Check Sheet

Company Name: Key Pharmaceuticals
Permit Number: AC 13-129899
PSD Number:
Permit Engineer:

Application:

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

Cross References:

- [ ]
- [ ]
- [ ]

Intent:

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

Correspondence with:

- [ ] EPA
- [ ] Park Services
- [ ] Other

- [x] Proof of Publication
  - [ ] Petitions - (Related to extensions, hearings, etc.)
  - [ ] Waiver of Department Action
  - [x] Other

Final Determination:

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

Post Permit Correspondence:

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

P 274 007 654

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED
NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to James R. Confroy Key Pharmaceuticals, Inc.	
Street and No. 50 N.W. 176th Street	
P.O., State and ZIP Code Miami, FL 33169-1307	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt showing to whom and Date Delivered	
Return Receipt showing to whom, Date, and Address of Delivery	
TOTAL Postage and Fees	$
Postmark or Date Mailed: 11/13/87 AC Ammendment: AC 13-129899	

PS Form 3800, June 1985

☆ U.S.G.P.O. 1985-480-794

PS Form 3811, July 1983 447-845

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

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

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

3. Article Addressed to: James R. Confroy, V.P.
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, FL 33169-1307

4. Type of Service:	Article Number
☐ Registered ☐ Insured ☒ Certified ☐ COD ☐ Express Mail	P 274 007 654

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

5. Signature – Addressee
X

6. Signature – Agent
X Kenneth L. Wright

7. Date of Delivery
NOV 17 1989

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

DOMESTIC RETURN RECEIPT

file

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

November 3, 1987

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Mr. James R. Confroy
Vice President Operations
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307

Dear Mr. Confroy:

Ref: Amendment of Conditions - Permit No. AC 13-129899

The Department has reviewed your October 26, 1987, request to amend the construction permit that was issued for the proposed carbon adsorption and solvent recovery system that is to be located at Key Pharmaceutical's Miami, Dade County, Florida facility. As the permitted VOC emissions are not increased, the request is acceptable, with conditions, and the permit to construct No. AC 13-129899 is amended as noted below.

ORIGINAL PERMIT

Description:

Authorization to construct 6 coating pans and 3 drying/curing rooms with ancillary equipment and connect this process equipment to the 90% efficient carbon adsorption/solvent recovery system that controls the emissions from four fluid bed processors (Glatt) and two Perforated Pan Coating Units (PPCU). This equipment will be located at the pharmaceutical plant at 50 N.W. 176th Street, Miami, Dade County, Florida. The UTM coordinates of this plant are zone 17, 579.9 km E and 2868.4 km N.

Specific Conditions:

1. Until the carbon adsorption/solvent recovery system is able to control the air pollutant emissions from the pan coating process, the permittee shall limit production from this process to 128 lots in 1987 and 128 lots in 1988.

2. Production after the carbon adsorption/solvent recovery system is placed in service shall not exceed the following without prior approval of the Department (BAQM):

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

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

Perforated Pan Coating Unit (PPCU) #1 - 1095 lots per year
Perforated Pan coating Unit (PPCU) #2 - 1095 lots per year
Each perforated pan coating unit lot uses approximately 600 lbs methylene chloride, 90 lbs methanol, and 400 lbs solids (excipients).

Pan Coating Process - 2,190 lots/year

Each pan coating process lot uses approximately 909 lbs of solids (excipients) and 166 lbs/VOC solvents (ethyl acetate, acetone, and isopropanol).

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

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

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

Unit	Methylene Chloride lb/hr	lb/day	TPY	VOC lb/hr	lb/day	TPY	PM lb/hr	TPY
Glatt No. 1	20.9	271.2	49.5	1.9	25.0	4.6		
Glatt No. 2	26.7	465.6	85.0	2.5	43.2	7.9		
Glatt No. 3	26.7	465.6	85.0	2.5	43.2	7.9		
Glatt No. 4	26.7	465.6	85.0	2.5	43.2	7.9		
PPCU No. 1	20.0	180.0	32.8	3.0	27.1	4.9	0.1*	0.23*
PPCU No. 2	20.0	180.0	32.8	3.0	27.1	4.9		
Pan Coat. Process	0	0	0	6.98	99.4	18.13	0.5	1
Total	141.0	2028.0	370.1	22.08	308.2	56.23	0.6	1.23

* Net emissions from Glatt and PPCU units.

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

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

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

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

The Department (SE District) shall be notified 15 days prior to any compliance test. Test results shall be submitted to the Department (SE District) within 45 days of any test.
6. This operation (Glatts, Perforated Pan Coating Units, Pan Coating Process, Carbon Adsorption/Solvent Recovery) shall not cause, suffer, allow, or permit the discharge of air pollutants which cause or contribute to an objectionable odor.

