

Check Sheet

Company Name: Key Pharmaceuticals, Inc.
Permit Number: AC 13-115383, 116005
PSD Number: _____
Permit Engineer: _____

Application:

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

Cross References:

-
-
-

Intent:

- Intent to Issue
- Notice of Intent to Issue
- Technical Evaluation
- BACT Determination
- Unsigned Permit

Correspondence with:

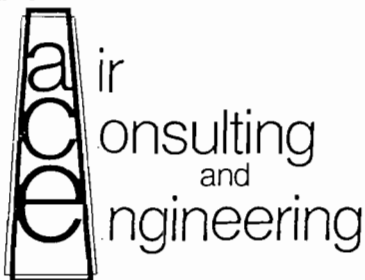
- EPA
- Park Services
- Other
- Proof of Publication
- Petitions - (Related to extensions, hearings, etc.)
- Waiver of Department Action
- Other

Final Determination:

- Final Determination
- Signed Permit
- BACT Determination
- Other

Post Permit Correspondence:

- Extensions/Amendments/Modifications
- Other



November 20, 1986
174 86 01

DER
NOV 24 1986
BAQM

Mr. Willard Hanks
Florida Department of
Environmental Regulation
Twin Tower Office Building
2600 Blair Stone Road
Tallahassee, Florida 32301

RE: Key Pharmaceutical's Methanol Reduction System Compliance Testing
(A0-13-114316)

Dear Mr. Hanks:

I wish to once again amend our proposed test protocol for the referenced project for purposes of facilitating protocol review. We will use the Tedlar[™] bag technique for this testing as described in Environmental Protection Agency (EPA) Method 18 (7.1.1.2). Due to the expected stack gas moisture percentage of about 10%, the sampling system will be modified to allow for simultaneous dilution of the sample with zero grade air or nitrogen (7.1.4). The sampling rate of stack gases will be 0.5 liters per minute (lpm) and the diluent gas rate will be 1.0 lpm although a higher dilution ratio may prove necessary to avoid moisture condensation. Three replicate test runs of nominally 1 hour in duration will be conducted.

EPA Methods 1 and 2 velocity and temperature measurements will also be conducted at the methanol scrubber outlet. A temporary stack extension will be utilized at this point to allow for two (2) ports at 90°. Stack gas moisture percentages will be determined by saturation vapor measure.

Envirofact, Inc., of Miami, Florida, will perform the sample analyses as per Method 18. Analysis will be performed within a 2-12 hour period following testing.

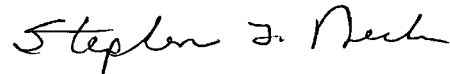
Should you wish to arrange for one or more audit samples to be analyzed in conjunction with this project, we have estimated the methanol concentrations to be approximately 350 ppm by volume.

Mr. Willard Hanks
November 20, 1986
Page 2

If you have any questions regarding this protocol, please contact me. We wish to perform this work sometime between December 10 and 20, 1986. We will advise you as to the exact date.

Respectfully,

AIR CONSULTING AND ENGINEERING

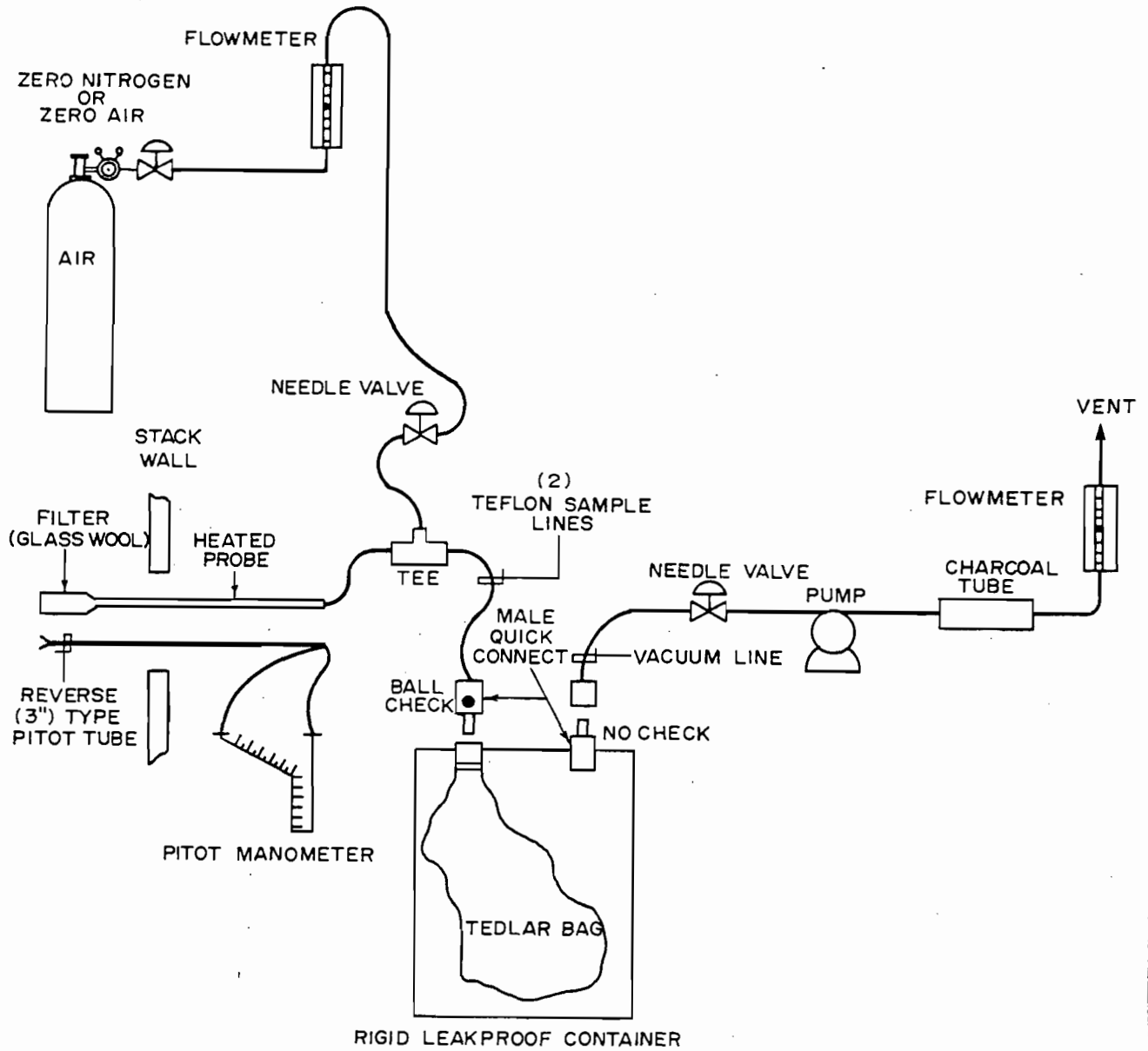


Stephen L. Neck, P.E.

SLN:ctg

attachment

cc: Mr. Tom Flachmeyer, Key Pharmaceuticals
Mr. Tom Tittle, FDER/WPB



ATTACHMENT A
PROPOSED METHANOL
SAMPLING TRAIN
KEY PHARMACEUTICALS

AIR CONSULTING
and ENGINEERING



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

October 21, 1986

Mr. Willard Hanks
Florida Department of
Environmental Regulations
Twin Tower Office Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

DER
OCT 31 1986
BAQM

Dear Mr. Hanks:

As you may be aware, over the last 6 months several major changes have occurred at Key Pharmaceuticals. These changes include the merger of the Corporation with Schering-Plough Corporation and numerous changes in personnel and responsibilities. I would therefore like to inform you of the following:

CORPORATE NAME: KEY PHARMACEUTICALS, INC.

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

PHONE: 305-654-2200

CORPORATE VICE PRESIDENT,
MIAMI & PUERTO RICO OPERATIONS: Mr. James R. Confroy

CORPORATE VICE PRESIDENT,
RESEARCH & DEVELOPMENT: Dr. Allan S. Kaplan

MANAGER OF ENVIRONMENTAL
ENGINEERING & WASTE MANAGEMENT: Mr. Thomas W. Flachmeyer

Mr. Confroy is the Vice President responsible for the following Key Pharmaceutical locations:

- 50 N.W. 176th Street
Miami, FL 33169
- 100 N.W. 176th Street
Miami, FL 33169
- 13900 N.W. 57th Court
Miami Lakes, FL 33104

Dr. Kaplan is the Vice President responsible for the following Key Pharmaceutical locations:

- 999 N.W. 159th Drive
Miami, FL 33169
- 1500 S.W. 66th Avenue
Pembroke Pines, FL 33023

Mr. Flachmeyer is responsible for the environmental activities at all Key Pharmaceutical locations.

Please reflect these personnel changes in all currently active permits for Key Pharmaceuticals and in all future correspondence.

Should you have any questions concerning this matter or anything else concerning Key Pharmaceuticals, please do not hesitate to call me at (305) 654-2240.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas W. Flachmeyer", with a long horizontal flourish extending to the right.

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

cc: Ms. S. Brooks



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.



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.

Dr. Allan S. Kaplan, Corporate
Vice President, Research and Development
ASK/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.

To BT 6/10/86

State of Florida
DEPARTMENT OF ENVIRONMENTAL REGULATION

INTEROFFICE MEMORANDUM

For Routing To District Offices And/Or To Other Than The Addressee		
To: _____	Loctn.: _____	
To: _____	Loctn.: _____	
To: _____	Loctn.: _____	
From: _____	Date: _____	
Reply Optional	Reply Required	Info. Only
Date Due: _____	Date Due: _____	

TO: Stephanie Brooks
THRU: Bill Thomas
FROM: Willard Hanks *umd*
DATE: June 10, 1986
SUBJ: Key Pharmaceuticals (AC 13-116005)

In response to your April 11, 1986, memorandum on Key's Accela-Cota Coating Pan process, BAQM's comments are:

SC #1 - The weight per lot, in this permit, should be considered an adjective, not a limit. The source would not be subject to different regulations or standards with heavier lots. Although the number of lots produced would have to increase significantly before the VOC emissions would subject the process to different regulations and standards, BAQM recommends any permit (construction or operation) for this source contain a cap on the number of lots. In this case, a higher number of lots can be authorized in the permit to operate provided the increase in VOC emissions does not subject the source to new regulations or, in SEFD judgement, different control requirements.

SC #1, 2, and 3 - In general, the department should be the office that issued the permit. In this case, SEFD could have issued the construction permit (a minor source at a minor facility). BAQM suggest SEFD handle any minor revisions for the source in the permit to operate.

SC #5 - This condition, basically, quotes the regulation. Generally, ambient air standards (which objectionable odors are similar to) are not enforced on plant property that the public does not have access to.

SC #7 - Any change to the process that does not subject the source to new regulations or, in SEFD judgement, a new standard or control can be authorized in the permit to operate. When a new regulation or standard is appropriate, a new construction permit, with public notice, will be required.

Please call me if you need more clarification on this matter.

WH/ks



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: Willard Hanks

FROM: Stephanie S. Brooks *Stephanie S Brooks*

DATE: April 11, 1986

RE: Key Pharmaceuticals AC 13-116005

The SEFD had the following comments:

SC #1 Are we limiting the weight of the lots in addition to the number of lots?

SC #1, 2 & 3 Who is the department?

SC #5 Should this state "... no objectionable odors off-site"?

SC #6 Is the calculated VOC emission is lbs./day and average number? This condition will not provide resonable assurance of compliance with SCs 1 and 2.

SC #7 If a new construction permit is required, we feel there shouldn't have to be a public notice period.

SSB:js:j2

DER

APR 16 1986

JAQM

P 408 532 124

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to Mr. Allen F. Gant	
Street and No.	
P.O., State and ZIP Code	
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 5/28/86	

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:
Mr. Allen F. Gant
Key Pharmaceuticals, Inc.
50 N.W. 176th St.
Miami, FL 33169

4. Type of Service:	Article Number
<input type="checkbox"/> Registered <input type="checkbox"/> Insured <input checked="" type="checkbox"/> Certified <input type="checkbox"/> COD <input type="checkbox"/> Express Mail	P 408 532 124

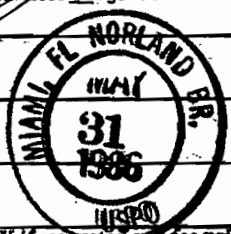
Always obtain signature of addressee or agent and **DATE DELIVERED.**

5. Signature - Addressee
X *Allen F. Gant*

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 32301-8241

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION
NOTICE OF PERMIT

Mr. Allen F. Gant
Vice President Production and Engineering
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169


May 28, 1986

Enclosed are Permit Numbers AC 13-116005 and AC 13-115383 to Key Pharmaceuticals, Inc. for the installation of a coating pan process and for the manufacture of GUANIDINE and QUINORA tablets at the Key Pharmaceuticals facilities in Miami, Dade County, Florida. These permits are issued pursuant to Section 403, Florida Statutes.

Any Party to these permits has 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 32301; 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

Copies furnished to:

Isidore Goldman
Patrick Wong

CERTIFICATE OF SERVICE

This is to certify that this NOTICE OF PERMIT and all copies were mailed before the close of business on May 28, 1986 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.

Patricia S. Adams
Clerk

May 28, 1986
Date

Final Determination

Key Pharmaceuticals, Inc.
Miami, Florida
Dade County

Accela-Cota Coating Pan
Permit No. AC 13-116005

Manufacture of GUANIDINE and QUINORA Tablets
Permit No. AC 13-115383

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

May 23, 1986

Final Determination

The Technical Evaluation and Preliminary Determinations for the Accela-Cota Coating Pan and manufacture of GUANIDINE and QUINORA Tablets projects were distributed on March 28, 1986, and April 2, 1986, respectively. Copies of the evaluations were available for public inspection at the Department's offices in West Palm Beach and Tallahassee and Dade County's Department of Environmental Resources Management's office in Miami. The Notice of Proposed Agency Action on the permit applications was published in the Miami News on April 18, 1986. No comments were received on the Department's intent to issue the construction permits. The final action of the Department will be to issue the construction permits for the projects as proposed in the Technical Evaluation and Preliminary Determinations.

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32301-8241



BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

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

Permit Number: AC 13-115383
Expiration Date: September 30, 1986
County: Dade
Latitude/Longitude: 25° 56' 03" N
80° 11' 42" W
Project: Manufacture of GUANIDINE
and QUINORA Tablets

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 manufacture two lots (231 lb/lot) of GUANIDINE tablets and eleven lots (878 lb/lot) of QUINORA tablets per year with existing granulation, wet sizing, drying, dry sizing, blending, compression, and packaging process equipment which uses a dust collector to control air pollution. This equipment is located at the pharmaceutical plant at 50 NW 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 operation shall be in accordance with the attached permit application, plans, documents and drawing except as noted in the specific conditions of this permit.

Attachments:

1. Application to Construct Air Pollution Sources, DER form 17-1.202(1), received January 29, 1986.
2. Key Pharmaceuticals, Inc. letter dated February 13, 1986.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-115383
Expiration Date: September 30, 1986

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.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-115383
Expiration Date: September 30, 1986

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.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-115383
Expiration Date: September 30, 1986

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.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-115383
Expiration Date: September 30, 1986

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. Production shall not exceed 2 lots of GUANIDINE (231 lb/lot) and 11 lots of QUINORA (878 lb/lot) per calendar year without prior approval of the department.
2. Production of these drugs is limited to 420 hour per year unless additional operation time is approved by the department.
3. Visible emissions from the process equipment and dust collector for this operation shall not exceed 5 percent opacity as determined by Method 9 which is described in 40 CFR 60, Appendix A.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-115383
Expiration Date: September 30, 1986

SPECIFIC CONDITIONS:

4. Volatile organic compounds emission from this process, as determined by a raw material balance, shall be calculated on a daily basis and not exceed 1 TPY.
5. This process shall not cause, suffer, allow or permit the discharge of air pollutants which cause or contribute to an objectionable odor.
6. These drugs shall not be manufactured unless the dust collection system is operating properly.
7. The permittee shall comply with all conditions of consent order No. 84-0644 (originally No. 83-0373).
8. Allowable VOC emissions from Glatts 1, 2, and 3, as authorized by permit No. AC 13-100437, shall not exceed 35 TPY.
9. The permittee will demonstrate compliance with the conditions of this construction permit and submit a complete application for permit to operate to the Southeast District office 90 days prior to the September 30, 1986, expiration date of this construction permit or 60 days after the new drugs are manufactured, whichever date occurs first. The permittee may continue to operate in compliance with all terms of this construction permit until its expiration data.
10. Any permit to operate issued for this process shall require annual operation reports which include, as a minimum, the annual VOC emissions from the manufacture of these drugs.

Issued this 23 day of May,
1986.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL REGULATION


VICTORIA J. TSCHINKEL, Secretary

___ pages attached.

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32301-8241



BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

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

Permit Number: AC 13-116005
Expiration Date: October 1, 1986
County: Dade
Latitude/Longitude: 25° 55' 26" N
80° 12' 58" W
Project: Coating Pan 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:

Installation of a coating pan process consisting of an agitated mixing vessel, spray unit, Accela-Cota Model 24-II coating pan, air handler unit, exhaust fan, and ducts at the permittee's existing research and development building located at 999 NW 159th Drive, Miami, Dade County, Florida. The UTM coordinates of this building are zone 17, 578.5 km E and 2867.4 km N.

The installation shall be in accordance with the attached permit application, plans, documents, and drawings except as noted in the specific conditions of this permit.

Attachments:

1. Application to Construct Air Pollution Source, DER form 17-1.202(1), received February 12, 1986.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-116005
Expiration Date: October 1, 1986

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.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-116005
Expiration Date: October 1, 1986

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.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-116005
Expiration Date: October 1, 1986

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.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-116005
Expiration Date: October 1, 1986

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. Production shall not exceed 130 lots/year of drugs (37.2 lbs/lot) without prior approval of the department.
2. Solvent used in the process, based on a material balance, is limited to 20.3 lbs/lot unless prior approval is obtained from the department.
3. The coating pan process shall not be used more than 1,040 hrs/year without prior approval of the department.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-116005
Expiration Date: October 1, 1986

SPECIFIC CONDITIONS:

4. Visible emissions from any component of the coating pan process shall not exceed 5 percent opacity as determined by Method 9 which is described in 40 CFR 60, Appendix A.

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

6. Any permit to operate issued for the coating pan system shall require annual reports which include, as a minimum, the number of drug lots manufactured with the coating pan process and the calculated VOC emissions in lb/day and TPY.

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)

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)

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)

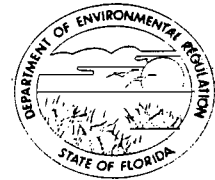
Issued this 23 day of May,
1986

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL REGULATION


VICTORIA J. TSCHINKEL, Secretary

___ pages attached.

State of Florida
DEPARTMENT OF ENVIRONMENTAL REGULATION



Interoffice Memorandum

TO: Victoria J. Tschinkel
FROM: Clair Fancy *Clair Fancy*
DATE: May 21, 1986
SUBJ: Approval of Air Construction Permits

FOR ROUTING TO OTHER THAN THE ADDRESSEE	
To: _____	LOCTN: _____
To: _____	LOCTN: _____
To: _____	LOCTN: _____
From: _____	DATE: _____

Attached for your approval and signature are two Air Construction Permits to Key Pharmaceuticals, Inc. for the installation of a coating pan process and the manufacture of GUANIDINE and QUINORA tablets at the Key Pharmaceuticals facilities in Miami, Dade County, Florida.

Day 90, after which the permits would be issued by default, is June 20, 1986.

The Bureau recommends your approval and signature.

