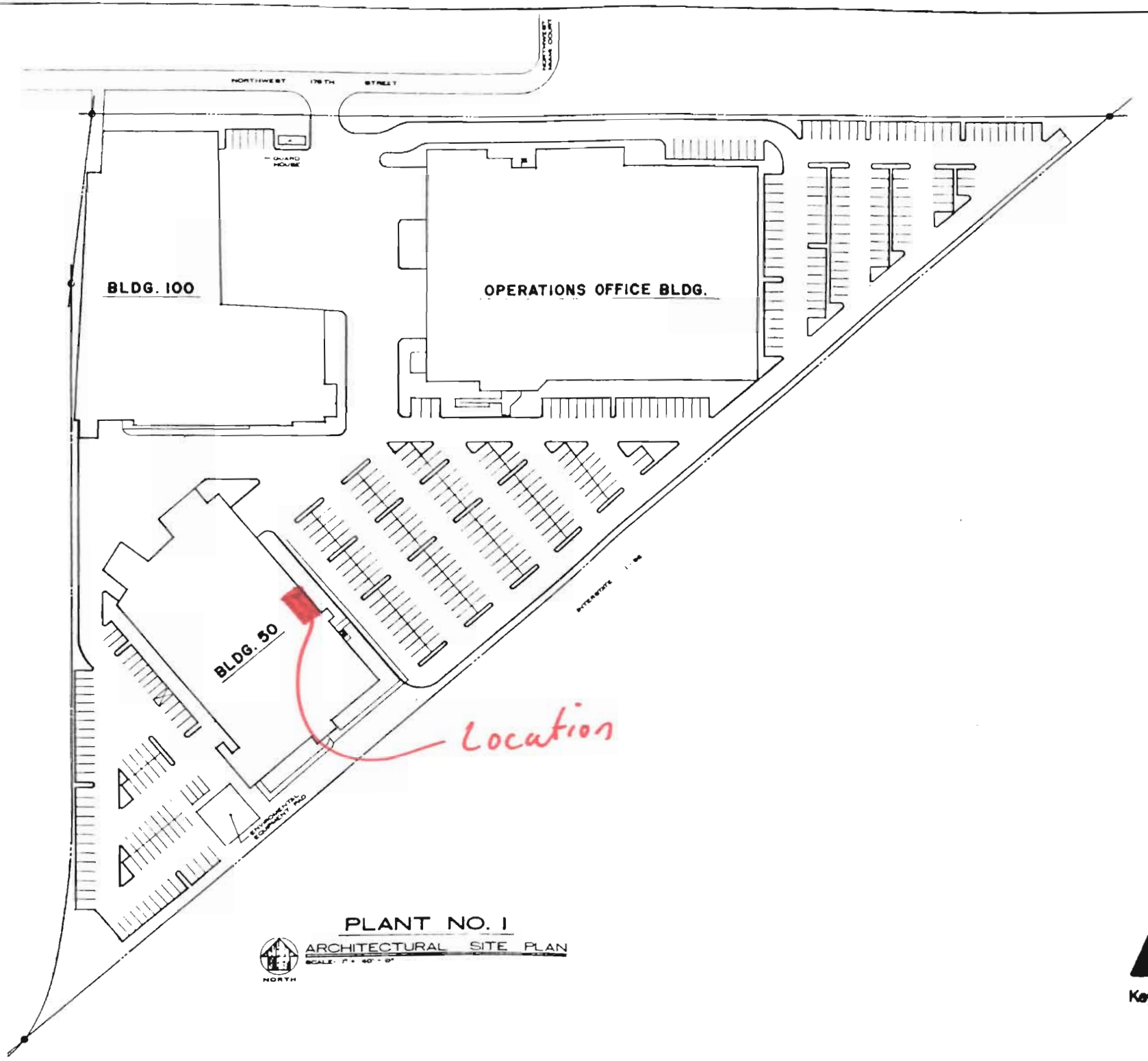
BEST AVAILABLE COPY



Key Pharmaceuticals, Inc.