REVISED PERMIT

Description:

Authorization to construct 6 coating pans and 3 drying/curing rooms with ancillary equipment and connect this process equipment to the 90% efficient carbon adsorption/solvent recovery system that controls the emissions from four fluid bed processors (Glatt). This equipment will be located at the pharmaceutical plant at 50 N.W. 176th Street, Miami, Dade County, Florida. The UTM coordinates of this plant are zone 17, 579.9 km E and 2868.4 km N.

Specific Conditions:

1. Until the carbon adsorption/solvent recovery system is able to control the air pollutant emissions from the pan coating process, the permittee shall limit production from this process to 160 lots in 1987 and 160 lots in 1988. Maximum VOC emissions from 160 lots shall not exceed 12.06 TPY as determined through production records.

2. Production after the carbon adsorption/solvent recovery system is placed in service shall not exceed the following without prior approval of the Department (BAQM):

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

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

Pan Coating Process - 2,190 lots/year

Each pan coating process lot uses approximately 909 lbs of solids (excipients) and 229 lbs/VOC solvents (ethyl acetate, acetone, and isopropanol, and chloroform). Stack height shall be increased to a minimum of 12.5 meters.

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

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

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

Unit	Methylene Chloride lb/hr	lb/day	TPY	VOC lb/hr	lb/day	TPY	PM lb/hr	TPY
Glatt No. 1	20.9	271.2	49.5	1.9	25.0	4.6		
Glatt No. 2	26.7	465.6	85.0	2.5	43.2	7.9		
Glatt No. 3	26.7	465.6	85.0	2.5	43.2	7.9	0.1*	0.23*
Glatt No. 4	26.7	465.6	85.0	2.5	43.2	7.9		
Pan Coat. Process	0	0	0	9.63	137.12	25.01	0.5	1
Total	141.0	2028.0	370.1	19.03	291.72	53.31	0.6	1.23

*Net emissions from the Glatt units.

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

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

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

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

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

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

Attachments to be Incorporated:

4. Key Pharmaceutical's letter dated October 26, 1987.
5. Key Pharmaceutical's letter dated October 29, 1987.

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

Sincerely,

Dale Twachtmann
Secretary

DT/ks

enclosure

CC: Thomas W. Hackmeyer, Key
I. Goldman - DER/W.P.B
P. Wang - DERM
Willard Hank
Reading file

11/13/87 MR

ATTACHMENT 4

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

Telex: 808235

October 26, 1987

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

RE: Permit No. AC 13-129899

Dear Mr. Fancy:

Key Pharmaceuticals, Inc. is currently in a position that requires a realignment of production activities. In light of this Key Pharmaceuticals, Inc. is requesting a modification to the above referenced permit. The specific modification request is as follows:

Drop from the permit

1) Two (2) Perforated Pan Coaters - 2,190 lots

2) Six (6) Coating Pans - 128 lots of QUINEL-DUR

This reduction in production equipment capacity will result in an allowable emission reduction of 0.03771 tons per year particulates, 15.49 tons per year of VOC's and 65.67 tons per year of Methylene Chloride. The solvents included in the VOC emission reduction use Acetone, Isopropyl Alcohol, Methanol and Ethyl Acetate.

As a trade off, Key Pharmaceuticals, Inc. is requesting permission to manufacture 160 lots of THEO-DUR 100 in 6 Coating Pans per year. This process will result in an annual emission of 0.01529 tons of particulate and 12.06 tons per year of VOC's. The VOC's involved in this process are Acetone, Isopropyl Alcohol, Diethyl Phthalate and Chloroform. As indicated in the original permit application the emissions from the Coating Pans will be controlled by the Carbon Adsorption/Solvent Recovery System once it come on line after July of 1988 or will cease.

This request, therefore, results in a net allowable emission decrease of the following:

	CURRENT ALLOWABLE 1987 (T/Y)	PROPOSED ALLOWABLE 1987 (T/Y)	NET DECREASE (T/Y)
PARTICULATE	0.09859	0.07616	0.02242
VOC	53.64	50.20	3.44
METHYLENE CHLORIDE	370.51	304.84	65.67

It should be noted that Dade County is a non-attainment area for Ozone and that this request will result in a decrease in permitted levels of VOC's in Dade County.

Key Pharmaceuticals, Inc. trusts that this request will receive your department's timely attention.