CF/pa

Attachments

DER DER
MAY 27 1986 MAY 2 1986
BAQM B7 M



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

April 21, 1986

Mr. C.H. Fancy, Deputy Chief
Bureau of Air Quality Management
Department of Environmental Regulation
2600 Blair Stone Road
Tallahassee, FL 32301-8241

RE: CONSTRUCT PERMIT AC 13-115383 and 116005

Dear Mr. Fancy:

As per the construction permit requirements, the public notice for both referenced permits was published in the Legal Ad Section of the Miami News on Friday, April 18, 1986. Therefore, the thirty (30) day public notice time should end on May 18, 1986. Attached is the page (12-C) from the Miami News to corroborate the above.

If there are any questions, please contact me.

Very truly yours,

KEY PHARMACEUTICALS, INC.

Stephen J. Goodstein, Manager
Environmental Engineering and
Waste Management

SJG/db

enclosure

cc: W. Smyth
R.A. Franke
T. Flachmeyer
E. Borbe
E. Mittleberg
P. Rothchild
C. Newcomb

DER
APR 25 1986
BAQM

100 ANNOUNCEMENTS



116 Legal Notices

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

The Department of Environmental Regulation gives notice of its intent to issue two permits to Key Pharmaceuticals, Inc. for the following:

1. To install a coating pan at Key Pharmaceuticals, Inc R & D laboratory at 999 N.W. 159th Drive, Miami (Dade County), Florida. The pan will emit 1.32 TPY VOC. A determination of best available control technology (BACT) was not required.

2. For the manufacture of QUINORA tablets at Key Pharmaceuticals, Inc. existing pharmaceutical plant located at 50 N.W. 176 Street, Miami (Dade County), Florida. The manufacture of these products will result in emissions of less than 1 TPY VOC. 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 Chapter 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 constitutes 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. Therefore persons who may not wish to file a petition may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Model Rule 28-5.207, Florida Administrative Code, 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, 8:00AM-5:00PM, Monday through Friday, except legal holidays, at:

DEPARTMENT OF ENVIRONMENTAL REGULATION Bureau of Air Quality Management 2600 Blair Stone Road Tallahassee, FL 32301 DEPARTMENT OF ENVIRONMENTAL REGULATION Southeast Florida District 3301 Gun Club Road West Palm Beach, Florida, 33402

DADE COUNTY DEPARTMENT OF ENVIRONMENTAL RESOURCES MANAGEMENT 111 N.W. First Avenue Miami FL 33128

Any person may send written comments on the proposed action to Mr. Bill Thomas 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 18, 1986 Ad No: 039-340N

Vertical text on the right side of the page, including 'A N', 'er', 'VE', 'Jer', 'Ger', 'cha', 'A', 'JC', 'Apri', 'VD', 'JMI', 'SE', '33', 'Jc', '140', 'FOI', 'to', 'w', 'gt', 'A', '142', 'FOI', 'm', 'St', '25', 'FOI', 've', 'ho', 'wk'.



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

April 14, 1986

Mr. C.H. Fancy
Deputy Chief
Bureau of Air Quality Management
State of Florida Department of
Environmental Regulation
2600 Blair Stone Road
Tallahassee, Florida 32301-8241

RE: CONSTRUCTION PERMITS AC-13-116005 and 115383

Dear Mr. Fancy:

Attached please find the proposed submission for publication to the Miami News for the two referenced permits. The two were combined into one publication for convenience. If there are any problems with this, let me know immediately.

They are being published within the thirty (30) day period based on the March 28, 1986 date prepared in your offices. However, as they did not reach me until April 8, 1986, a petition for alteration by Key will not be prepared until after the 14-day comment period. It will be in your office by April 21, 1986.

In the future, all correspondence should be directed to William Smyth, Executive Director of Production or to me. Mr. Allen F. Gant has recently resigned.

All of the above matters have been discussed with Mr. Willard Hanks of your offices.

If there are any questions, please contact me.

Very truly yours,

Stephen J. Goodstein, Manager
Environmental Engineering and
Waste Management



SJG/db

attachment

cc: W. Smyth
R.A. Franke
E. Mittleberg
T. Flachmeyer
E. Borbe

DER

APR 18 1986

BAQM



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

The Department of Environmental Regulation gives notice of its intent to issue two permits to Key Pharmaceuticals, Inc. for the following:

1. To install a coating pan at Key Pharmaceuticals', Inc. R & D laboratory at 999 N.W. 159th Drive, Miami (Dade County), Florida. The pan will emit 1.32 TPY VOC. A determination of best available control technology (BACT) was not required.
2. For the manufacture of GUANIDINE and QUINORA tablets at Key Pharmaceuticals', Inc. existing pharmaceutical plant located at 50 N.W. 176th Street, Miami (Dade County), Florida. The manufacture of these products will result in emissions of less than 1 TPY VOC. 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 constitutes 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 proposed agency action. Therefore, persons who may not wish to file a petition may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Model Rule 28-5.207, Florida Administrative Code, 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 AM - 5:00 PM, Monday through Friday, except legal holidays, at:

DEPARTMENT OF ENVIRONMENTAL REGULATION
Bureau of Air Quality Management
2600 Blair Stone Road
Tallahassee, FL 32301

DEPARTMENT OF ENVIRONMENTAL REGULATION
Southeast Florida District
3301 Gun Club Road
West Palm Beach, FL 33402

DADE COUNTY DEPARTMENT OF ENVIRONMENTAL RESOURCES MANAGEMENT
111 N.W. First Avenue
Miami, FL 33128

Any person may send written comments on the proposed action to Mr. Bill Thomas 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.

P 408 533 205
 RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
 NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to Mr. Allen F. Gant	
Street and No.	
P.O., State and ZIP Code	
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 4/2/86	

PS Form 3800, Feb. 1982

PS Form 3811, July 1983

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.

- Show to whom, date and address of delivery.
- Restricted Delivery.

3. Article Addressed to:
 Mr. Allen F. Gant
 Key Pharmaceuticals, Inc.
 50 N.W. 176th Street
 Miami, FL 33169

4. Type of Service:	Article Number
<input type="checkbox"/> Registered <input checked="" type="checkbox"/> Certified <input type="checkbox"/> Express Mail	<input type="checkbox"/> Insured <input type="checkbox"/> COB 408 533 205

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 32301-8241



BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

March 28, 1986

CERTIFIED MAIL--RETURN RECEIPT REQUESTED

Mr. Allen F. Gant
Vice President Production and Engineering
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169

Dear Mr. Gant:

Attached is one copy of the Technical Evaluation and Preliminary Determination, and proposed permit to manufacture GUANIDINE and QUINORA 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

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 manufacture of GUANIDINE and QUINORA tablets at their existing pharmaceutical plant located at 50 N.W. 176th Street, Miami, Dade County, Florida. The manufacture of these products will result in emissions of less than 1 TPY VOC. 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 constitutes 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 proposed agency action. Therefore, persons who may not wish to file a petition may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Model Rule 28-5.207, Florida Administrative Code, 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
Bureau of Air Quality Management
2600 Blair Stone Road
Tallahassee, Florida 32301

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

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 13-115383

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 28, 1986, to the Department of Environmental Regulation for a permit to manufacture GUANIDINE and QUINORA tablets at their existing pharmaceutical plant in Miami, Dade County, Florida.

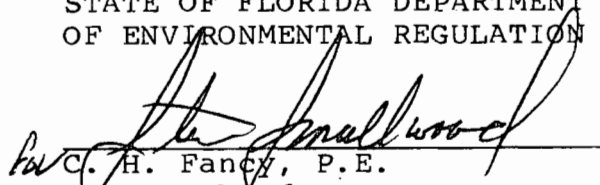
The Department has permitting jurisdiction under Chapter 403, Florida Statutes and Florida Administrative Code Rules 17-2 and 17-4. The project is not exempt from permitting procedures. The Department has determined that an air construction permit was needed for the proposed work.

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 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:

Mr. Allen F. Gant
Mr. Isidore Goldman
Mr. 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, 1986.

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.

Patricia G. Adams April 2, 1986
Clerk Date

DEPARTMENT RULES OF ADMINISTRATIVE PROCEDURE - NON-RULEMAKING 17-103

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 an administrative determination (hearing) under Section 120.57, F.S.

(4) Notice to substantially affected persons concerning applications for Department permits is an essential and integral part of the state environmental licensing process. Therefore, no application for a permit for which publication of notice is required shall be granted until and unless proof of publication of Notice is furnished to the appropriate Department permitting office.

(5)(a) Any applicant or person benefiting from the Department's action may elect to publish notice of proposed agency action in the manner provided by subsection (2) or (3). Any person who elects to publish notice of proposed agency action, upon presentation of proof of publication to the Department, prior to final agency action, shall be entitled to the same benefits under this rule as a person who is required to publish notice of proposed agency action. Since persons whose substantial interests are affected by a Department decision on a permit application may petition for an administrative proceeding within fourteen (14) days after receipt of notice and since, unless notice is given or published as prescribed in this rule, receipt of notice can occur at any time, the applicant or persons benefiting from the Department's action cannot justifiably rely on the finality of

the Department's decision without the notice having been duly given or published.

(b) The notices required by this rule may be combined with other notices required by the Department pursuant to Chapter 403, 376, or 253, F.S., or Chapter 17, FAC.

(c) The provisions of this section shall also apply to the permitting of hazardous waste facilities, but only to the extent it is consistent with Chapter 17-30, Part IV, FAC. Whenever Chapter 17-30, Part IV, FAC, provides for a different time or notice procedure than that set forth in this section the time and notice provisions of Chapter 17-30 shall govern.

(6) Failure to publish any notice of application, notice of proposed agency action, or notice of agency action required by the Department shall be an independent basis for the denial of a permit.
 Specific Authority: 120.53, 403.0376, 403.815, F.S. Law Implemented: 120.53, F.S.
 History: New 9-20-79, Amended 4-28-81, Transferred from 17-1.62 and Amended 6-1-84.

17-103.155 Petition for Administrative Hearing; Waiver of Right to Administrative Proceeding.

(1)(a) Any person whose substantial interests may be affected by proposed or final agency action may file a petition for administrative proceeding. A petition shall be in the form required by this Chapter and Chapter 28-5, FAC, and shall be filed (received) in the Office of General Counsel of the Department within fourteen (14) days of receipt of notice of proposed agency action or within fourteen (14) days of receipt of notice of

DEPT. RULES OF ADMINISTRATIVE PROCEDURE - NON-RULEMAKING 17-103

agency action whenever there is no public notice of proposed agency action. In addition to the requirements of Rule 28-5.201, FAC, the Petition must specify the county in which the project is or will be located.

(b) Failure to file a petition within fourteen (14) days of receipt of notice of agency action or fourteen (14) days of receipt of notice of proposed agency action, whichever first occurs, shall constitute a waiver of any right to request an administrative proceeding under Chapter 120, F.S.

(c) When there has been no publication of notice of agency action or notice of proposed agency action as prescribed in Rule 17-103.150, FAC, a person who has actual knowledge of the agency action or has knowledge which would lead a reasonable person to conclude that the Department has taken final agency action, has a duty to make further inquiry within fourteen (14) days of obtaining such knowledge by contacting the Department to ascertain whether action has occurred. The Department shall upon receipt of such an inquiry, if agency action has occurred, promptly provide the person with notice as prescribed by Rule 17-103.150, FAC. Failure of the person to make inquiry with the Department within fourteen (14) days after obtaining such knowledge may estop the person from obtaining an administrative proceeding on the agency action.

(2)(a) "Receipt of notice of agency action" means receipt of written notice of final agency action, as prescribed by Department rule, or the publication, pursuant to Department rule, of notice of final agency action, whichever first

occurs.

(b) "Receipt of notice of proposed agency action" means receipt of written notice (such as a letter of intent) that the Department proposes to take certain action, or the publication pursuant to Department rule of notice of proposed agency action, whichever first occurs.

(3) Notwithstanding any other provision in this Chapter, should a substantially affected person who fails to timely request a hearing under Section 120.57, F.S., administratively appeal the final Department action or order, the record on appeal should be limited to:

(a) the application, and accompanying documentation submitted by the applicant prior to the issuance of the agency's intent to issue or deny the requested permit.

(b) the materials and information relied upon by the agency in determining the final agency action or order;

(c) any notices issued or published; and

(d) the final agency action or order entered concerning the permit application.

(4) In such cases where persons do not timely exercise their rights accorded by Section 120.57(1), Florida Statutes, the allegations of fact contained in or incorporated by the final agency action shall be deemed uncontested and true, and appellants may not dispute the truth of such allegations upon subsequent appeal.

(5) Any applicant may challenge the Department's request for additional information by filing with the Office of General Counsel an appropriate petition for administrative proceeding pursuant to Section 120.60, F.S., following receipt by

GENERAL RULES OF ADMINISTRATIVE PROCEDURE - NON RULEMAKING, 17-103

the applicant of the Department's notification, pursuant to Section 403.0876, F.S., that additional information is required.

Specific Authority: 120.53, 403.0876, 403.815, F.S. Law

Implemented: 120.53, F.S.

History: New 9-20-79, Amended 4-28-81, Transferred from 17-1.62 and Amended 6-1-84.

17-103.160 Uniformity in Approval and Denial of Applications for Department Permits and Certifications. To the extent possible and consistent with the public interest, the Department approves and denies applications for permits and certifications on a uniform and consistent basis. Final Department actions on applications for permits and certifications shall be consistent with prior Department actions, unless deviation therefrom is explained by the Department in writing or the hearing officer who submits a recommended order to the Department for final agency action in accordance with Section 120.57, Florida Statutes.

Specific Authority: 120.53(1), F.S. Law Implemented: 120.53(1), 120.68(12), F.S. History: New 2-5-78, Transferred from 17-1.63, 6-1-84.

17-103.170 Designation, Preparation and Transmittal of Record for Administrative Appeals.

When any Department action or order is the subject of an administrative appeal under Chapter 17-103, Part II, FAC, the following requirements shall apply:

(1) Designation of Record. Within fifteen (15) days of rendition of the Department's final order, the appellant shall designate

to the Department, in writing, with copies to other parties, those documents or things under the control of or in the possession of the Department which the appellant desires to have included in the record, and which were received or considered in the Department proceeding below. If a proceeding was reported by mechanical recording devices, the appellant shall designate those portions of the proceeding for which it requires written transcription or tapes for transcription. Any other party may designate other portions of the record in the manner provided herein. Such cross-designation shall be filed with the Department, with copies provided other parties, within seven (7) days after receipt of the designation by the appellant.

(2) Original Record. The Department shall thereupon include in the record all of the designated portions of the original papers and exhibits in the proceedings or matter from which administrative appeal is taken, together with a copy of any such parts of the proceedings as were stenographically reported or transcribed from tapes, and as have been designated by the parties and certified by a notary public, the reporter, or other officer for inclusion in the record on appeal or review, and certified copies of the order, if any, of which review is sought. The Department may, at its discretion, substitute certified copies for original papers or documents in its possession.

(3) Preparation of Record. Upon tender or deposit by appellant of the estimated cost of preparation, the Department shall prepare the record in accordance with the designations of the parties. The cost of preparation, and reproduction,

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

Manufacture of GUANIDINE and QUINORA tablets
File No: AC13-115383

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

March 28, 1986

I. Application

A. Applicant

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

B. Request

Mr. Stephen J. Goodstein, Manager of Environmental Engineering and Waste Management for Key Pharmaceuticals, Inc., submitted an application for permit to construct dated January 21, 1986, for the manufacture of GUANIDINE and QUINORA tablets. The application was considered complete on receipt of their February 13, 1986, letter.

C. Project and Location

Key Pharmaceuticals, Inc. has requested permission to manufacture 462 lb/yr of GUANIDINE and 9,658 lb/yr of QUINORA tablets at their existing pharmaceutical plant (SIC 2834) located 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 tablets will be made with existing granulating, drying, sizing, compression and packaging equipment. An existing dust collection system will be used to control the emissions from the process.

D. Air Pollutant Emissions

Particulate matter (PM) and volatile organic compounds (VOC) are emitted during the manufacture of the tablets.

The process equipment is vented to a 4000 CFM Torit TD 2300 dust collector that is estimated to be 99 percent efficient in capturing particulate matter. The applicant estimates that less than 1 pound of particulate matter will be emitted during the 420 hours per year these tablets will be manufactured.

Isopropanol is used in the manufacture of GUANIDINE tablets. It is estimated that 154 lb/year of this alcohol will be used to manufacture these tablets. No VOC pollution control equipment will be installed on the process and all of this alcohol will escape to the atmosphere. The VOC emissions from this process are estimated to be 9.6 lb/hr and 0.08 tons/year.

Ethanol (3A alcohol) is used in the manufacture of QUANIDINE tablets. It is estimated that 1,760 lb/year of alcohol will be used in the manufacture of these tablets. The VOC emissions from this process will escape to the atmosphere and are estimated to be 20.0 lb/hr and 0.88 TPY.

In conjunction with this process, Key Pharmaceuticals, Inc. has requested the department reduce the allowable VOC emissions from other process equipment at this plant [Glatt units installed by AC 13-100437] from 40 TPY to 35 TPY.

The following tables shows the change in emissions associated with this project.

VOC-TPY

Source	Present	Proposed	Change *
Glatts	40	35.0	-5.0
GUANIDINE	0	0.08	+0.08
QUINORA	0	0.88	+0.88
Total	40	35.96	-4.04

* Potential PM emissions will increase by a total of less than 1 TPY from the GUANIDINE and QUINORA tablet manufacturing process. Other processes at this plant emit VOC.

As shown in the table, the manufacture of the new products will not result in a significant net emission increase of 40 TPY VOC at this facility.

II. Rule Applicability

A. State Regulations

The proposed project, manufacturing of GUANIDINE and QUINORA tablets, is subject to preconstruction review under the provisions of Chapter 403, Florida Statutes, and Chapter 17-2, Florida Administrative Code.

The pharmaceuticals plant 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 presently exceed 100 TPY. However, 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 and consent order No. 84-0644. Allowable particulate matter emissions shall be based on 17-2.610(1), the process weight table.

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

Dust generated by handling the ingredients used to make the tablets will be captured by a dust collector. The applicant estimates that less than 1 lb/year of particulate matter will escape to the atmosphere from this operation. The process weight table would allow up to 0.25 lb/hr of particulate matter emissions from this operation. However, emissions at this rate from these operations would be economically prohibitive to the company. The department will specify a surrogate emission standard of 5 percent opacity, as authorized by 17-2.700(1)(d)6., instead of a particulate matter standard for these operations. Less than 1 TPY of alcohols (VOC) will be used to manufacture the tablets. All of the alcohols will evaporate and escape to the atmosphere. Air pollution control equipment is not justified for this low of a rate of VOC emissions.

IV. Air Quality Analysis

The manufacture of the proposed products 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. Modeling shows that the concentration of alcohols in the atmosphere as a result of the manufacture of the tablets will be less than 1 percent of the recommended Threshold Limit Values-Time Weighted Average concentration (TLV-TWA). Although the department has not established ambient air quality standards for alcohols, other states have set standards of 1-2 percent of the TLV-TWA. Based on the analysis, the department has reasonable assurance that the emissions of alcohols from this process will not endanger public health.

V. Conclusion

Based on the data submitted by the permittee, the department has concluded that the emissions from the proposed process will comply with the state regulations. The department proposes to issue a construction permit that will authorize the proposed production. The General and Specific Conditions in the proposed permit (draft attached) will assure compliance of the new operations with the state air pollution control regulations.

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32301-8241



BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

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

Permit Number: AC 13-115383
Expiration Date: September 30, 1986
County: Dade
Latitude/Longitude: 25° 56' 03" N
80° 11' 42" W
Project: Manufacture of GUANIDINE
and QUINORA Tablets

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 manufacture two lots (231 lb/lot) of GUANIDINE tablets and eleven lots (878 lb/lot) of QUINORA tablets per year with existing granulation, wet sizing, drying, dry sizing, blending, compression, and packaging process equipment which uses a dust collector to control air pollution. This equipment is located at the pharmaceutical plant at 50 NW 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 operation shall be in accordance with the attached permit application, plans, documents and drawing except as noted in the specific conditions of this permit.