VICINITY MAP

Miami Beach, Florida

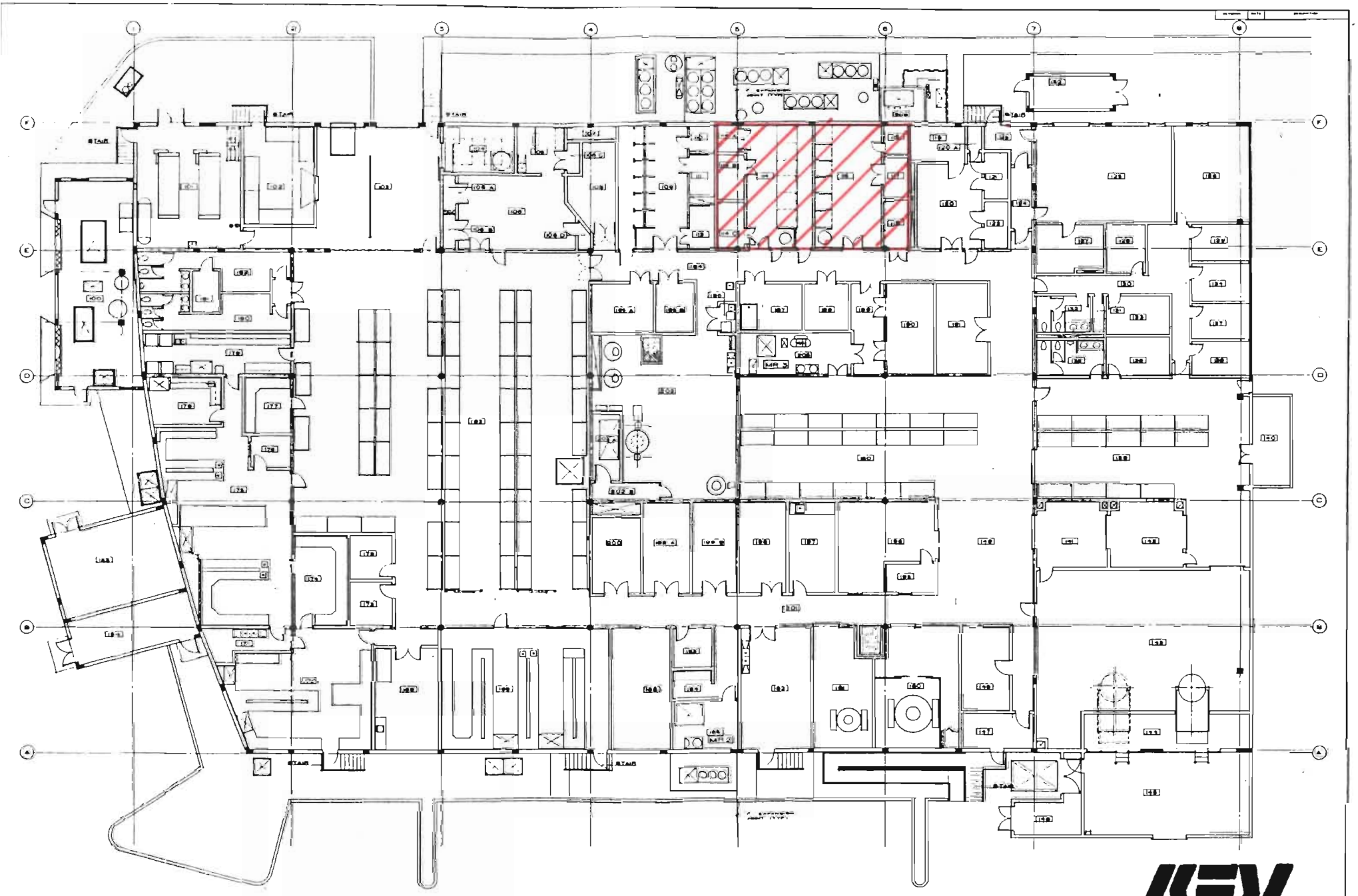


PLANT NO. 1

ARCHITECTURAL SITE PLAN

SCALE: 1" = 60'-0"

Key Pharmaceuticals, Inc.