Attachments:

1. Application to Construct Air Pollution Sources, DER form 17-1.202(1), received January 29, 1986.
2. Key Pharmaceuticals, Inc. letter dated February 13, 1986.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-115383
Expiration Date: September 30, 1986

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.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-115383
Expiration Date: September 30, 1986

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.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-115383
Expiration Date: September 30, 1986

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.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-115383
Expiration Date: September 30, 1986

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. Production shall not exceed 2 lots of GUANIDINE (231 lb/lot) and 11 lots of QUINORA (878 lb/lot) per calendar year without prior approval of the department.
2. Production of these drugs is limited to 420 hour per year unless additional operation time is approved by the department.
3. Visible emissions from the process equipment and dust collector for this operation shall not exceed 5 percent opacity as determined by Method 9 which is described in 40 CFR 60, Appendix A.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-115383
Expiration Date: September 30, 1986

SPECIFIC CONDITIONS:

4. Volatile organic compounds emission from this process, as determined by a raw material balance, shall be calculated on a daily basis and not exceed 1 TPY.
5. This process shall not cause, suffer, allow or permit the discharge of air pollutants which cause or contribute to an objectionable odor.
6. These drugs shall not be manufactured unless the dust collection system is operating properly.
7. The permittee shall comply with all conditions of consent order No. 84-0644 (originally No. 83-0373).
8. Allowable VOC emissions from Glatts 1, 2, and 3, as authorized by permit No. AC 13-100437, shall not exceed 35 TPY.
9. The permittee will demonstrate compliance with the conditions of this construction permit and submit a complete application for permit to operate to the Southeast District office 90 days prior to the September 30, 1986, expiration date of this construction permit or 60 days after the new drugs are manufactured, whichever date occurs first. The permittee may continue to operate in compliance with all terms of this construction permit until its expiration date.
10. Any permit to operate issued for this process shall require annual operation reports which include, as a minimum, the annual VOC emissions from the manufacture of these drugs.

Issued this _____ day of _____,
19__.

**STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL REGULATION**

VICTORIA J. TSCHINKEL, Secretary

_____ pages attached.

P 408 533 208

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to Mr. Allen F. Gant	
Street and No.	
P.O., State and ZIP Code	
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 3/28/86	

PS Form 3800, Feb. 1982

PS Form 3811, July 1983

● **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.

- Show to whom, date and address of delivery.
- Restricted Delivery.

3. Article Addressed to:
Mr. Allen F. Gant
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169

4. Type of Service:	Article Number
<input type="checkbox"/> Registered <input type="checkbox"/> Insured <input checked="" type="checkbox"/> Certified <input type="checkbox"/> COD <input type="checkbox"/> Express Mail	P 408 533 208

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

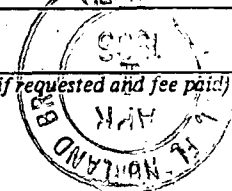
5. Signature — Addressee
X

6. Signature — Agent
X *Osvaldo M. ...*

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 32301-8241



BOB GRAHAM
GOVERNOR
VICTORIA J. TSCHINKEL
SECRETARY

March 28, 1986

CERTIFIED MAIL-RETURN RECEIPT REQUESTED


Mr. Allen F. Gant
Vice President Production and Engineering
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169

Dear Mr. Gant:

Attached is one copy of the Technical Evaluation and Preliminary Determination, and proposed permit to install a coating pan at your R & D laboratory 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. Pancy, P.E.
Deputy Chief
Bureau of Air Quality
Management

CHF/pa

Attachments

cc: Isidore Goldman
Patrick Wong

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 install a coating pan at Key Pharmaceuticals, Inc.'s R & D laboratory located at 999 NW 159th Drive, Miami, Dade County, Florida. The pan will emit 1.32 TPY VOC. 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 constitutes 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 proposed agency action. Therefore, persons who may not wish to file a petition may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Model Rule 28-5.207, Florida Administrative Code, 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
Bureau of Air Quality Management
2600 Blair Stone Road
Tallahassee, Florida 32301

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

Dade County Department of Environmental
Resources Management
801 S.W. 3rd Avenue
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 13-116005

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 February 12, 1986, to the Department of Environmental Regulation for a permit to install a coating pan at their existing R & D laboratory located at 999 NW 159th Drive, 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 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:

Mr. Allen F. Gant
Mr. Isidore Goldman
Mr. 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 _____.

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.

Clerk

Date

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

Accela-Cota Coating Pan
File No: AC 13-116005

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

March 27, 1986

I. Application

A. Applicant

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

B. Request

On February 12, 1986, Mr. Stephen J. Goodstein, Manager of Environmental Engineering and Waste Management, submitted an application for a permit to install a coating pan to manufacture drugs in a research and development facility. The application was considered complete on receipt.

C. Project and Location

Key Pharmaceuticals, Inc. has requested permission to install and operate an Accela-Cota coating pan in their research and development facility (SIC 2834) located at 999 NW 159th Drive, Miami, Dade County, Florida. The UTM coordinates of this site are zone 17, 578.5 km E and 2867.4 km N. Coatings, prepared in a mixing vessel, will be applied to tablets on a coating pan using a variety of slurries, suspensions or solutions. Air will be pulled through the drugs on the coating pan to evaporate and remove the solvents.

II. Rule Applicability

A. State Regulations

The proposed project, installation of a coating pan process, is subject to preconstruction review under the provisions of Chapter 403, Florida Statutes, and Chapter 17-2, Florida Administrative Code.

The proposed source will be located in an area designated nonattainment for ozone (Rule 17-2.410, FAC), and attainment for the other criteria pollutants (17-2.420).

Pharmaceutical plants, which are chemical process plants, are listed in Table 500-2, Major Facility Categories (list of 28). This plant is not a major facility (17-2.100) because it does not emit 100 TPY of any criteria pollutant.

Another major facility operated by the applicant has a compliance schedule approved by the department (17-2.510(4)(b)).

The project is not subject to the prevention of significant deterioration regulations (17-2.500) and 17-2.510(4) of the new source review for nonattainment areas (17-2.510) because it is a new minor facility (17-2.500(2)(d)1. and 17-2.510(2)(d)1.). An

emission standard is not specified for pharmaceutical plants in 17-2.650 (RACT). Therefore, the process will be required to comply with 17-2.620, General Pollutant Emission Limiting Standards.

B. Federal Regulations

The proposed project, a new minor source in an area designated nonattainment for ozone, is not subject to review under federal regulation 40 CFR 52.21.

III. Technical Evaluation

The applicant proposes to produce 130 lots of drugs per year with the coating pan process. Each lot will contain 35.2 lbs of substrate (tablets or pellets), 1.98 lbs of coating material, and use 20.3 lbs of solvent (50-100% VOC). The solvents used include acetone, isopropanol, ethyl acetate, ethanol, methylene chloride, and methanol.

The coating (1.98 lbs) and solvent (20.3 lbs) are blended in a mixing vessel and sprayed on the substrate (tablet or pellet) in the coating pan. Any fugitive emissions from the mixing vessel are confined indoors. Air is blown through the drugs on the coating pan. The air evaporates all of the solvent (VOC) and entrained traces of particulate matter (PM). An exhaust fan removes the contaminated air and discharges it through the roof of the building into the atmosphere.

The average emissions from the process are estimated at 1.27 to 2.54 lbs/hr of VOC and traces of PM. Maximum emissions are estimated to be 1.32 TPY VOC.

The use of air pollution control equipment is not justified for this small quantity of emissions.

IV. Air Quality Analysis

The project source will not result in a significant net emissions increase as set forth in Rule 17-2.500(2)(3)2., FAC. Therefore, no air quality analysis is required by the regulations. Modeling shows that the maximum increase ambient air concentration of the solvents proposed for this source will be less than 1 percent of the threshold limit value of the solvents. This concentration is considered safe.

V. Conclusion

Based on the data submitted by Key Pharmaceuticals, Inc., the department has concluded that the emissions from the coating pan process in the research and development building will comply with the state regulations. The department proposes to issue a

construction permit that will authorize the installation and operation of the proposed source. The General and Specific Conditions in the proposed permit (draft attached) will assure compliance of the new source with the air pollution control regulations.

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

TWIN TOWERS OFFICE BUILDING
2600 BLAIR STONE ROAD
TALLAHASSEE, FLORIDA 32301-8241



BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

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

Permit Number: AC 13-116005
Expiration Date: October 1, 1986
County: Dade
Latitude/Longitude: 25° 55' 26" N
80° 12' 58" W
Project: Coating Pan 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:

Installation of a coating pan process consisting of an agitated mixing vessel, spray unit, Accela-Cota Model 24-II coating pan, air handler unit, exhaust fan, and ducts at the permittee's existing research and development building located at 999 NW 159th Drive, Miami, Dade County, Florida. The UTM coordinates of this building are zone 17, 578.5 km E and 2867.4 km N.

The installation shall be in accordance with the attached permit application, plans, documents, and drawings except as noted in the specific conditions of this permit.

Attachments:

1. Application to Construct Air Pollution Source, DER form 17-1.202(1), received February 12, 1986.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-116005
Expiration Date: October 1, 1986

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.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-116005
Expiration Date: October 1, 1986

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.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-116005
Expiration Date: October 1, 1986

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.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-116005
Expiration Date: October 1, 1986

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. Production shall not exceed 130 lots/year of drugs (37.2 lbs/lot) without prior approval of the department.
2. Solvent used in the process, based on a material balance, is limited to 20.3 lbs/lot unless prior approval is obtained from the department.
3. The coating pan process shall not be used more than 1,040 hrs/year without prior approval of the department.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-116005
Expiration Date: October 1, 1986

SPECIFIC CONDITIONS:

4. Visible emissions from any component of the coating pan process shall not exceed 5 percent opacity as determined by Method 9 which is described in 40 CFR 60, Appendix A.

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

6. Any permit to operate issued for the coating pan system shall require annual reports which include, as a minimum, the number of drug lots manufactured with the coating pan process and the calculated VOC emissions in lb/day and TPY.

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)

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)

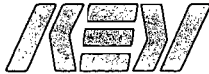
If the construction permit expires prior to the permittee requesting an extension or obtaining a permit to operate, then all activities at the project must cease and the permittee must apply for a new permit to construct which can take up to 90 days to process a complete application. (FAC Rule 17-4.10)

Issued this _____ day of _____,
19__.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL REGULATION

VICTORIA J. TSCHINKEL, Secretary

_____ pages attached.



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

February 13, 1986

Willard Hanks
Bureau of Air Quality Management
Florida State Department of Environmental Regulation
Twin Towers Building
2600 Blair Stone Road
Tallahassee, Florida 32301-8241

Dear Willard:

As we discussed at our meeting of February 12, 1986, please find the following:

1. Letter to C. H. Fancy requesting:
 - a. decrease in cap of VOC effluent in construct permit AC 100437 from 40 to 35 tons/year.
 - b. change in expiration date of the same permit from February 28, 1986, to April 01, 1987.
 - c. review of the operating permit (AC 114316) as an interim permit for the Glatts I & II followed by the addition of Glatt III after successful testing in 1987.
2. Two copies of the reprint article from the mid-November issue of Chemical Processing outlining the control equipment for Key's Puerto Rico plant.
3. Copy of Key's 1984 Hazardous Waste Report to DER.

If you have any other questions, please contact me.

Very truly yours,
KEY PHARMACEUTICALS, INC.

Steve J. Goodstein, Manager
Environmental Engineering &
Waste Management

:ocq

xc: A.F. Gant W.J. Smyth T. Flachmeyer
 R. Quinlan P. Rothchild E. Borbe
 R.A. Franke R. Glover

DER

FEB 14 1986

BAQM



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

February 13, 1986

C.H. Fancy, Deputy Chief
Bureau of Air Quality Management
Florida State Department of Environmental Regulation
Twin Towers Building
2600 Blair Stone Road
Tallahassee, Florida 32301-8241

Dear Mr. Fancy:

On Wednesday, February 12, 1986, Bill Smyth and I from Key Pharmaceuticals, Inc., visited your offices and met with Willard Hanks and Bill Thomas to discuss present and future permitting. Based on these discussions, it was found that a 40 ton/year cap was placed on the Glatt I thru III (i.e., AC 100437) and the expiration date was February 28, 1986.

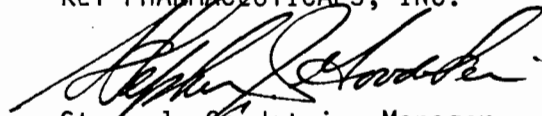
The 40 ton/year cap does not allow for either of the two small permits now in your possession to be reviewed. These are (1) for Guanidine and Quinora Tablets with a potential of 0.96 tons/year and (2) for an Accela-Cota pan operation at our R & D facility (999 N.W. 159 Drive, Miami, Florida) with a potential of 1.32 tons/year. Therefore, it is requested that the cap on permit AC 100437 be reduced to 35 tons/year.

Secondly, the expiration date of the construct permit needs to be changed. Glatts I and II are now ready for operation. However, Glatt III will not be installed and operating until early in 1987. Therefore, two things need to occur. First is to extend the construct permit to April 01, 1987, to allow for the installation and operation of Glatt III. This should allow enough time for its installation. If not, either another extension or a new permit would be applied for. Secondly, the operating permit already submitted (i.e., A0 114316) should be reviewed as an interim operating permit for Glatts I & II only and then when Glatt III is operational add that based on acceptable testing (i.e., EPA Methods 25 and 9).

C.H. Fancy, Deputy Chief
February 13, 1986
Page 2

Please review the above with your people and let me know of the results of the three requests. If there are any questions, please contact me.

Very truly yours,
KEY PHARMACEUTICALS, INC.



Steve J. Goodstein, Manager
Environmental Engineering &
Waste Management

:ocq

xc:	A.F. Gant	T. Flachmeyer	W.J. Smyth
	R. Quinlan	E. Borbe	P. Rothchild
	R.A. Franke	R. Glover	

Willard

please get this
original to Claire.
your letter already
has a copy of this
letter. THANKS

STEVE GOODSTEIN

Bill Willard 2/17
I don't see a problem
with this -
Claire



Key
Pharmaceuticals,
Inc.

March 22, 1985

Annual Report Coordinator
Hazardous Waste Management Program
Department of Environmental Regulation
2600 Blair Stone Road
Tallahassee, Florida

Dear Sirs:

Attached please find the "Generator Annual Hazardous Waste Report" for 1984 hazardous waste shipments from the following Key Pharmaceuticals, Inc. locations:

- 50 N. W. 176th Street, Miami, FL 33169
- 999 N. W. 159th Drive, Miami, FL 33169
- 1850 N. W. 69th Avenue, Plantation, FL 33313
- 13900 N. W. 57th Court, Miami Lakes, FL 33014

A form was not received for the 50 N. W. 176th Street facility, so a duplicate form from another facility was utilized.

I trust these forms are completed to your satisfaction. Should you have any questions, please do not hesitate to call me at (305) 652-2276.

Sincerely,

Thomas W. Flachmeyer
Senior Environmental Engineer
Certified Hazardous Waste Manager

TWF: 10

cc: A. F. Gant
R. Quinlan
~~R. Glover~~
C. Hsiao
B. Culbertson
S. Bannister

Best Available Copy

DEPARTMENT OF ENVIRONMENTAL REGULATION
GENERATOR ANNUAL HAZARDOUS WASTE REPORT

THIS REPORT IS FOR THE CALENDAR YEAR ENDING DECEMBER 31, 1984

GENERAL INSTRUCTIONS: PLEASE REFER TO THE SPECIFIC INSTRUCTIONS BEFORE COMPLETING THIS FORM. THE INFORMATION REQUESTED IN THIS REPORT IS REQUIRED BY RULE (CHAPTER 17-30, FLORIDA ADMINISTRATIVE CODE).

THE DATA BELOW IS WHAT THE DEPARTMENT OF ENVIRONMENTAL REGULATION HAS ON FILE. IF ANY ITEM IS INCORRECT, PLEASE FILL IN THE CORRECTED INFORMATION IN THE SPACE PROVIDED.

EPA/DER ID NUMBER: ~~FL0005673429~~
FACILITY NAME: KEY PHARMACEUTICALS INC
MAILING ADDRESS: 50 NW 176 ST
CITY, STATE, ZIP: MIAMI FL 33169
FACILITY LOCATION: ~~509 N. 159TH DRIVE, MIAMI, FL~~
CONTACT PERSON: STEPHEN GOODSTEIN, ENV ENG
PHONE: ~~305-652-2276~~
LAT/LONG: ~~26.0010753, -80.10~~

- I. EPA/DER ID NUMBER FLD004121398
- II. GENERATOR NAME Key Pharmaceuticals, Inc.
- III. MAILING ADDRESS 50 N. W. 176th Street
CITY, STATE, ZIP Miami, FL 33169
- IV. FACILITY LOCATION 50 N. W. 176th Street
CITY, STATE, ZIP Miami, FL 33169
- V. CONTACT PERSON Steve Goodstein
PHONE (305) 652 - 2276
- VI. LATITUDE LONGITUDE 25° . 56' . 03"N / 80° . 11' . 42"W
- VII. CERTIFICATION.

I CERTIFY UNDER PENALTY OF LAW THAT I HAVE PERSONALLY EXAMINED AND AM FAMILIAR WITH THE INFORMATION SUBMITTED IN THIS AND ALL ATTACHED DOCUMENTS, AND THAT BASED ON MY INQUIRY OF THOSE INDIVIDUALS IMMEDIATELY RESPONSIBLE FOR OBTAINING THE INFORMATION, I BELIEVE THAT THE SUBMITTED INFORMATION IS TRUE, ACCURATE, AND COMPLETE. I AM AWARE THAT THERE ARE SIGNIFICANT PENALTIES FOR SUBMITTING FALSE INFORMATION, INCLUDING THE POSSIBILITY OF FINE AND IMPRISONMENT.

Stephen Goodstein Manager Environmental Engineering & Waste Management
PRINT/TYPED NAME TITLE
Stephen Goodstein March 22, 1985
SIGNATURE OF AUTHORIZED REPRESENTATIVE DATE SIGNED

DEPARTMENT OF ENVIRONMENTAL REGULATION
GENERATOR ANNUAL HAZARDOUS WASTE REPORT

THIS REPORT IS FOR THE CALENDAR YEAR ENDING DECEMBER 31, 1984

VIII. THIS SECTION MUST BE COMPLETED BY GENERATORS THAT NOTIFIED EPA OF EFF OF HAZARDOUS WASTE ACTIVITY UNDER SECTION 3010 OF RCRA OR CHAPTER 403, FS, BUT DID NOT HANDLE QUANTITIES OF HAZARDOUS WASTE AT ANY TIME DURING THE REPORTING YEAR THAT ARE SUBJECT TO THE GENERATOR ANNUAL REPORTING REQUIREMENTS.

PLEASE CIRCLE THE APPROPRIATE CODE(S) AT RIGHT WHICH BEST DESCRIBES YOUR INSTALLATION STATUS FOR THE REPORTING YEAR.

CODE

- A. NON-HANDLER -- DID NOT HANDLE HAZARDOUS WASTE IN ANY QUANTITY DURING THE REPORTING YEAR..... 1
- B. SMALL QUANTITY GENERATOR -- DID NOT GENERATE MORE THAN 1000 KG. OF HAZARDOUS WASTE (OR 1 KG. OF ACUTELY HAZARDOUS WASTE) IN ANY SINGLE MONTH OR ACCUMULATE MORE THAN 1000 KG. OF HAZARDOUS WASTE (OR 1 KG. OF ACUTELY HAZARDOUS WASTE) ON-SITE AT ANY TIME DURING THE REPORTING YEAR IN ACCORDANCE WITH 40 CFR PART 261.5 2
- C. EXEMPT - ALL WASTES GENERATED IN FARMING OPERATIONS IN ACCORDANCE WITH 40 CFR PART 262.51, OR EXEMPT PURSUANT TO 40 CFR PART 261.4 3
- D. BENEFICIAL USE -- ALL HAZARDOUS WASTE GENERATED WAS BENEFICIALLY USED, REUSED, OR RECYCLED IN ACCORDANCE WITH 40 CFR PART 261.6(A)..... 4
- E. CLOSED -- INSTALLATION WAS CLOSED PRIOR TO THE REPORTING YEAR 5

GENERATORS THAT MEET ONE OF THE ABOVE EXEMPTIONS ARE NOT REQUIRED TO COMPLETE SECTIONS IX - XI OF THIS ANNUAL REPORT IDENTIFYING HAZARDOUS WASTE SHIPPED OFF-SITE DURING THE REPORTING YEAR.

DEPARTMENT OF ENVIRONMENTAL REGULATION
GENERATOR ANNUAL HAZARDOUS WASTE REPORT

THIS REPORT IS FOR THE CALENDAR YEAR ENDING DECEMBER 31, 1984

IX. FACILITY NAME AND LOCATION TO WHICH ALL WASTES LISTED ON THIS PAGE WERE SHIPPED. A COPY OF THIS SHEET MUST BE FILLED OUT FOR EACH FACILITY THAT RECEIVED HAZARDOUS WASTES.

FACILITY NAME Chemical Waste Management EPA/DER ID NO FLD000776708
 FACILITY LOCATION 2700 N. W. 48th Street
 CITY Pompano Beach STATE FL ZIP CODE 33067

X. TRANSPORTATION SERVICES USED. LIST THE NAME AND EPA/DER IDENTIFICATION NUMBER OF ALL TRANSPORTERS WHOSE SERVICES WERE USED DURING THE REPORTING YEAR. COMPLETE THIS SECTION ONLY ONCE. DO NOT REPEAT ON SUPPLEMENTAL SHEETS. (SEE INSTRUCTIONS)

TRANSPORTER NAME	TRANSPORTER EPA/DER ID NO
<u>Chemical Waste Management</u>	<u>FLD000776708</u>
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XI. WASTE IDENTIFICATION

(A) DESCRIPTION OF WASTE	(B) DOT HAZARD CODE	(C) EPA HAZARDOUS WASTE NUMBER (SEE INSTRUCTIONS)	(D) AMOUNT OF WASTE	(E) UNIT OF MEASURE
<u>1 Waste Flammable Liquid</u>	<u>* 08</u>	<u>* F003 * D001</u>	<u>* 18976</u>	<u>* K</u>
<u>2 Waste Flammable Liquid</u>	<u>* 08</u>	<u>* F003 * F005</u>	<u>* 2706</u>	<u>* K</u>
<u>3 Waste Flammable Liquid</u>	<u>* 08</u>	<u>* F003 * F005</u>	<u>* 1249</u>	<u>* K</u>
<u>4 Waste Flammable Liquid</u>	<u>* 08</u>	<u>* F003 * D001</u>	<u>* 1665</u>	<u>* K</u>
<u>5 Waste Chloroform</u>	<u>* 15</u>	<u>* U044</u>	<u>* 1249</u>	<u>* K</u>
<u>6 -----</u>	<u>* -----</u>	<u>* -----</u>	<u>* -----</u>	<u>* -----</u>

COMMENTS:

DEPARTMENT OF ENVIRONMENTAL REGULATION
GENERATOR ANNUAL HAZARDOUS WASTE REPORT

THIS REPORT IS FOR THE CALENDAR YEAR ENDING DECEMBER 31, 1984

IX. FACILITY NAME AND LOCATION TO WHICH ALL WASTES LISTED ON THIS PAGE WERE SHIPPED. A COPY OF THIS SHEET MUST BE FILLED OUT FOR EACH FACILITY THAT RECEIVED HAZARDOUS WASTES.

FACILITY NAME Environmental Enterprises EPA/DER ID NO OHD08337010

FACILITY LOCATION 4650 Spring Grove Avenue

CITY Cincinnati STATE OH ZIP CODE 45232

X. TRANSPORTATION SERVICES USED. LIST THE NAME AND EPA/DER IDENTIFICATION NUMBER OF ALL TRANSPORTERS WHOSE SERVICES WERE USED DURING THE REPORTING YEAR. COMPLETE THIS SECTION ONLY ONCE. DO NOT REPEAT ON SUPPLEMENTAL SHEETS. (SEE INSTRUCTIONS)

TRANSPORTER NAME	TRANSPORTER EPA/DER ID NO
<u>Chemical Conservation Corp.</u>	<u>FLD980559728</u>
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XI. WASTE IDENTIFICATION

(A) DESCRIPTION OF WASTE	(B) * DOT * HAZARD * CODE	(C) * EPA HAZARDOUS * WASTE NUMBER * (SEE INSTRUCTIONS)	(D) * AMOUNT * OF WASTE	(E) * UNIT * OF * MEASURE
<u>1 Waste Spirits of Nitro- glycerin</u>	<u>* 15</u>	<u>* P081</u>	<u>* 3331</u>	<u>* Kg</u>
<u>2 -----</u>	<u>* -----</u>	<u>* -----</u>	<u>* -----</u>	<u>* -----</u>
<u>3 -----</u>	<u>* -----</u>	<u>* -----</u>	<u>* -----</u>	<u>* -----</u>
<u>4 -----</u>	<u>* -----</u>	<u>* -----</u>	<u>* -----</u>	<u>* -----</u>
<u>5 -----</u>	<u>* -----</u>	<u>* -----</u>	<u>* -----</u>	<u>* -----</u>
<u>6 -----</u>	<u>* -----</u>	<u>* -----</u>	<u>* -----</u>	<u>* -----</u>

COMMENTS:

DEPARTMENT OF ENVIRONMENTAL REGULATION
GENERATOR ANNUAL HAZARDOUS WASTE REPORT

THIS REPORT IS FOR THE CALENDAR YEAR ENDING DECEMBER 31, 1984

IX. FACILITY NAME AND LOCATION TO WHICH ALL WASTES LISTED ON THIS PAGE WERE SHIPPED. A COPY OF THIS SHEET MUST BE FILLED OUT FOR EACH FACILITY THAT RECEIVED HAZARDOUS WASTES.

FACILITY NAME Chem-Met Services EPA/DER ID NO MID096963194

FACILITY LOCATION 18550 Allen Road

CITY Wyandotte STATE MI ZIP CODE 48192

X. TRANSPORTATION SERVICES USED. LIST THE NAME AND EPA/DER IDENTIFICATION NUMBER OF ALL TRANSPORTERS WHOSE SERVICES WERE USED DURING THE REPORTING YEAR. COMPLETE THIS SECTION ONLY ONCE. DO NOT REPEAT ON SUPPLEMENTAL SHEETS. (SEE INSTRUCTIONS)

TRANSPORTER NAME	TRANSPORTER EPA/DER ID NO
<u>Chemical Conservation Corp.</u>	<u>FLD980559728</u>
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XI. WASTE IDENTIFICATION

(A) DESCRIPTION OF WASTE	(B) DOT HAZARD CODE	(C) EPA HAZARDOUS WASTE NUMBER (SEE INSTRUCTIONS)	(D) AMOUNT OF WASTE	(E) UNIT OF MEASURE
<u>1 Waste Hydrogen Peroxide</u>	<u>16</u>	<u>D002</u>	<u>997</u>	<u>K</u>
<u>2</u>	<u>*</u>	<u>*</u>	<u>*</u>	<u>*</u>
<u>3</u>	<u>*</u>	<u>*</u>	<u>*</u>	<u>*</u>
<u>4</u>	<u>*</u>	<u>*</u>	<u>*</u>	<u>*</u>
<u>5</u>	<u>*</u>	<u>*</u>	<u>*</u>	<u>*</u>
<u>6</u>	<u>*</u>	<u>*</u>	<u>*</u>	<u>*</u>

COMMENTS:

DEPARTMENT OF ENVIRONMENTAL REGULATION
GENERATOR ANNUAL HAZARDOUS WASTE REPORT

THIS REPORT IS FOR THE CALENDAR YEAR ENDING DECEMBER 31, 1984

IX. FACILITY NAME AND LOCATION TO WHICH ALL WASTES LISTED ON THIS PAGE WERE SHIPPED. A COPY OF THIS SHEET MUST BE FILLED OUT FOR EACH FACILITY THAT RECEIVED HAZARDOUS WASTES.

FACILITY NAME Seaboard Chemical Corp. EPA/DER ID NO NCD071574164

FACILITY LOCATION 5899 Riverside Drive

CITY Greensboro STATE NC ZIP CODE 27282

X. TRANSPORTATION SERVICES USED. LIST THE NAME AND EPA/DER IDENTIFICATION NUMBER OF ALL TRANSPORTERS WHOSE SERVICES WERE USED DURING THE REPORTING YEAR. COMPLETE THIS SECTION ONLY ONCE. DO NOT REPEAT ON SUPPLEMENTAL SHEETS. (SEE INSTRUCTIONS)

TRANSPORTER NAME	TRANSPORTER EPA/DER ID NO
<u>Chemical Conservation Corp.</u>	<u>FLD980559728</u>
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XI. WASTE IDENTIFICATION

(A) DESCRIPTION OF WASTE	(B) DOT * HAZARD * CODE	(C) EPA HAZARDOUS * WASTE NUMBER * (SEE INSTRUCTIONS)	(D) AMOUNT * OF WASTE	(E) UNIT * OF * MEASURE
<u>1 Waste Acetone</u>	<u>* 08</u>	<u>* F003</u>	<u>* 399</u>	<u>* K</u>
<u>2</u>	<u>*</u>	<u>*</u>	<u>*</u>	<u>*</u>
<u>3</u>	<u>*</u>	<u>*</u>	<u>*</u>	<u>*</u>
<u>4</u>	<u>*</u>	<u>*</u>	<u>*</u>	<u>*</u>
<u>5</u>	<u>*</u>	<u>*</u>	<u>*</u>	<u>*</u>
<u>6</u>	<u>*</u>	<u>*</u>	<u>*</u>	<u>*</u>

COMMENTS:

Best Available Copy

DEPARTMENT OF ENVIRONMENTAL REGULATION
GENERATOR ANNUAL HAZARDOUS WASTE REPORT

THIS REPORT IS FOR THE CALENDAR YEAR ENDING DECEMBER 31, 1984

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THE DATA BELOW IS WHAT THE DEPARTMENT OF ENVIRONMENTAL REGULATION HAS ON FILE. IF ANY ITEM IS INCORRECT, PLEASE FILL IN THE CORRECTED INFORMATION IN THE SPACE PROVIDED.

EPA/DER ID NUMBER: FLD980839435
FACILITY NAME: KEY PHARMACEUTICALS INC
MAILING ADDRESS: 50 NW 176TH STREET
CITY, STATE, ZIP: PLANTATION FL 33313
FACILITY LOCATION: 1850 NW 69TH AVENUE, PLANTATION, FL
CONTACT PERSON: STEPHEN GOODSTEIN, ENV ENG
PHONE: 305-652-2276
LAT/LONG: 26.07.18/80.14.15

I. EPA/DER ID NUMBER FLD980839435
II. GENERATOR NAME Key Pharmaceuticals, Inc.
III. MAILING ADDRESS 50 N. W. 176th Street
CITY, STATE, ZIP Miami, FL 33169
IV. FACILITY LOCATION 1850 N. W. 69th Avenue
CITY, STATE, ZIP Plantation, FL 33313
V. CONTACT PERSON Stephen Goodstein
PHONE (305) 652 - 2276
VI. LATITUDE LONGITUDE 26 . 07 . 18 / 80 . 14 . 15

VII. CERTIFICATION

I CERTIFY UNDER PENALTY OF LAW THAT I HAVE PERSONALLY EXAMINED AND AM FAMILIAR WITH THE INFORMATION SUBMITTED IN THIS AND ALL ATTACHED DOCUMENTS, AND THAT BASED ON MY INQUIRY OF THOSE INDIVIDUALS IMMEDIATELY RESPONSIBLE FOR OBTAINING THE INFORMATION, I BELIEVE THAT THE SUBMITTED INFORMATION IS TRUE, ACCURATE, AND COMPLETE. I AM AWARE THAT THERE ARE SIGNIFICANT PENALTIES FOR SUBMITTING FALSE INFORMATION, INCLUDING THE POSSIBILITY OF FINE AND IMPRISONMENT.

Stephen Goodstein Manager Environmental Engineering & Waste Management
PRINT/TYPED NAME TITLE
Stephen Goodstein March 22, 1985
SIGNATURE OF AUTHORIZED REPRESENTATIVE DATE SIGNED

DEPARTMENT OF ENVIRONMENTAL REGULATION
GENERATOR ANNUAL HAZARDOUS WASTE REPORT

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VIII. THIS SECTION MUST BE COMPLETED BY GENERATORS THAT NOTIFIED EPA OR DLR OF HAZARDOUS WASTE ACTIVITY UNDER SECTION 3010 OF RCRA OR CHAPTER 403, FS, BUT DID NOT HANDLE QUANTITIES OF HAZARDOUS WASTE AT ANY TIME DURING THE REPORTING YEAR THAT ARE SUBJECT TO THE GENERATOR ANNUAL REPORTING REQUIREMENTS.

PLEASE CIRCLE THE APPROPRIATE CODE(S) AT RIGHT WHICH BEST DESCRIBES YOUR INSTALLATION STATUS FOR THE REPORTING YEAR.

CODE

- A. NON-HANDLER -- DID NOT HANDLE HAZARDOUS WASTE IN ANY QUANTITY DURING THE REPORTING YEAR..... 1
- B. SMALL QUANTITY GENERATOR -- DID NOT GENERATE MORE THAN 1000 KG. OF HAZARDOUS WASTE (OR 1 KG. OF ACUTELY HAZARDOUS WASTE) IN ANY SINGLE MONTH OR ACCUMULATE MORE THAN 1000 KG. OF HAZARDOUS WASTE (OR 1 KG. OF ACUTELY HAZARDOUS WASTE) ON-SITE AT ANY TIME DURING THE REPORTING YEAR IN ACCORDANCE WITH 40 CFR PART 261.5 2
- C. EXEMPT - ALL WASTES GENERATED IN FARMING OPERATIONS IN ACCORDANCE WITH 40 CFR PART 262.51, OR EXEMPT PURSUANT TO 40 CFR PART 261.4 3
- D. BENEFICIAL USE -- ALL HAZARDOUS WASTE GENERATED WAS BENEFICIALLY USED, REUSED, OR RECYCLED IN ACCORDANCE WITH 40 CFR PART 261.6(A)..... 4
- E. CLOSED -- INSTALLATION WAS CLOSED PRIOR TO THE REPORTING YEAR 5

GENERATORS THAT MEET ONE OF THE ABOVE EXEMPTIONS ARE NOT REQUIRED TO COMPLETE SECTIONS IX - XI OF THIS ANNUAL REPORT IDENTIFYING HAZARDOUS WASTE SHIPPED OFF-SITE DURING THE REPORTING YEAR.

DEPARTMENT OF ENVIRONMENTAL REGULATION
GENERATOR ANNUAL HAZARDOUS WASTE REPORT

THIS REPORT IS FOR THE CALENDAR YEAR ENDING DECEMBER 31, 1984

IX. FACILITY NAME AND LOCATION TO WHICH ALL WASTES LISTED ON THIS PAGE WERE SHIPPED. A COPY OF THIS SHEET MUST BE FILLED OUT FOR EACH FACILITY THAT RECEIVED HAZARDOUS WASTES.

FACILITY NAME Chemical Waste Management EPA/DER ID NO FLD000776708

FACILITY LOCATION 2700 N. W. 48th Street

CITY Pompano Beach STATE FL ZIP CODE 33067

X. TRANSPORTATION SERVICES USED. LIST THE NAME AND EPA/DER IDENTIFICATION NUMBER OF ALL TRANSPORTERS WHOSE SERVICES WERE USED DURING THE REPORTING YEAR. COMPLETE THIS SECTION ONLY ONCE. DO NOT REPEAT ON SUPPLEMENTAL SHEETS. (SEE INSTRUCTIONS)

TRANSPORTER NAME	TRANSPORTER EPA/DER ID NO
<u>Chemical Waste Management</u>	<u>FLD000776708</u>
-----	-----
-----	-----
-----	-----

XI. WASTE IDENTIFICATION

(A) DESCRIPTION OF WASTE	(B) DOT HAZARD CODE	(C) EPA HAZARDOUS WASTE NUMBER (SEE INSTRUCTIONS)	(D) AMOUNT OF WASTE	(E) UNIT CF MEASURE
<u>1 Waste Flammable Liquid</u>	<u>*</u>	<u>F003 U044</u>	<u>F005 P001</u>	<u>2174.5</u> <u>K</u>
<u>2</u>	<u>*</u>	<u>-----</u>	<u>-----</u>	<u>-----</u>
<u>3</u>	<u>*</u>	<u>-----</u>	<u>-----</u>	<u>-----</u>
<u>4</u>	<u>*</u>	<u>-----</u>	<u>-----</u>	<u>-----</u>
<u>5</u>	<u>*</u>	<u>-----</u>	<u>-----</u>	<u>-----</u>
<u>6</u>	<u>*</u>	<u>-----</u>	<u>-----</u>	<u>-----</u>

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EPA/DER ID NUMBER: FLD980839377
FACILITY NAME: KEY PHARMACEUTICALS INC
MAILING ADDRESS: 50 NW 176 ST
CITY, STATE, ZIP: MIAMI FL 33169
FACILITY LOCATION: 13900 N. 57TH COURT, MIAMI LAKES, FL
CONTACT PERSON: STEPHEN GOODSTEIN
PHONE: 305-652-2276
LAT/LONG: 25.46.00/80.15.26

- I. EPA/DER ID NUMBER FLD980839377
- II. GENERATOR NAME Key Pharmaceuticals, Inc.
- III. MAILING ADDRESS 50 N. W. 176th Street
CITY, STATE, ZIP Miami, FL 33169
- IV. FACILITY LOCATION 13900 N. W. 57th Court
CITY, STATE, ZIP Miami Lakes, FL 33014
- V. CONTACT PERSON Stephen Goodstein
PHONE (305) 652 - 2276
- VI. LATITUDE LONGITUDE 25 . 46 . 00 / 80 . 15 . 26
- VII. CERTIFICATION

I CERTIFY UNDER PENALTY OF LAW THAT I HAVE PERSONALLY EXAMINED AND AM FAMILIAR WITH THE INFORMATION SUBMITTED IN THIS AND ALL ATTACHED DOCUMENTS, AND THAT BASED ON MY INQUIRY OF THOSE INDIVIDUALS IMMEDIATELY RESPONSIBLE FOR OBTAINING THE INFORMATION, I BELIEVE THAT THE SUBMITTED INFORMATION IS TRUE, ACCURATE, AND COMPLETE. I AM AWARE THAT THERE ARE SIGNIFICANT PENALTIES FOR SUBMITTING FALSE INFORMATION, INCLUDING THE POSSIBILITY OF FINE AND IMPRISONMENT.