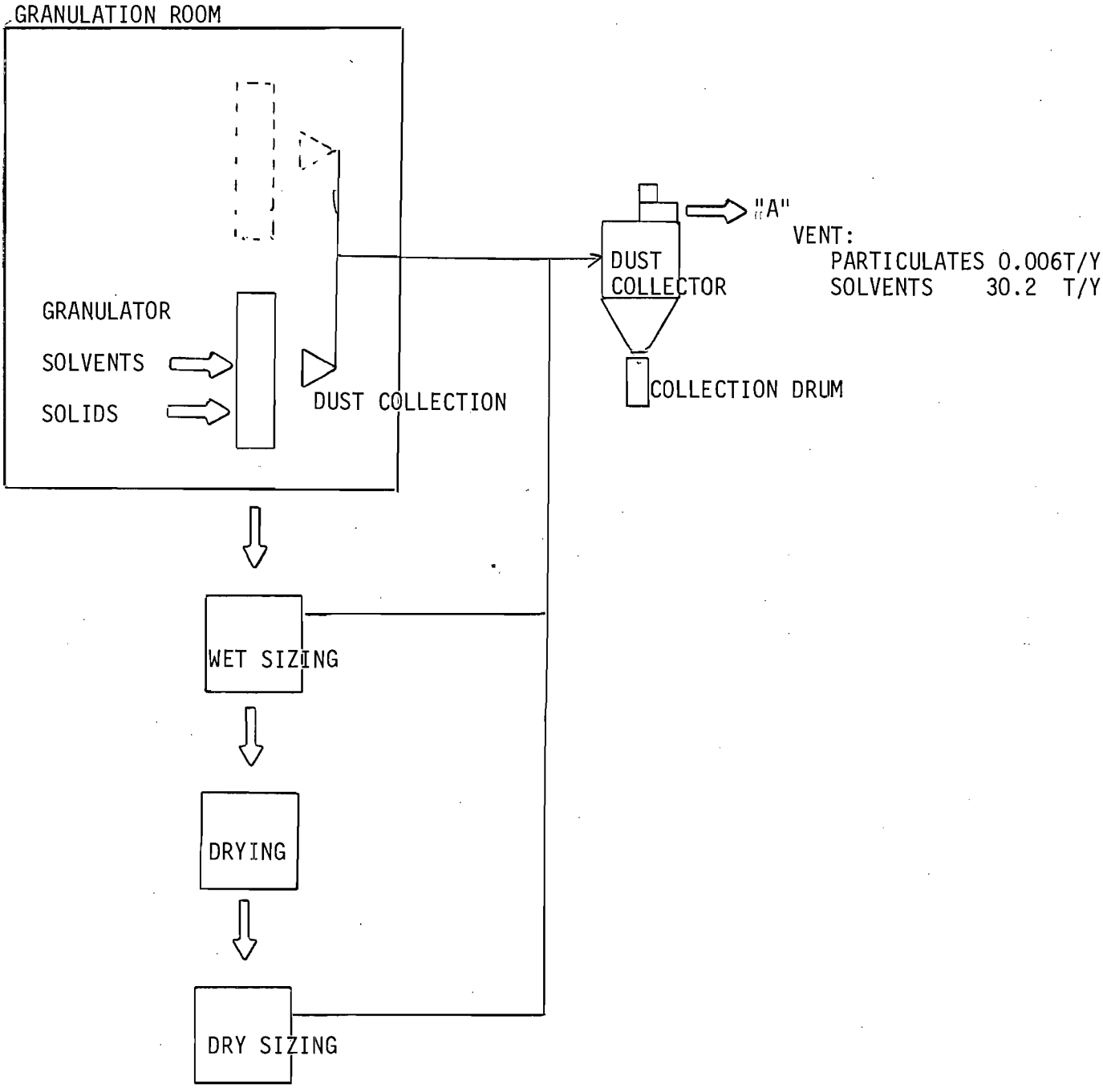
BUILDING 50 FLOOR PLAN

Key Pharmaceuticals, Inc.

CHARGE Solvent Granulation DATE 1-18-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 1 of 1 FILE NO. _____

SUBJECT Process Flow - Solvent Granulation



CHARGE Granulation - Solvents DATE 1-19-87

PREPARED BY TWF CHECKED BY _____ SHEET NO. 1 of 1 FILE NO. _____

SUBJECT Emission Calculation for Solvent Granulation

Basis:

Machine maximum capacity for solvent granulations - 300 kg

1 Granulation machine

1 lot cycle is 24 Hrs including drying

Lot Specification

300 kg Solids

75 kg IPA or 3A Alcohol

Maximum thruput 120.7 Tons/year solids
30.2 Tons/year VOC

Emissions

VOC - Emission Potential 30.2 T/y

No emission control

Annual Emissions 30.2 T/y

6.9 lb/Hr

Solids - Emission Potential (½ of 1% of Solids) 0.6 T/y

Dust Collector Design - 99% removal efficiency

Annual Emissions 0.006 T/y
0.001 lb/Hr

PM
12-9-86
Gainesville, FL

129893

Air Consulting and Engineering

DER
DEC 9 1986
BAQM

December 5, 1986
174 86 01

Mr. Willard Hanks
Florida Department of
Environmental Regulation
Twin Tower Office Building
2600 Blair Stone Road
Tallahassee, Florida 32301

Dear Mr. Hanks:

We wish to inform you that the compliance test scheduled to be performed at Key Pharmaceutical's methanol reduction system in Miami, Florida, on December 10 and 20, 1986, has been postponed to a later date. At this time, we have scheduled the testing for January 8 and 9, 1987. Should this date not be convenient for you, please let us know at your earliest convenience so that we may reschedule.

Thank you for your cooperation.

Sincerely,

AIR CONSULTING AND ENGINEERING

Carolyn T. Graham

Carolyn T. Graham
Office Manager

/ctg

cc: Mr. Tom Flachmeyer,
Key Pharmaceuticals

2106 N.W. 67th Place, Suite 4 • Gainesville, Florida 32606 • (904) 335-1889