Stephen Goodstein Manager Environmental Engineering & Waste Management
 PRINT/TYPE NAME TITLE
Stephen Goodstein March 22, 1985
 SIGNATURE OF AUTHORIZED REPRESENTATIVE DATE SIGNED

DEPARTMENT OF ENVIRONMENTAL REGULATION
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EPA/DER ID NUMBER: FLD980838429
FACILITY NAME: KEY PHARMACEUTICALS INC
MAILING ADDRESS: 50 NW 176 ST
CITY, STATE, ZIP: MIAMI FL 33169
FACILITY LOCATION: 999 NW 159TH DRIVE, MIAMI, FL
CONTACT PERSON: STEPHEN GOODSTEIN, ENV ENG
PHONE: 305-652-2276
LAT/LONG: 26.00.10/80.08.20

I. EPA/DER ID NUMBER FLD980838429
II. GENERATOR NAME Key Pharmaceuticals, Inc.
III. MAILING ADDRESS 50 N. W. 176th Street
CITY, STATE, ZIP Miami, FL 33169
IV. FACILITY LOCATION 999 N. W. 159th Drive
CITY, STATE, ZIP Miami, FL 33169
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VI. LATITUDE LONGITUDE 26 . 00 . 10 / 80 . 08 . 20

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Stephen Goodstein Manager Environmental Engineering & Waste Management
PRINT/TYPED NAME TITLE
Stephen Goodstein March 22, 1985
SIGNATURE OF AUTHORIZED REPRESENTATIVE DATE SIGNED

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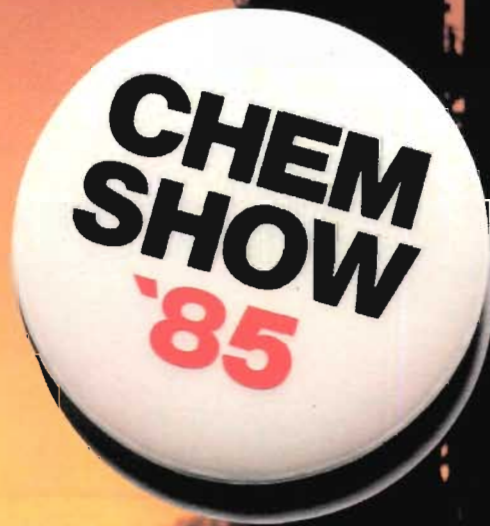
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CHEMICAL PROCESSING[®]

A PUTMAN PUBLICATION

MID-NOVEMBER 1985





Solvent recovery combines with catalytic incineration to effectively control fumes

STEPHEN GOODSTEIN

Manager, Environmental Engineering & Waste Mgmt.

THOMAS FLACHMEYER

Senior Environmental Engineer
Key Pharmaceuticals Inc.
Miami, FL

CONSTANCE P. WICKERSHAM

Philadelphia Regional Editor

New Solutions to Plant Problems

Problem: When the engineering staff at Key Pharmaceuticals Inc. was charged with the challenge to design, construct and troubleshoot a new facility, the environmental engineers had a very large task. The facility, to be constructed in Las Piedras, Puerto Rico beginning in late 1983, would fall under the regulatory control of EPA Region II.

The plant was designed to manufacture pharmaceutical products used to combat bronchial asthma. An Environmental Assessment was required to be filed prior to the construction phase. It would outline the proposed procedures to remove or destroy the solvents used in production, thereby preventing their release to the atmosphere.

Since the solvents required in the manufacturing process represented two different classes of materials, chlorinated and non-chlorinated solvents, the treatment decision became complicated. Single system treatment options were not viable.

Solution: A solvent recovery system and a catalytic incinerator were installed in a parallel arrangement to treat chlorinated and non-chlorinated solvents, respectively. This arrangement was possible because the two types of solvents are mutually exclusive in their manufacturing uses. Decisions are made in the individual processing rooms from one system to the other when a change in production occurs.



Key Pharmaceuticals needed to install a solvent recovery system and a catalytic incinerator to treat both chlorinated and non-chlorinated solvents

Each solvent recovery vessel contains carbon filter elements where all of the micropores are at the surface





Catalytic incineration occurs via a platinum metal catalyst

The solvent recovery system has two vessels in parallel, each containing ten carbon mat filter elements. With one vessel on-line (and the other being regenerated and then on stand-by), the system has a maximum flowrate of 24,000 scfm and can be expanded to 38,000 scfm with an additional vessel.

Solvent-laden air is forced into the carbon adsorption unit by a blower. The cylindrically wound carbon filter elements remove the chlorinated solvents, and clean air exits through a top outlet.

The elements are regenerated by steam desorption. Solvent is recovered in a series of condensers and a separator. Reuse of the solvent is not possible at this time since all materials must be of pharmaceutical USP grade, so the chlorinated solvents are drummed and removed to an approved waste reclaimer or waste disposal site.

A carbon bed monitor warns of solvent bed breakthrough and signals for bed changeover. The monitor has a single beam, long pathlength, broad spectral range (infrared) analyzer. It can be set to measure general hydrocarbons or, as in this case, to selectively monitor a particular hydrocarbon.

For non-chlorinated solvents, catalytic incineration via a platinum metal catalyst on a ceramic honeycomb substrate is controlled by regulating inlet and outlet temperatures. The catalyst increases the chemical oxidation rate to permit the reaction to proceed at a lower energy level than would be experienced with a thermal incinerator.

A scavenger filter bed protects the catalyst from fouling or contamination. With this precaution, the catalyst should have a projected lifetime of from three to ten years.

The incinerator has a 10:1 turndown ratio; it can oxidize from 4500 to 44,600 cfm of solvent-laden air at a maximum organic loading of 2000 ppm. A propane pilot and #2 fuel oil are used to achieve startup temperature of 600°F. High temperature requirements are minimized by the catalyst, cutting fuel requirements—a major consideration in the selection of this system.

Flame ionization detectors are used to constantly analyze inlet and outlet streams for hydrocarbons, enabling the incinerator to be as fuel efficiently as possible. The detectors employ solid-state electronics with integrated circuits

and plug-in circuit boards for easy removal and replacement.

To protect the catalytic incinerator in this parallel system, a supervisory system of gas chromatographs monitors each process line for chlorinated solvents. If a sensor detects chlorinated solvents going to the incinerator, that stream is automatically diverted to the adsorber.

Results: Both the solvent recovery and the catalytic incineration systems were installed in April, 1985 and started up in July, 1985. The catalytic incinerator has treated process exhausts with normal solvent concentrations of 1000-1200 ppm and as high as 2000 ppm—with a conversion rate of 97%, well above regulatory compliance requirements.

The solvent recovery unit has been operating so well that chlorinated fume abatement has been 95% or better. Adsorption and desorption rates have been kept high by the patented carbon filter elements; all of the micropores are at the surface of the element to provide active adsorption sites. A 50% expansion capability, as noted previously, was built into the solvent recovery system for flexibility.

The management at Key Pharmaceutical feels that the reliability and performance levels exhibited by both the catalytic incinerator and the carbon adsorption solvent recovery system warranted the high initial capital expense. ■

Series 1000 Type KF carbon adsorption system is a product of Met-Pro Corp., Systems Div., 160 Cassell Rd., Box 144, Harleysville, PA 19438. Booth #2117

Series 1000 catalytic incinerator is also available from Met-Pro Corp., Systems Div.

Model 970A carbon bed monitors and Model 931A process gas chromatographs manufactured by The Foxboro Co., Foxboro, MA 02035.

Model 400 hydrocarbon analyzer manufactured by Beckman Industrial Corp. (a subsidiary of Emerson Electric Co.), Process Instruments Div., 600 S. Harbor Blvd., La Habra, CA 90631.



Systems Division

160 CASSELL ROAD • BOX 144 • HARLEYSVILLE, PA 19438-9990
(215) 723-6751 • TELEX: 244-903



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

February 11, 1986

Mr. Bill Thomas
Bureau of Air Quality Management
Florida State Department of
Environmental Regulation
Twin Towers Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

DER
FEB 12 1986
BAQM

Dear Bill:

Presently, Key Pharmaceuticals, Inc. has requests for several permits in either the construct or operating stage including:

1. Operating Permit (AO 114316) for Glatts 1, 2, and 3.
2. Construct Permit to manufacture GUANIDINE and QUINORA tablets.
3. Construct Permit for a coating pan (i.e. Accela-Cota) in the R & D facility.

Furthermore, Key is under a consent decree (OCG Case No. 83-0373) that will result in all THEO-DUR operations and the accompanying solvent discharges to move to Puerto Rico in 1986.

In order to aid you in reviewing the present and any future permits two pieces of information need to be reviewed. These are:

1. Projected Controlled and Uncontrolled emissions in 1987 through 1990.
2. Pharmaceutical Processes involved at Key.

The attached table denotes the various solvents used in the current and planned processes at Key's Miami site for 1987 - 1990. The controls as noted are on the methanol using the current permitted process (i.e. wet scrubbing followed by biological treatment). The numbers are ranged as they are estimates based on new products being approved by the FDA. Therefore, the actual quantities could easily be skewed lower. The average total controlled VOC's start out at 26.5 tons/year and increase to 76.9 tons/year in 1990. Again, these numbers represent controls only on methanol.

February 11, 1986

Mr. W. Thomas

Page 2 (of 3)

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Pharmaceutical processes typically are isolated to the following:

GRANULATION

COATING (either in coating pans or a fluidized bed unit, i.e. Glatt).

BLENDING

COMPRESSING

PACKAGING

These are defined as follows:

- A. GRANULATION - dry powders (active plus excipients) are mixed together in a mixer (e.g. ribbon, Sigma) with a granulating solution (aqueous or solvent). The material is wet sized and placed on trays and dried. After drying it is dry sized, sampled, and stored. Emissions consist of solvent and dust.
- B. COATING
 - i. COATING PANS - a substrate is placed in the coating pan and various coating solutions are applied. These include a solvent based film former plus dry powder (active), wax solutions and clear film former. After coating, the material (pellets) is allowed to dry. Emissions consist of solvent and dust.
 - ii. FLUID BED UNIT - the substrate is placed in the coating unit. All material applied is in the form of solutions or slurries sprayed onto the substrate. Drying of the pellets occurs in the same unit. Once completed, the pellets are stored.
- C. BLENDING - this is performed in a double cone unit termed a Gemco. The pellets and granulations (or pellets only) made previously are added to the blender along with dry excipients which include a dry lubricant. Blending is performed for a set time. Emissions include dust only.
- D. COMPRESSING - the blended material is placed on a rotary tableting machine to form tablets. Emissions consist of dust only.
- E. PACKAGING - the tablets produced are put in bottles along with cotton, capped and palletized. A very small amount of dust can be generated.

February 11, 1986

Mr. W. Thomas

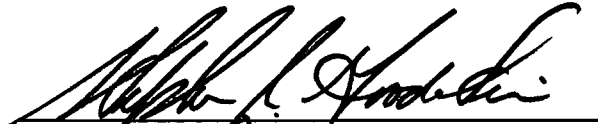
Page 3 (of 3)

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It is hoped that this information aids in the review of our present and future permits. If there are any additional questions, do not hesitate to contact me.

Very truly yours,

KEY PHARMACEUTICALS, INC.



Stephen J. Goodstein, Manager
Environmental Engineering and
Waste Management

SJG/db

attachment

cc: A.F. Gant
R. Quinlan
R.A. Franke
W. Smyth
T. Flachmeyer
E. Borbe
R. Glover

February 11, 1986

Mr. W. Thomas
Attachment

PROJECTED EMISSIONS (VOC's) IN TONS PER YEAR

	1 9 8 7		1 9 8 8		1 9 8 9		1 9 9 0	
	<u>UNCONT</u>	<u>CONTROL</u>	<u>UNCONT</u>	<u>CONTROL</u>	<u>UNCONT</u>	<u>CONTROL</u>	<u>UNCONT</u>	<u>CONTROL</u>
ISOPROPYL ALCOHOL	0-3.6	0-3.6	5.1-14.6	5.1-14.6	8-23.3	8-23.3	9.7-27.3	9.7-27.3
ACETONE	0-3.3	0-3.3	1.8-9.9	1.8-9.9	2.8-16.4	2.8-16.4	3.4-18.5	3.4-18.5
ETHYL ACETATE	0-3.1	0-3.1	0-7.2	0-7.2	0-12.4	0-12.4	0-13.4	0-13.4
METHANOL	169-251	16.9-25.1	210-316	21-31.6	263-394	26.3-39.4	323-456	32.3-45.6
METHYLENE CHLORIDE *	878-1303	878-1303	1087-1641	1087-1641	1364-2042	1364-2042	1676-2360	1676-2360
3A ALCOHOL	0-0.9	0-0.9	0-0.9	0-0.9	0-3.0	0-3.0	0-3.6	0-3.6
TOTAL VOC's *	169-261.9	16.9-36	216.9-348.6	27.9-64.2	273.8-449.1	37.1-94.5	336.1-518.8	45.4-108.4
AVG TOTAL VOC's CONTROLLED		26.5		46.1		65.8		76.9

* METHYLENE CHLORIDE IS NOT A VOC AS PER 17-2.510 AND IS NOT INCLUDED IN THE TOTALS.



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

DER

FEB 12 1986

BAQM

February 4, 1986

Mr. C.H. Fancy, Deputy Chief
Bureau of Air Quality Management
Florida State Department of
Environmental Regulation
Twin Towers Building
2600 Blair Stone Road
Tallahassee, Florida 32301-8241

Dear Mr. Fancy:

Attached please find a Construction Permit application for the installation of an Accela-Cota Coating Pan in the R & D facility, located at 999 N.W. 159th Drive, Miami, Florida 33169. Total actual emissions (VOC's) for the year for this unit will be under 0.7 tons/year. This quantity plus the projected quantities for the most recent Construct Permit (i.e. for GUANIDINE and QUINORA tablets) and K-DUR (AC 100437 & AO 114316) total well under 40 tons/year of VOC. Therefore, the impact of this installation is minor.

Under separate cover, I will submit to Bill Thomas of your offices, projected solvent usages and emissions once THEO-DUR operations move to Puerto Rico (i.e. Consent Decree OGC Case No. 83-0373). At that time total VOC emissions will be less than 100 tons/year making Key Pharmaceuticals, Inc. a minor source.

Please review the attached permit and let me know if there are any questions.

Very truly yours,

KEY PHARMACEUTICALS, INC.

Stephen J. Goodstein, Manager
Environmental Engineering and
Waste Management

SJG/db

attachment



Key
Pharmaceuticals,
Inc.

DER

FEB 12 1986

BAQM

August 10, 1984

Florida Department of Environmental Regulation
2600 Blairstone Road
Tallahassee, Florida 32301

TO WHOM IT MAY CONCERN:

This letter serves as the authorization for Allen F. Gant,
Vice President of Production and Engineering, to act on behalf of
Key Pharmaceuticals, Inc. on all current DER related matters.

Yours truly,

D. M. Bell
Senior Vice President
Operations



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

February 7, 1986

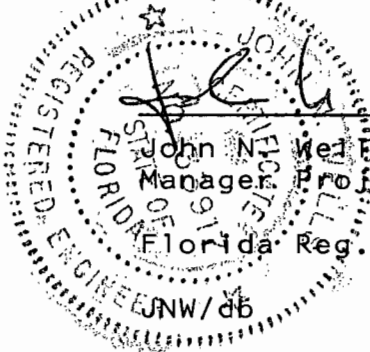
Florida Department of
Environmental Regulation
2600 Blair Stone Road
Tallahassee, Florida 32301

To Whom it May Concern:

I have reviewed the calculations presented in this permit application and have found them to be accurate with respect to the information provided.

Sincerely,

KEY PHARMACEUTICALS, INC.



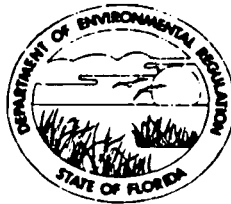
John N. Welles
John N. Welles, P.E.
Manager, Project Engineering
Florida Reg. No. 33917
JNW/db

AC 13-116005

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION
DER

SOUTHEAST FLORIDA
DISTRICT

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



FEB 12 1986

BAQM

BOB GRAHAM
GOVERNOR
VICTORIA J. TSCHINKEL
SECRETARY
ROY DUKE
DISTRICT MANAGER

APPLICATION TO OPERATE/CONSTRUCT AIR POLLUTION SOURCES

SOURCE TYPE: AIR POLLUTION New¹ Existing¹

APPLICATION TYPE: 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) COATING ROOM

SOURCE LOCATION: Street 999 N.W. 159TH DRIVE City MIAMI

UTM: East 578500 North 2867365

Latitude 25 ° 55' 26"N Longitude 80 ° 12' 58"W

APPLICANT NAME AND TITLE: ALLEN F. GANT, VICE PRESIDENT PRODUCTION AND ENGINEERING

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: Allen F. Gant

ALLEN F. GANT, VICE PRESIDENT PRODUCTION AND
Name and Title (Please Type) ENGINEERING

Date: 2-10-86 Telephone No. 305-578-5800

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 Attachment

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
JOHN N. WELLS, P.E.

KEY PHARMACEUTICALS, INC.
Name (Please Type)

50 N.W. 176TH STREET, MIAMI, FLORIDA 33169
Company Name (Please Type)

50 N.W. 176TH STREET, MIAMI, FLORIDA 33169
Mailing Address (Please Type)

Florida Registration No. 33917 Date: 2/7/86 Telephone No. 305-578-5800

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 USE OF AN ACCELA-COTA (COATING PAN) IN AN R & D ENVIRONMENT TO COAT TABLETS OR PELLETS USING SLURRIES, SUSPENSIONS, OR SOLUTIONS WHICH CONTAIN DIFFERENT SOLVENT SYSTEMS. TYPICAL SOLVENTS INCLUDE ACETONE; ISOPROPANOL; ETHYL ACETATE; 3A ALCOHOL; METHYLENE CHLORIDE; AND METHANOL.

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

Start of Construction FEB'86 Completion of Construction MAR'86

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.)

NO POLLUTION CONTROL EQUIPMENT WILL BE INSTALLED. TOTAL VOC EMISSIONS ARE ESTIMATED AT LESS THAN 0.7 TONS/YEAR. SUCH ADDITION TO PRESENT EMISSIONS DOES NOT WARRANT CONTROL MEASURES.

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

1. CONSENT ORDER FOR HALTING OR PERMITTING THEO-DUR OPERATIONS IN MIAMI BY NOV'86, OGC CASE NO. 83-0373.
2. PERMIT FOR GLATT 2 CATALYTIC INCINERATOR.
3. CONSTRUCT & OPERATING PERMIT FOR GLATTS 1 - 3 FOR K-DUR, AC-100437 & AO-114316.
4. CONSTRUCT PERMIT FOR GUANIDINE & QUINORA TABLETS.

E. Requested permitted equipment operating time: hrs/day 8 ; days/wk 2½ ; 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? | <u>YES</u> |
| a. If yes, has "offset" been applied? | <u>NO</u> |
| b. If yes, has "Lowest Achievable Emission Rate" been applied? | <u>NO</u> |
| c. If yes, list non-attainment pollutants. _____ | <u>OZONE</u> |
| 2. Does best available control technology (BACT) apply to this source?
If yes, see Section VI. | <u>NO</u> |
| 3. Does the State "Prevention of Significant Deterioration" (PSD)
requirement apply to this source? If yes, see Sections VI and VII. | <u>NO</u> |
| 4. Do "Standards of Performance for New Stationary Sources" (NSPS)
apply to this source? | <u>NO</u> |
| 5. Do "National Emission Standards for Hazardous Air Pollutants"
(NESHAP) apply to this source? | <u>NO</u> |
| H. Do "Reasonably Available Control Technology" (RACT) requirements apply
to this source? | <u>NO</u> |
| 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 justifi-
cation 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		
ORGANIC SOLVENTS	VOC	100	2.540	" A "
(EG. ACETONE, IPA,				
ETHYL ACETATE, 3A				
ALCOHOL; METHYLENE CHLORIDE, METHANOL)				

* BASED ON ALL SOLVENTS USED IN 8 HOURS.

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

1. Total Process Input Rate (lbs/hr): 2.54 SPRAYED ONTO 35.2 LB OF SUBSTRATE

2. Product Weight (lbs/hr): 0.25 LB/HR OF SOLIDS ONTO SUBSTRATE PLUS 2.54 LB/HR SOLVENT TO ATMOSPHERE.

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	
PARTICULATES	ESSENTIALLY 0		N / A	N / A	0		" A "
ORGANIC SOLVENTS							
(EG. ACETONE	2.54	* 0.7	N / A	N / A	1.32		" A "
IPA, ETHYL							
ACETATE, 3A							
ALCOHOL ; METHYLENE CHLORIDE, METHANOL)							

See Section V, Item 2.

* BASED ON ALL SOLVENTS BEING USED UP IN 8 HOURS.

²Reference 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)

³Calculated from operating rate and applicable standard.

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

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

N / A

Name and Type (Model & Serial No.)	Contaminant	Efficiency	Range of Particles Size Collected (in microns) (If applicable)	Basis for Efficiency (Section V Item 5)

E. Fuels N / A

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.

- NONE - FROM PROCESS CONDITIONS

IF ANY LIQUID IS REJECTED FOR SOME REASON, IT WOULD BE DISPOSED OF VIA APPROVED
HAULERS FOR BENEFICIAL RE-USE.

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

Stack Height: ABOUT 4' ABOVE ROOF ft. Stack Diameter: 0.67 ft.
 Gas Flow Rate: 335 ACFM @ 70°F DSCFM Gas Exit Temperature: MAX 150 °F.
 Water Vapor Content: ABOUT 50-60% RH % Velocity: 18.8 FPS
 BASED ON 150°F

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

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:

¹Explain method of determining efficiency.

²Energy 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 Devices:

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 devices, 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:

¹Explain method of determining efficiency.

²Energy to be reported in units of electrical power - KWH design rate.

2. Instrumentation, Field and Laboratory

- a. Was instrumentation EPA referenced or its equivalent? [] Yes [] No
- b. Was instrumentation calibrated in accordance with Department proceduree?
[] Yes [] No [] Unknown

B. Meteorological Data Used for Air Quality Modeling

- 1. ____ Year(e) 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, taxss, 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.

(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:

¹Applicant 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

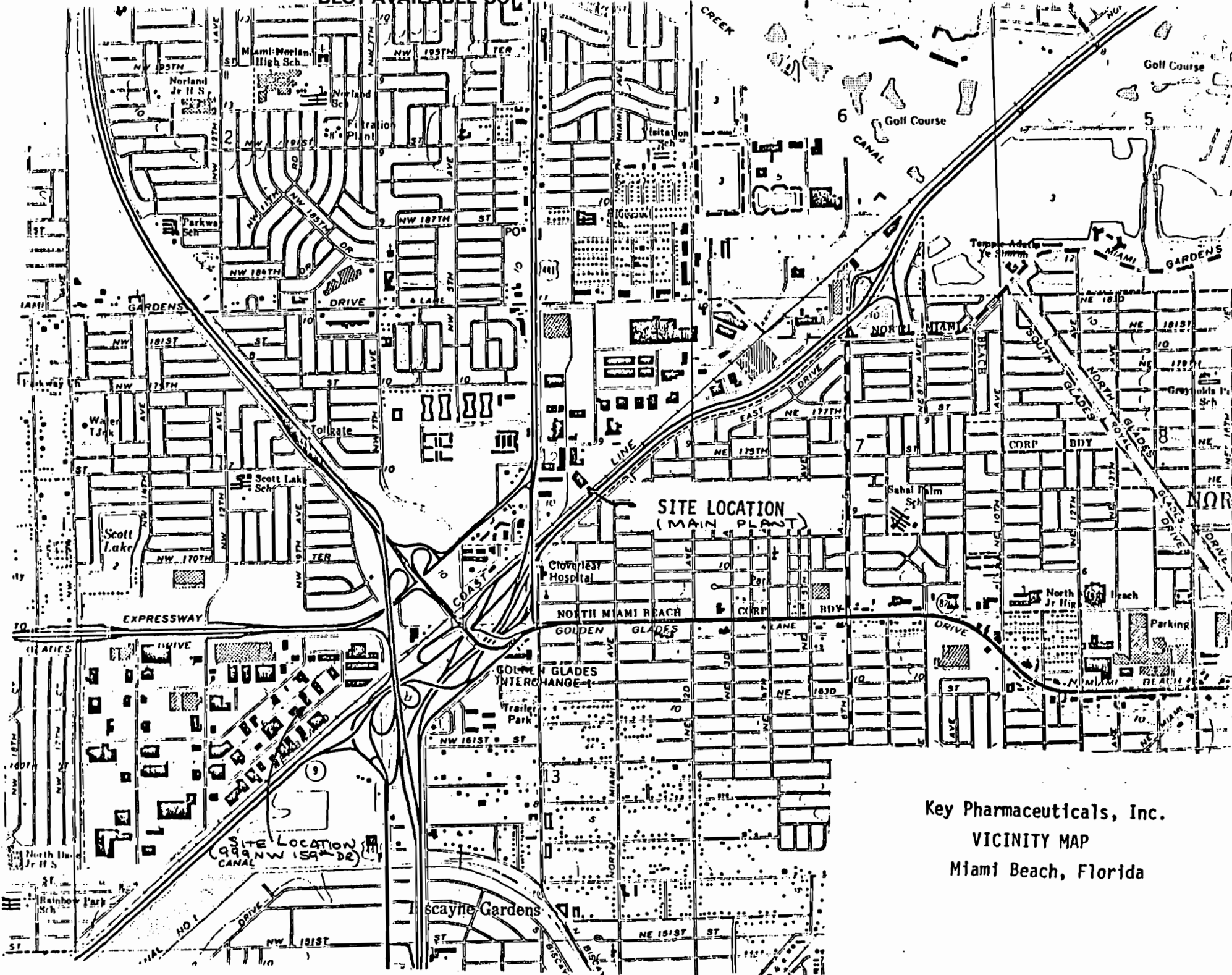
1. _____ no. sites _____ TSP _____ () SO₂* _____ Wind spd/dir

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

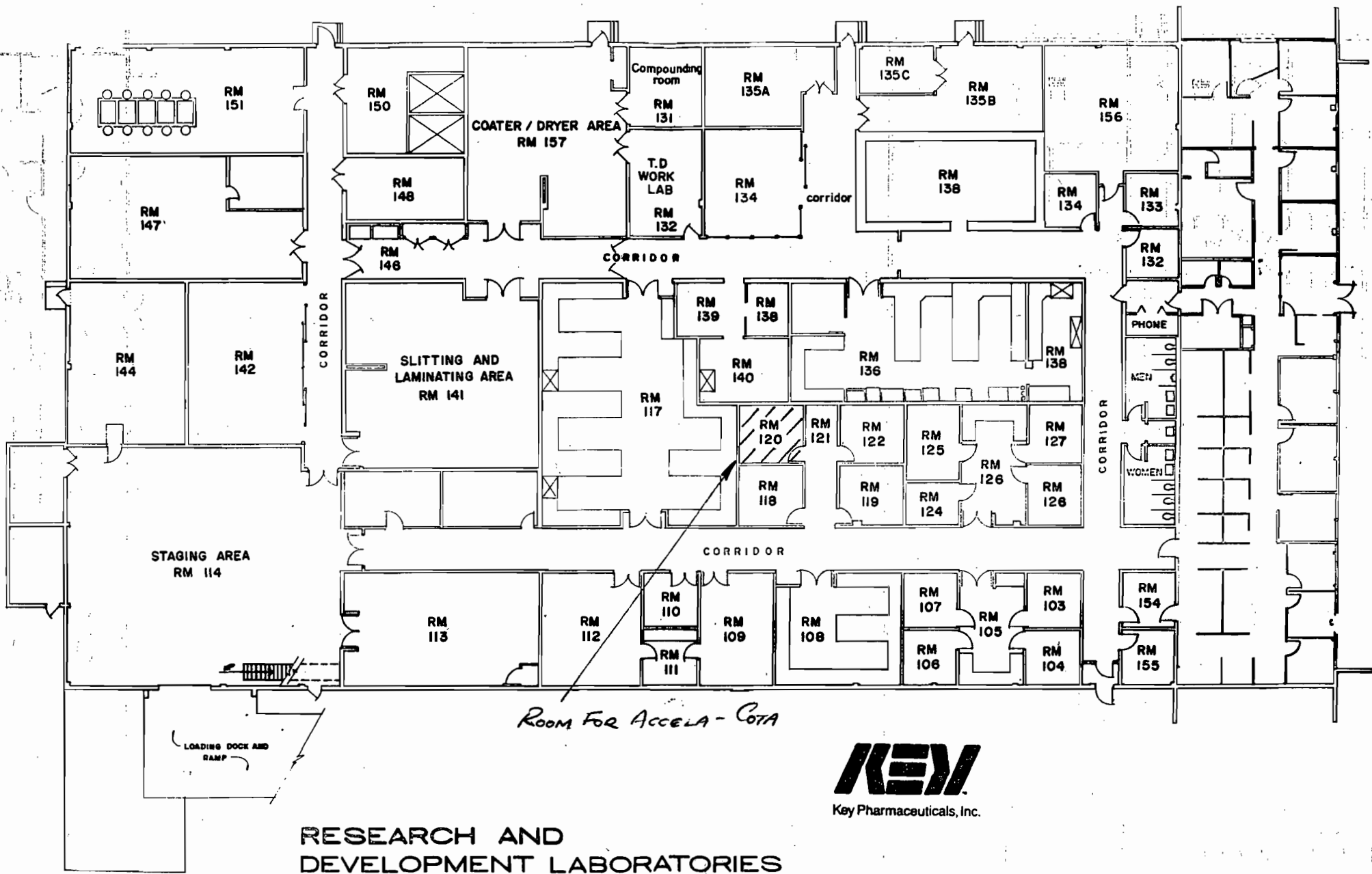
Other data recorded _____

Attach all data or statistical summaries to this application.

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



Key Pharmaceuticals, Inc.
VICINITY MAP
Miami Beach, Florida

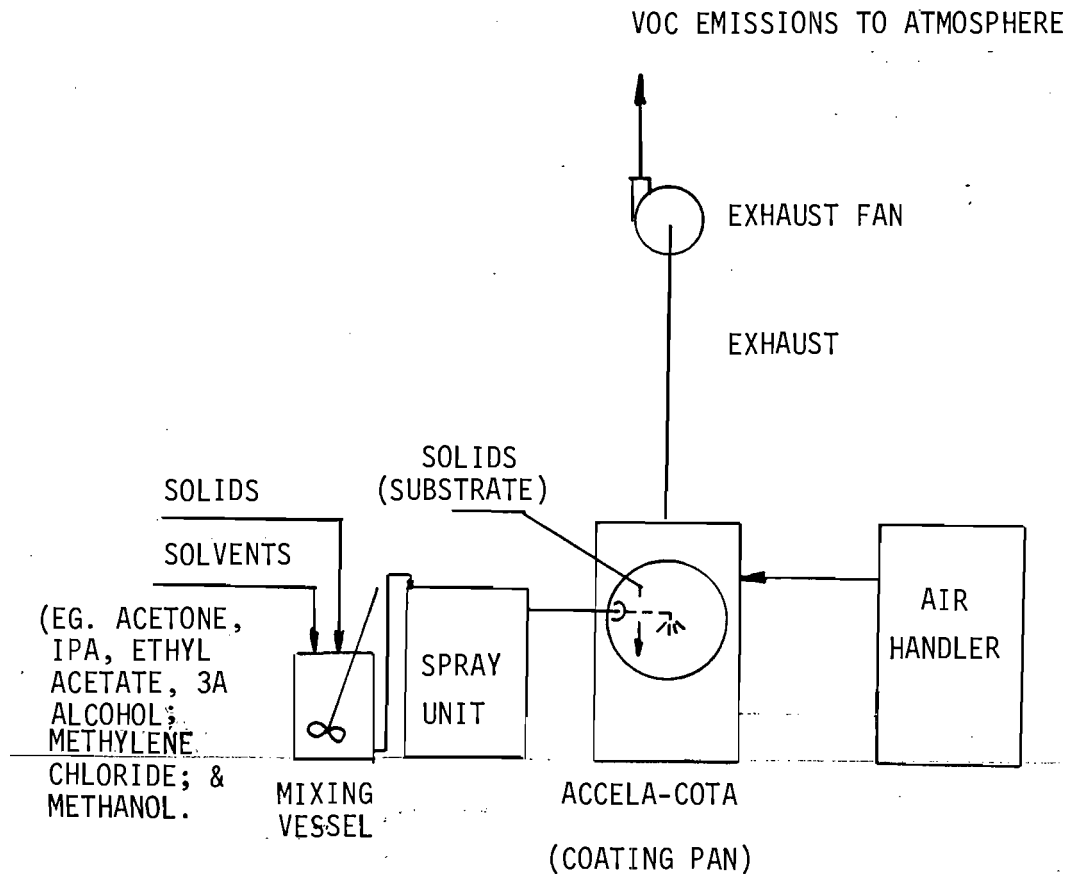


Room For ACCELA-COTA



**RESEARCH AND
DEVELOPMENT LABORATORIES**

PROCESS FLOW SHEET " A "



CALCULATION SHEET

SUBSTRATE LOAD TO ACCELA-COTA: 16 KG = 35.2 LB

COATING SOLUTION: SOLIDS = .898 KG = 1.98 LB

SOLVENTS = 9.22 KG = 20.3 LB *

TOTAL = 22.28 LB

% SOLIDS = 8.9 BY WEIGHT

* NOTE - IN MOST CASES, THE TOTAL VOC IN THIS QUANTITY WILL BE SUBSTANTIALLY LESS. IN MANY OF THE BATCHES THE VOC QUANTITY MAY ONLY BE 16 % BY WEIGHT, AS THE MAJOR COMPONENT IS METHYLENE CHLORIDE WHICH IS NOT A VOC AS PER FLORIDA CODE 17-2.510.

PROCESS INPUT

$22.28 \div 8 = 2.785$ LB/HR SPRAYED ONTO 35.2 LB OF SUBSTRATE

PRODUCT WEIGHT

1.98 LB \div 8 HR = 0.25 LB/HR OF SOLIDS ONTO SUBSTRATE, PLUS

20.3 LB \div 8 HR = 2.54 LB/HR OF SOLVENT TO ATMOSPHERE.

POTENTIAL EMISSIONS

130 LOTS/YR \times 20.3 LB/LOT = 1.32 TONS/YR

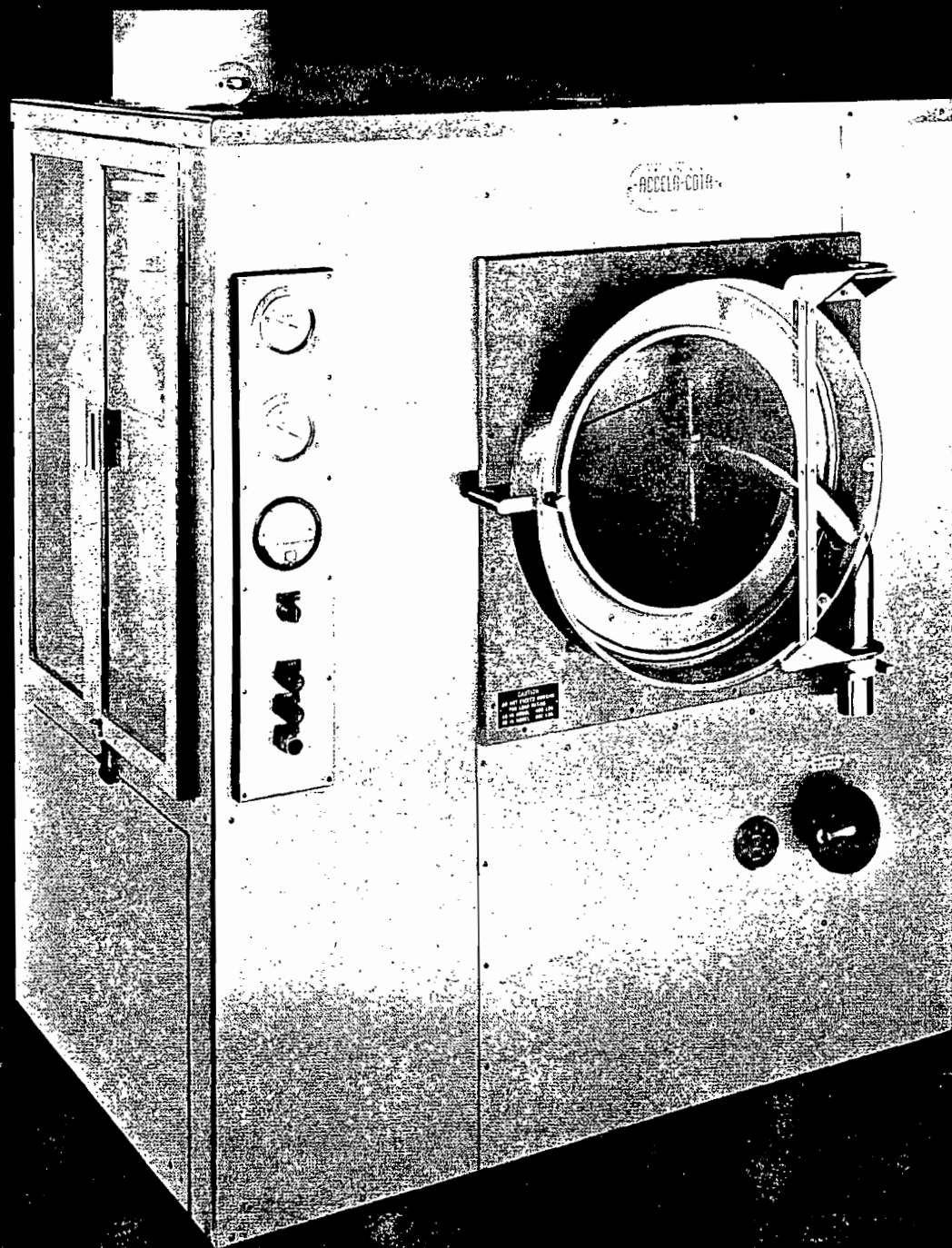
ACTUAL EMISSIONS MAY CONTAIN ONLY 50% BY WEIGHT VOC = 0.66 TONS/YR

Calculated by
Steph J. Woodstein 2/5/04

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.

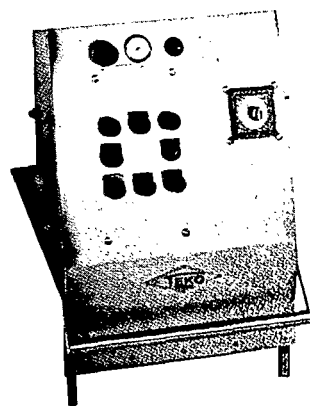
Whether spraying or ladling, either aqueous or solvent systems, film or sugar coating, the **ACCELA•COTA** Action/Air coating pan provides the ultimate in coating efficiency. Ideal for an almost unlimited variety of candy and tablet coating assignments.

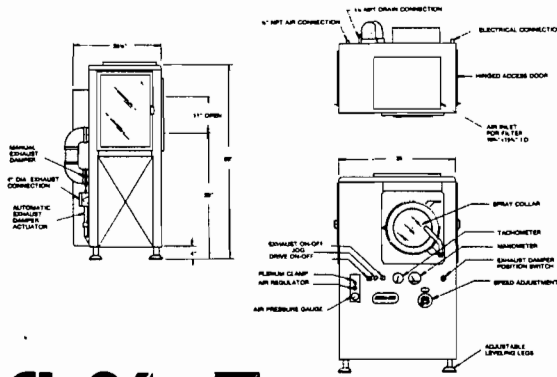
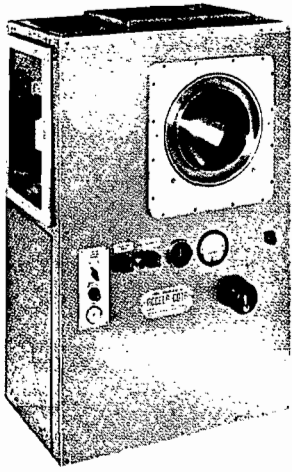
ACCELA•SPRAY II

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.

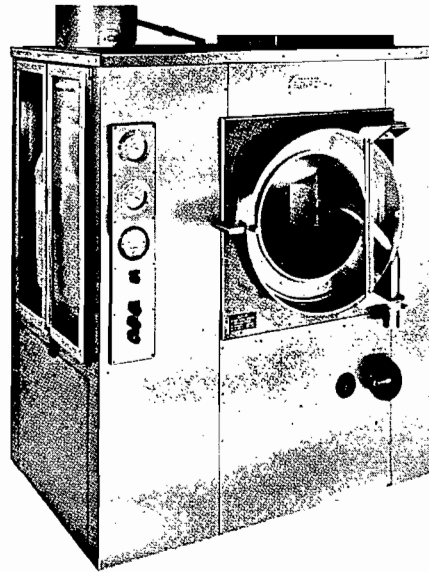
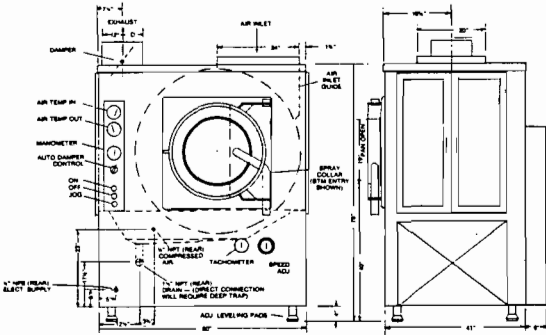




MODEL 24 - II

A semi-production model with an approximate working capacity of 40 pounds. Suitable for development work as well as small batch production.

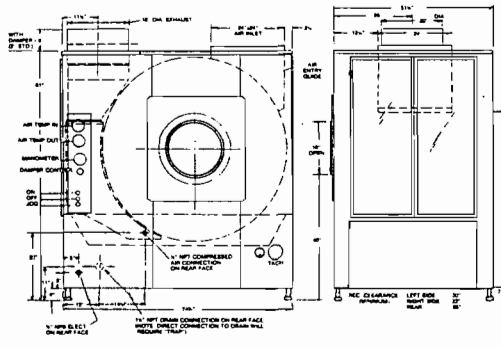
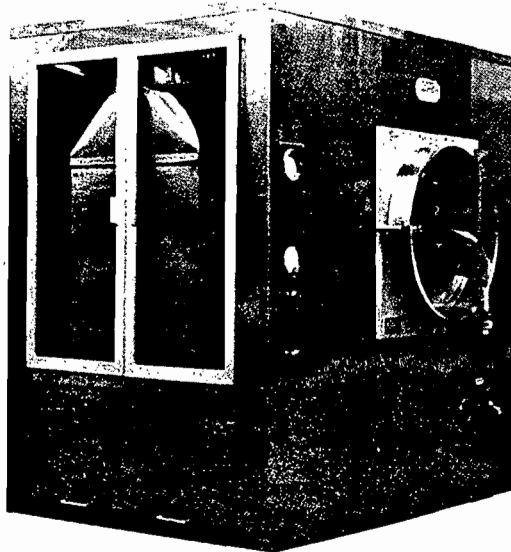
Now Available in Four Models



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.

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	1¼-13	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# <i>184g</i>	900# <i>40g</i>	1800# <i>81g</i>	+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.

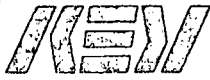
The **ACCELA•SCOOP** fastens to the pan simply and conveniently. Jog the pan for 3-4 revolutions and *all* of the tablets are unloaded.



THOMAS ENGINEERING INC.

CENTRAL AND ELA ROADS, P.O. BOX 198
312/358-5800

• HOFFMAN ESTATES, ILLINOIS 60195
• TELEX 28-1054



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

February 11, 1986

Mr. Bill Thomas
Bureau of Air Quality Management
Florida State Department of
Environmental Regulation
Twin Towers Building
2600 Blair Stone Road
Tallahassee, FL 32301-8241

DER

FEB 12 1986

BAQM

Dear Bill:

Presently, Key Pharmaceuticals, Inc. has requests for several permits in either the construct or operating stage including:

1. Operating Permit (AO 114316) for Glatts 1, 2, and 3.
2. Construct Permit to manufacture GUANIDINE and QUINORA tablets.
3. Construct Permit for a coating pan (i.e. Accela-Cota) in the R & D facility.

Furthermore, Key is under a consent decree (OCG Case No. 83-0373) that will result in all THEO-DUR operations and the accompanying solvent discharges to move to Puerto Rico in 1986.

In order to aid you in reviewing the present and any future permits two pieces of information need to be reviewed. These are:

1. Projected Controlled and Uncontrolled emissions in 1987 through 1990.
2. Pharmaceutical Processes involved at Key.

The attached table denotes the various solvents used in the current and planned processes at Key's Miami site for 1987 - 1990. The controls as noted are on the methanol using the current permitted process (i.e. wet scrubbing followed by biological treatment). The numbers are ranged as they are estimates based on new products being approved by the FDA. Therefore, the actual quantities could easily be skewed lower. The average total controlled VOC's start out at 26.5 tons/year and increase to 76.9 tons/year in 1990. Again, these numbers represent controls only on methanol.

February 11, 1986

Mr. W. Thomas

Page 2 (of 3)

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Pharmaceutical processes typically are isolated to the following:

GRANULATION

COATING (either in coating pans or a fluidized bed unit, i.e. Glatt).

BLENDING

COMPRESSING

PACKAGING

These are defined as follows:

- A. GRANULATION - dry powders (active plus excipients) are mixed together in a mixer (e.g. ribbon, Sigma) with a granulating solution (aqueous or solvent). The material is wet sized and placed on trays and dried. After drying it is dry sized, sampled, and stored. Emissions consist of solvent and dust.
- B. COATING
 - i. COATING PANS - a substrate is placed in the coating pan and various coating solutions are applied. These include a solvent based film former plus dry powder (active), wax solutions and clear film former. After coating, the material (pellets) is allowed to dry. Emissions consist of solvent and dust.
 - ii. FLUID BED UNIT - the substrate is placed in the coating unit. All material applied is in the form of solutions or slurries sprayed onto the substrate. Drying of the pellets occurs in the same unit. Once completed, the pellets are stored.
- C. BLENDING - this is performed in a double cone unit termed a Gemco. The pellets and granulations (or pellets only) made previously are added to the blender along with dry excipients which include a dry lubricant. Blending is performed for a set time. Emissions include dust only.
- D. COMPRESSING - the blended material is placed on a rotary tableting machine to form tablets. Emissions consist of dust only.
- E. PACKAGING - the tablets produced are put in bottles along with cotton, capped and palletized. A very small amount of dust can be generated.

February 11, 1986

Mr. W. Thomas

Page 3 (of 3)

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It is hoped that this information aids in the review of our present and future permits. If there are any additional questions, do not hesitate to contact me.

Very truly yours,

KEY PHARMACEUTICALS, INC.



Stephen J. Goodstein, Manager
Environmental Engineering and
Waste Management

SJG/db

attachment

cc: A.F. Gant
R. Quinlan
R.A. Franke
W. Smyth
T. Flachmeyer
E. Borbe
R. Glover

February 11, 1986

Mr. W. Thomas
Attachment

PROJECTED EMISSIONS (VOC's) IN TONS PER YEAR

	1 9 8 7		1 9 8 8		1 9 8 9		1 9 9 0	
	<u>UNCONT</u>	<u>CONTROL</u>	<u>UNCONT</u>	<u>CONTROL</u>	<u>UNCONT</u>	<u>CONTROL</u>	<u>UNCONT</u>	<u>CONTROL</u>
ISOPROPYL ALCOHOL	0-3.6	0-3.6	5.1-14.6	5.1-14.6	8-23.3	8-23.3	9.7-27.3	9.7-27.3
ACETONE	0-3.3	0-3.3	1.8-9.9	1.8-9.9	2.8-16.4	2.8-16.4	3.4-18.5	3.4-18.5
ETHYL ACETATE	0-3.1	0-3.1	0-7.2	0-7.2	0-12.4	0-12.4	0-13.4	0-13.4
METHANOL	169-251	16.9-25.1	210-316	21-31.6	263-394	26.3-39.4	323-456	32.3-45.6
METHYLENE CHLORIDE *	878-1303	878-1303	1087-1641	1087-1641	1364-2042	1364-2042	1676-2360	1676-2360
3A ALCOHOL	0-0.9	0-0.9	0-0.9	0-0.9	0-3.0	0-3.0	0-3.6	0-3.6
TOTAL VOC's *	169-261.9	16.9-36	216.9-348.6	27.9-64.2	273.8-449.1	37.1-94.5	336.1-518.8	45.4-108.4
AVG TOTAL VOC's CONTROLLED		26.5		46.1		65.8		76.9

* METHYLENE CHLORIDE IS NOT A VOC AS PER 17-2.510 AND IS NOT INCLUDED IN THE TOTALS.

7700017
11/13/86

Key Pharmaceuticals Inc
1400 Biscayne Boulevard
Miami Florida 33137

BEST AVAILABLE COPY

REFERENCE

CHECK NO

CHECK DATE

01 23 86

PAY THIS AMOUNT

***100.00

VOID AFTER 60 DAYS

PAY THE SUM OF

***100.DOLLARS AND 00 CENTS

FLORIDA STATE DEPT OF ENVIRONMENTAL REGULATION

BY *David L. W.*
BY *Wayne R.*

INVOICE DATE	INVOICE NO	DESCRIPTION	GROSS AMOUNT	DISCOUNT AMOUNT	NET AMOUNT PAID
01 21 86		PERMITTING FEE FOR CONSTRUCT PERMIT TO MAKE GUANIDINE & QUINORA TABLETS AT KEY			\$100.00
CHECK NO	CHECK DATE	VENDOR NUMBER	VENDOR NAME	TOTAL AMOUNT OF CHECK	

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

No 76105

RECEIPT FOR APPLICATION FEES AND MISCELLANEOUS REVENUE

Received from Key Pharmaceuticals Inc Date Feb. 10, 1986

Address 4400 Biscayne Blvd, Miami FL 33137 Dollars \$ 100.00

Applicant Name & Address Same as above

Source of Revenue _____

Revenue Code 001031 Application Number AC 13-115383

By Patricia B. Adams



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

DER
JAN 29 1986
BAQM

January 21, 1986

C. H. Fancy, Deputy Chief
Bureau of Air Quality Management
Twin Towers Building
2600 Blairstone Road
Tallahassee, FL 32301-8241

Dear Mr. Fancy:

For some time now, Key Pharmaceuticals, Inc. has been manufacturing GUANIDINE HCl and QUINORA 300mg tablets. GUANIDINE HCl is an orphan drug manufactured at no profit for a rare disorder known as Eaton-Lambert Syndrome. QUINORA 300mg tablets are an antiarrhythmic drug. Both products are granulated with a solvent; namely Isopropanol for GUANIDINE and 3A Alcohol for QUINORA. All of the solvents are presently emitted to the atmosphere.

For the past several years, these products were made for Key by Phoenix Pharmaceuticals in New Jersey. However, recently they have shut down the New Jersey facility. FDA regulations require considerable time for approval (up to two years) for new manufacturing sites. Therefore, approval for manufacturing outside of Key is not feasible. Furthermore, based on the present consent decree (OGC Case No. 83-0373), most of Key's present manufacturing workload (i.e., THEO-DUR tablets and SPRINKLE) will shift to Puerto Rico by November, 1986, if not sooner. Therefore, the attached permit is requesting that these two products be allowed to be manufactured at the Miami plant site. The total added emissions are less than one ton/year and would not impact on the plant emissions once the THEO-DUR operations leave (i.e., less than 40 tons/year of VOC).

Please process the attached permit as soon as possible. I have had verbal discussions with Bill Thomas of your office on this subject.

If there are any questions, please contact me.

Very truly yours,

Stephen D. Goodstein, Manager
Environmental Engineering and
Waste Management

SJG:1J

AC 13-115383

DER

JAN 29 1986

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION **BAQM**

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 New¹ Existing¹

APPLICATION TYPE: 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) Granulation Rooms

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: Allen F. Gant, Vice President, Production & Engineering

APPLICANT ADDRESS: 50 NW 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: Allen F. Gant
Allen F. Gant
Vice President, Production & Engineering
Name and Title (Please Type)

Date: 21 Jan 86 Telephone No. 305/578-5800

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 on

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 two products.

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: 1/22/86 Telephone No. (305) 578-5800



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.

INETS

The project entails the production of two different tablet formulations; namely Guanidine and Quinora tablets. Both tablets are made by granulating active plus excipients with alcohol (either Isopropanol or 3A) followed by drying, sizing, compression and packaging operations.

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

Start of Construction April 1986 Completion of Construction April 1986

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.)

No pollution control systems other than the present dust collector will be added. As the total effluent of VOC for these products is less than 1 ton/year, such addition to present emissions do not warrant new pollution control equipment.

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

1. Consent Order for halting or permitting Theo-Dur operations in Miami by 11/86, OGC Case No. 83-0373
2. Permit for Glatt 2 Catalytic Incinerator
3. Construct & Operating Permit for Glatts I, II & III for Project 0410 (K-Dur), AC-100437

E. Requested permitted equipment operating time: hrs/day _____; days/wk _____; wks/yr _____; if power plant, hrs/yr _____; if seasonal, describe: Less than 420 hrs/year. Only 2 lots per year of Guanidine and 11 lots per year of Quinora are planned. Each lot takes less than 24 hours (total lot time is 32 hours) where solvents are emitted. The lots could be made at any time during the year.

17 1/2 days

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.

$$E = 17.31(\rho) 0.62$$

$$= (13.59)(7.22/2000)^{0.62} = 0.16 \text{ lb/hr}$$

$$= (13.59)(27.4/2000)^{0.62} = 0.25 \text{ lb/hr}$$

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		
Isopropanol (in Guanidine)	VOC	100	3.2	"A"
3A Alcohol (in Quinora)	VOC	100	6.67	"A"

* Based on all solvent being used in 24 hours

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

1. Total Process Input Rate (lbs/hr): Quinora - 27.40
 ** Guanidine - 7.22

2. Product Weight (lbs/hr): Quinora - 27.3
 ** Guanidine - 7.18

** Based on 32 hours/lot

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	
Particulates	<.010	.00025	N/A	N/A		.025	"A"
Isopropanol	9.6***	0.077	N/A	N/A		0.077	"A"
3A Alcohol	20.0***	0.88	N/A	N/A		0.88	"A"

¹ See Section V, Item 2. *** Based on all solvent used in 8 hrs.

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 TD 2300	Particulates	99+%	1 micron or larger	Supplier's Design

E. Fuels N/A

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. N/A

Annual Average _____ Maximum _____

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

Approximately 0.025 tons/year of particulates will be generated in drums and disposed
of in an off-site disposal area.

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

Stack Height: Off roof - about 11 ft. Stack Diameter: 12" x 12" ft.
 Gas Flow Rate: 4000 SCFM 5 DSCFM Gas Exit Temperature: 70 °F.
 Water Vapor Content: About 50 - 60% RH % Velocity: 67 FPS

SECTION IV: INCINERATOR INFORMATION N/A

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 devices: 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

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 devices, 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:

¹Explain method of determining efficiency.

²Energy 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:

¹Explain method of determining efficiency.

²Energy 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:

¹Applicant 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 _____ () SO₂* _____ Wind spd/dir

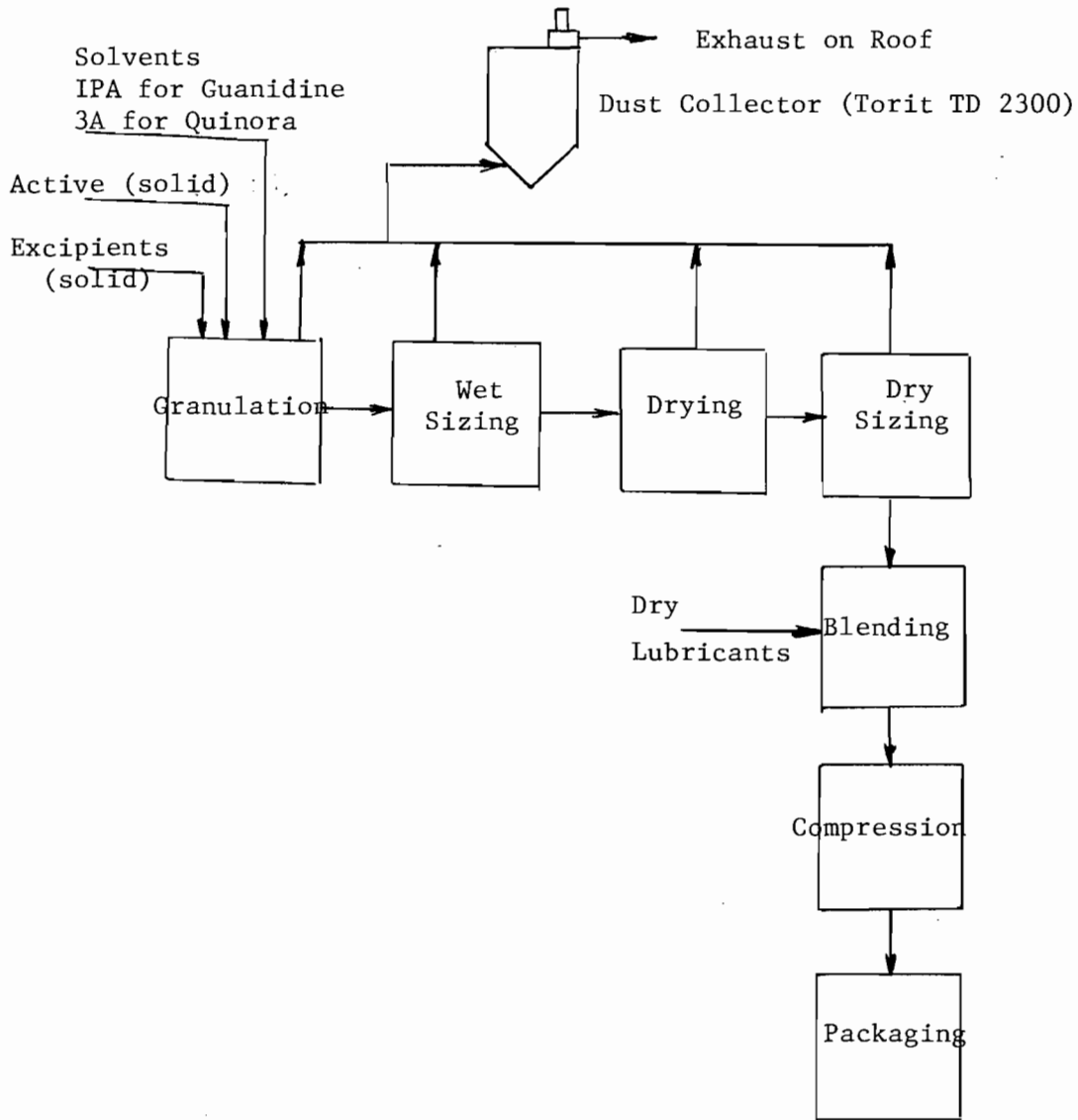
Period of Monitoring _____ / _____ / _____ to _____ / _____ / _____
month day year month day year

Other data recorded _____

Attach all data or statistical summaries to this application.

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

PROCESS FLOW SHEET "A"



C. AIRBORNE CONTAMINANTS EMITTED

(i) PARTICULATES

(a) GUANIDINE TABLETS

NO. OF LOTS/YEAR - 2
WEIGHT PER LOT - 231 LB/LOT
TOTAL WEIGHT/YEAR - 462 LB/YEAR

POTENTIAL EMISSIONS = 1/2 OF 1% OF TOTAL WEIGHT
(w/o CONTROL)
= 2.31 LB/YEAR

Efficiency of Collector = 99%

∴ EMISSIONS = 0.0231 LB/YEAR
(w. CONTROL)

0.0231
- 0.506

0.5291

(b) QUINORA TABLETS

NO. OF LOTS/YEAR - 11
WEIGHT PER LOT - 878 LB/LOT
TOTAL WEIGHT/YEAR - 9658 LB/YEAR

POTENTIAL EMISSIONS = 48.3 LB/YEAR
(w/o CONTROL)

EMISSIONS (w. CONTROL) = 0.483 LB/YEAR

TOTAL POTENTIAL EMISSIONS (w/o CONTROLS) = 50.6 LB/YEAR
= 0.0253 TONS/YEAR

TOTAL EMISSIONS (w. CONTROLS) = 0.506 LB/YEAR
= 0.000253 TONS/YEAR

(ii) VOC

GUANIDINE - ISOPROPRANOL - 77 LB/LOT = 154 LB/YEAR

QUINORA - 3A ALCOHOL - 160 LB/LOT = 1760 LB/YEAR

TOTAL = 1914 LB/YEAR
= 0.957 TONS/YEAR

calculated by
Stephen J. Kovacic Jan 20, 1986

1760
+ 154

1914



Key
Pharmaceuticals,
Inc.

August 10, 1984

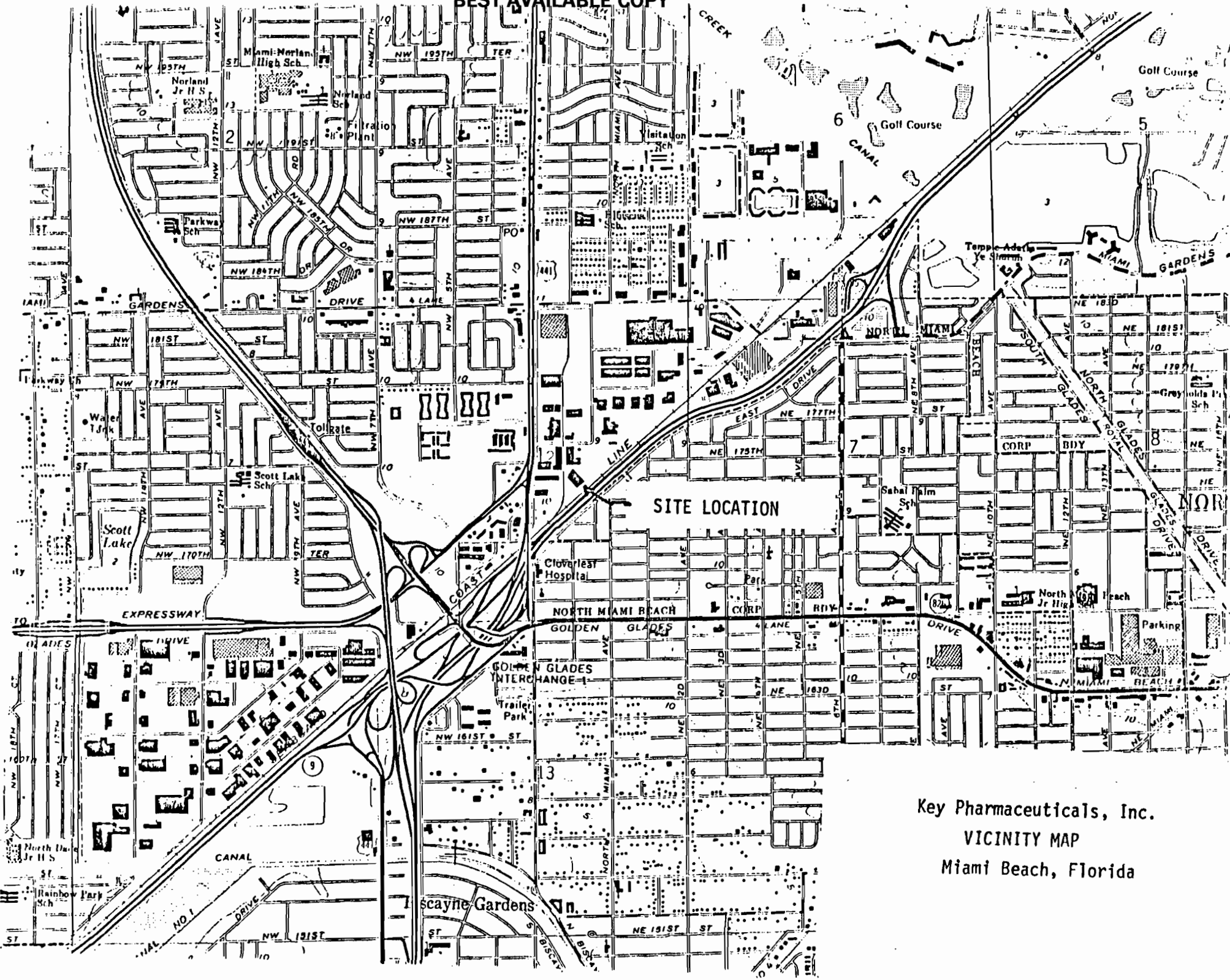
Florida Department of Environmental Regulation
2600 Blairstone Road
Tallahassee, Florida 32301

TO WHOM IT MAY CONCERN:

This letter serves as the authorization for Allen F. Gant,
Vice President of Production and Engineering, to act on behalf of
Key Pharmaceuticals, Inc. on all current DER related matters.

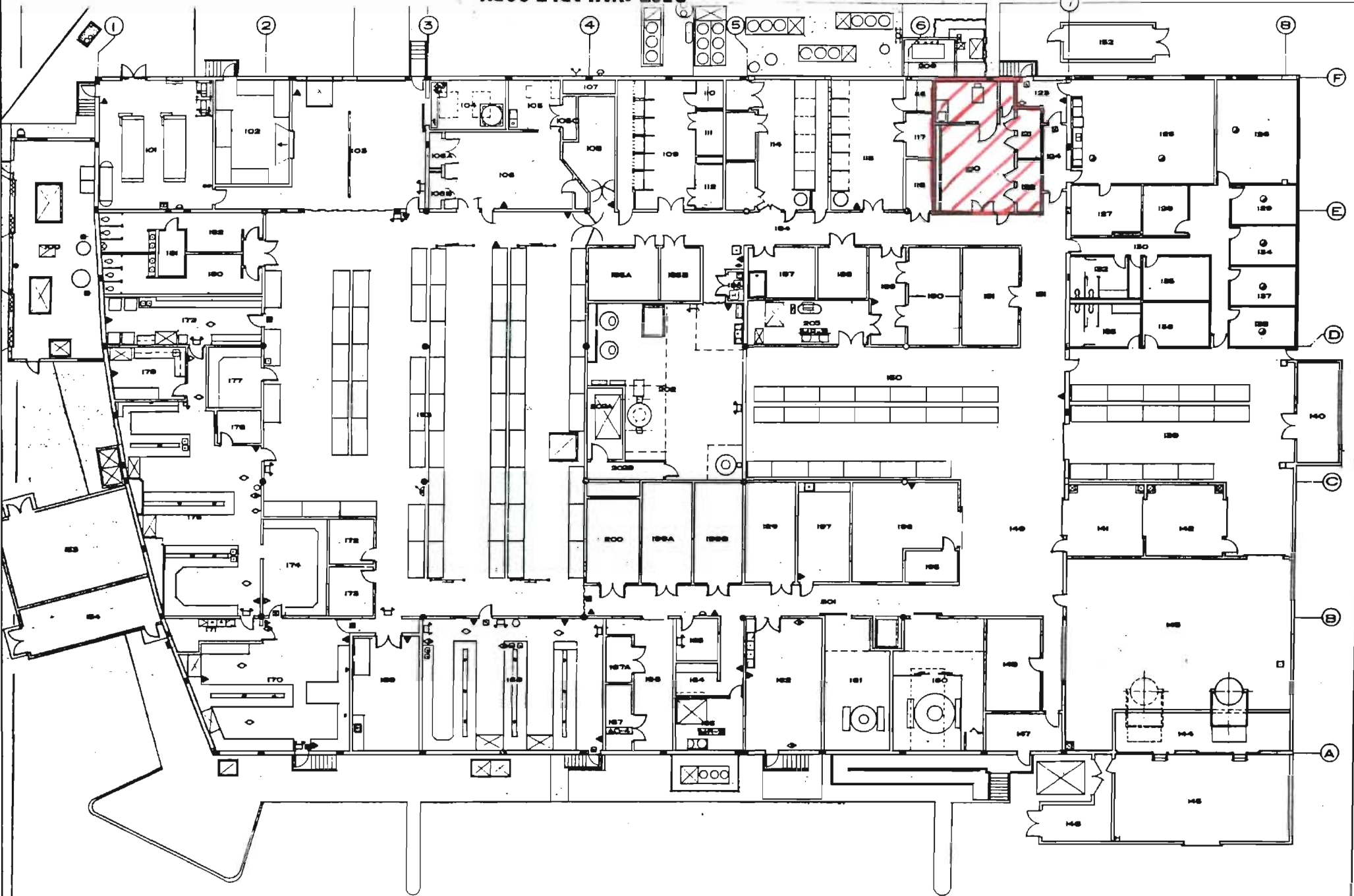
Yours truly,

D. M. Bell
Senior Vice President
Operations



Key Pharmaceuticals, Inc.
VICINITY MAP
Miami Beach, Florida

BEST AVAILABLE COPY



BUILDING 50

FLOOR PLAN

1/8"

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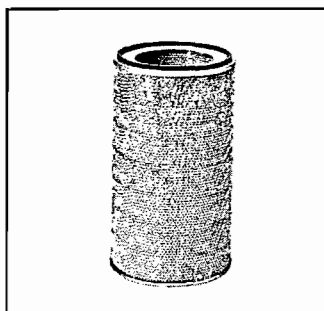


DUST COLLECTORS

FILTER CARTRIDGE SYSTEMS/TD 2300

NEW FILTRATION TECHNOLOGY

The new TD 2300 is based on a unique combination of technologies. It involves the application of cartridge-type filters to a continuous-duty dust collection system. It offers you many advantages for



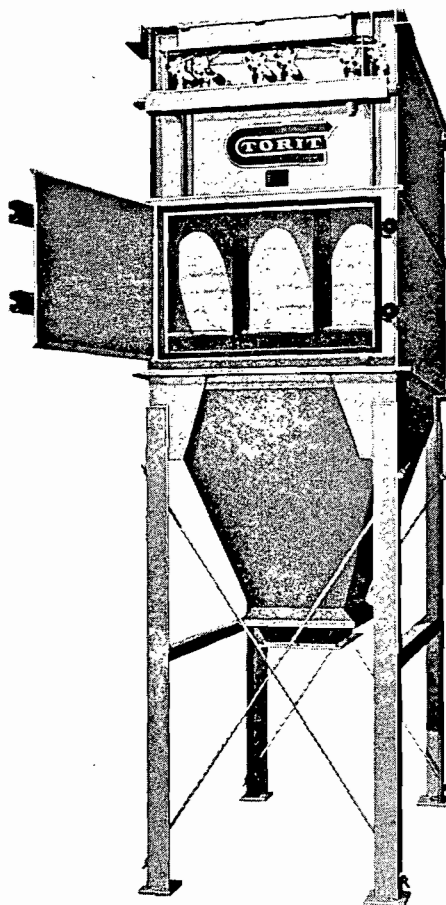
treating large volumes of dust-laden air on a continuing basis: highly efficient filtration; increased filtering area for lower air-to-media ratios; increased ease of maintenance and operation; and substantially decreased collector headroom.

EFFECTIVE FINE PARTICLE CONTROL

The use of pleated, non-woven filter media is the key to the TD 2300's filtering efficiency. Dust-laden air enters through the inlet of the collector— heavy particles fall immediately into the hopper bottom. As the air is drawn in through the filter cartridges, dust is deposited on the outside of the filtering media. With 12 filter cartridges, the system has 2208 square feet of filter area, almost *four times* as much as a conventional tube house of the same size. The generous filter area means low filtration velocity and high efficiency when handling sub-micron particulate.

CONTINUOUS PULSE-JET CLEANING

The TD 2300's filter cartridges are cleaned automatically and continually—the system remains on-line at all times. Continuous filtration means full-time pollution control and longer life for manufacturing equipment. A remotely-mounted solid state timer controls the cycle time. Solenoid valves introduce jets of high-pressure air into each pair of filter cartridges in turn, through the venturi opening above each cartridge. The resulting reverse air flow cleans the filter cartridges. Dust removed from the filters settles to the bottom of the collector. As a pair of cartridges is cleaned in succession, the remaining 10 continue their operation. Extremely high dust loadings are handled easily.



EASY-TO-HANDLE FLEXIBILITY

The TD 2300 requires up to 25% less headroom than conventional tube houses—the highly efficient filter cartridges are 26" long, instead of standard 96" cloth tubes. Its compact size gives you great flexibility in location. Also, the TD 2300 does the job with 12 cartridges, instead of the 48 or more filters in tube houses of the same size.

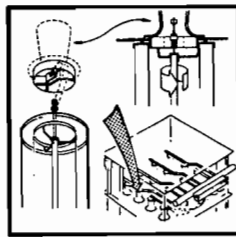
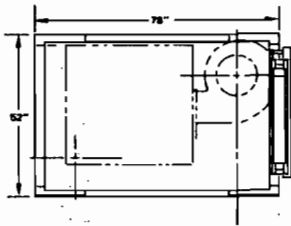
The TD 2300 is delivered to you in major assemblies. The system is available with different blower pack combinations for single-unit or multiple-unit applications. Its hopper can be fitted for 55-gallon drums, or for a rotary air lock adapter. The TD is made with the same high quality TORIT puts into all its dust collection systems: air-tight all-steel construction, sealed seams, and gasketed doors and fittings. The TD 2300 filter cartridge system is a major innovation in effective air pollution control, from TORIT.



DUST COLLECTORS

FILTER CARTRIDGE SYSTEMS/TD 2300

Quick-change feature allows fast cartridge removal and installation.



SPECIFICATIONS

Actual Filter Area	2712 sq. ft.
Number of Valves	6
Number of Filter Cartridges	12
Filter Cartridge	
Dimensions	12 $\frac{3}{4}$ " OD x 8 $\frac{3}{8}$ " ID x 26" long
Number of Hopper Outlets	1
Hopper Outlet Size	14 $\frac{1}{4}$ " square
Hopper Size	38 cu. ft.
Shipping Weight	est. 2040 lbs.
Wind Load Rating	100 m.p.h.
Seismic Rating	Zone 3

Specifications subject to change without notice.

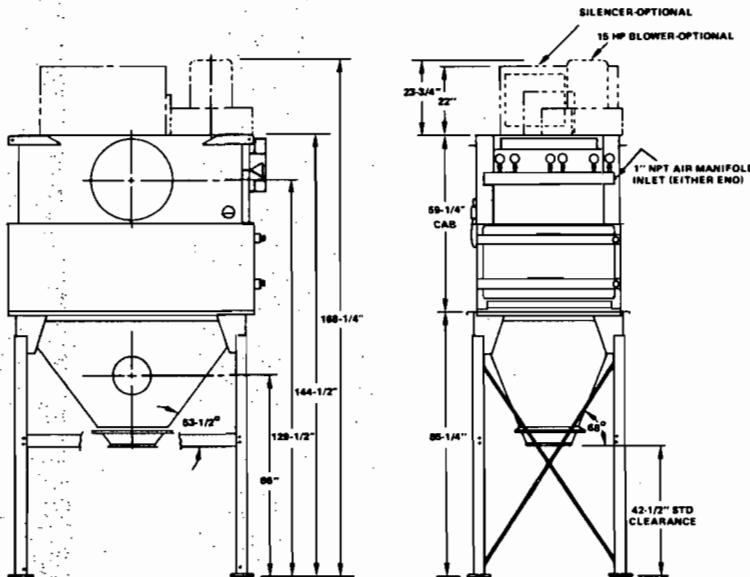
NOTES

- Inlet sizes available in 1-inch increments from 9" ID to 22" ID with built-on deflectors. Please specify.
- Standard legs provide 42 $\frac{1}{2}$ " clearance under the hopper flange. Bolt-on legs for special height requirements are available.
- TD systems must be attached to 90-100 PSIG in-plant compressed air supply for cleaning mechanism to function.
- Valves and control system operate on 120v, 60-cycle power.
- TD units are painted with blue acrylic enamel.
- Roof slope 2 inches.

PERFORMANCE TESTED

Performance ratings and A-scale sound level readings are available on each TD collector-power pack combination. These ratings are read and verified under standard test conditions in TORIT's laboratories.

TORIT district sales representatives are conveniently located throughout the United States and Canada. One will gladly work with you on your in-plant air pollution problems, and offer complete recommendations at no obligation to you. Check your Yellow Pages, under "Dust Collecting Systems", for local listing, or write.



OPTIONAL EQUIPMENT

- Blower pack options include 3HP, 5HP, 10HP, 15HP, 20HP or remote exhausters as required. 15HP is standard equipment. Please state in-plant line voltage when ordering.
- Sound attenuator packages.
- Explosion vents.
- Rotary airlock and adapter.



LEADERS IN CONTROL OF IN-PLANT AIR POLLUTION
 TORIT DIVISION/DONALDSON COMPANY, INC./BOX 1299/MINNEAPOLIS, MINNESOTA 55440



Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307
(305) 578-5800

Cable: KEYPHARM
Telex: 808235

February 13, 1986

C.H. Fancy, Deputy Chief
Bureau of Air Quality Management
Florida State Department of Environmental Regulation
Twin Towers Building
2600 Blair Stone Road
Tallahassee, Florida 32301-8241

Dear Mr. Fancy:

On Wednesday, February 12, 1986, Bill Smyth and I from Key Pharmaceuticals, Inc., visited your offices and met with Willard Hanks and Bill Thomas to discuss present and future permitting. Based on these discussions, it was found that a 40 ton/year cap was placed on the Glatt I thru III (i.e., AC 100437) and the expiration date was February 28, 1986.

The 40 ton/year cap does not allow for either of the two small permits now in your possession to be reviewed. These are (1) for Guanidine and Quinora Tablets with a potential of 0.96 tons/year and (2) for an Accela-Cota pan operation at our R & D facility (999 N.W. 159 Drive, Miami, Florida) with a potential of 1.32 tons/year. Therefore, it is requested that the cap on permit AC 100437 be reduced to 35 tons/year.

Secondly, the expiration date of the construct permit needs to be changed. Glatts I and II are now ready for operation. However, Glatt III will not be installed and operating until early in 1987. Therefore, two things need to occur. First is to extend the construct permit to April 01, 1987, to allow for the installation and operation of Glatt III. This should allow enough time for its installation. If not, either another extension or a new permit would be applied for. Secondly, the operating permit already submitted (i.e., A0 114316) should be reviewed as an interim operating permit for Glatts I & II only and then when Glatt III is operational add that based on acceptable testing (i.e., EPA Methods 25 and 9).

DER

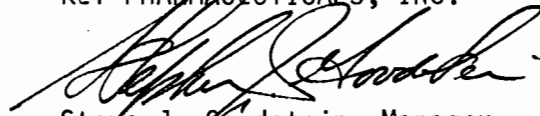
FEB 14 1986

BAQM

C.H. Fancy, Deputy Chief
February 13, 1986
Page 2

Please review the above with your people and let me know of the results of the three requests. If there are any questions, please contact me.

Very truly yours,
KEY PHARMACEUTICALS, INC.



Steve J. Goodstein, Manager
Environmental Engineering &
Waste Management

:ocq

xc:	A.F. Gant	T. Flachmeyer	W.J. Smyth
	R. Quinlan	E. Borbe	P. Rothchild
	R.A. Franke	R. Glover	

DER
FEB 14 1986
BAQM