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

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

ATTACHMENT 5

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

Telex: 808235

DER

OCT 30 1987

BAQM

October 29, 1987

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

Dear Mr. Fancy:

Reference: Permit No. AC 13-129899

In response to Mr. Willard Hanks' request, Key Pharmaceuticals, Inc. has modeled the Chloroform emissions from the Pan Coating process proposed under the above referenced permit. The model utilized for this is the Industrial Source Complex Short Term (ISCST) model. This model takes into account not only the specific parameters of the source, but also the meteorological data for the location of the source. The meteorological data utilized in this model is data supplied by Trinity Consultants taken from actual National Weather Service data for the greater Miami area. The model predicts the average annual ground level concentration of a particular contaminant. The source parameters utilized in this model area as follows:

MODEL	ISCST
STACK HEIGHT	40'
STACK DIAMETER	1.6'
EMISSION FLOW RATE	7,000 acfm
STACK GAS TEMP	70°F
EMISSION LOADING	39.3 LB/HR

Utilizing the above parameters the model predicts an average concentration of Chloroform of 31 micrograms per cubic meter. This information can be compared to the following standards.

OSHA Ceiling (29 CFR 1910.1000)	240,000 $\mu g/m^3$
TLV of Amer. Conf. Gov. Ind Hyg. (1981)	50,000 $\mu g/m^3$
New York State Guideline AAL *	167 $\mu g/m^3$
Key concentration modeled	31 $\mu g/m^3$

* AAL: Acceptable ambient level equal to the annual average ambient concentration not to be exceeded at any off-site receptor.

The model utilized by Key Pharmaceuticals, Inc. predicts a concentration that is 18.5% of the allowable levels under the New York State AAL Guidelines. This is well within the requirements set forth by the State of New York for toxic air emissions.

Key Pharmaceuticals, Inc. is of the opinion that this data supports the application letter of October 26, 1987, and that these emissions are in compliance with all Florida regulations.

In addition, Key Pharmaceuticals, Inc. would like to be authorized to utilize Ethyl Acetate as one of the solvents permitted under the VOC emissions.

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

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF

cc: Mr. Patrick Wong
Ms. Stephanie Brooks

ISCST (DATED 86322)
AN AIR QUALITY DISPERSION MODEL IN
SECTION I. GUIDELINE MODELS
IN UNAMAP (VERSION 6) JULY 86.
SOURCE: FILE 6 ON UNAMAP MAGNETIC TAPE FROM NTIS.

IBM-PC VERSION (1.40)

SERIAL NUMBER 5257 SOLD TO SCHERING PLOUGH CORPORATION
RUN BEGAN ON 10-30-87 AT 05:58:07

*** PREDICTION OF CHLOROFORM CONCENTRATION FROM THEO-DUR COATING ***

*** METEOROLOGICAL DAYS TO BE PROCESSED ***
(IF=1)

```
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1
```

*** UPPER BOUND OF FIRST THROUGH FIFTH WIND SPEED CATEGORIES ***
(METERS/SEC)

1.54, 3.09, 5.14, 8.23, 10.80,

*** WIND PROFILE EXPONENTS ***

STABILITY	WIND SPEED CATEGORY					
CATEGORY	1	2	3	4	5	6
A	.15000E+00	.15000E+00	.15000E+00	.15000E+00	.15000E+00	.15000E+00
B	.15000E+00	.15000E+00	.15000E+00	.15000E+00	.15000E+00	.15000E+00
C	.20000E+00	.20000E+00	.20000E+00	.20000E+00	.20000E+00	.20000E+00
D	.25000E+00	.25000E+00	.25000E+00	.25000E+00	.25000E+00	.25000E+00
E	.30000E+00	.30000E+00	.30000E+00	.30000E+00	.30000E+00	.30000E+00
F	.30000E+00	.30000E+00	.30000E+00	.30000E+00	.30000E+00	.30000E+00

*** VERTICAL POTENTIAL TEMPERATURE GRADIENTS ***
(DEGREES KELVIN PER METER)

STABILITY	WIND SPEED CATEGORY					
CATEGORY	1	2	3	4	5	6
A	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00
B	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00
C	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00
D	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00
E	.20000E-01	.20000E-01	.20000E-01	.20000E-01	.20000E-01	.20000E-01
F	.35000E-01	.35000E-01	.35000E-01	.35000E-01	.35000E-01	.35000E-01

*** PREDICTION OF CHLOROFORM CONCENTRATION FROM THEO-DUR COATING ***

X,Y-COORDINATES OF THE CENTER OF THE POLAR RECEPTOR GRID (METERS) = (0., 0.)

*** RANGES OF POLAR GRID SYSTEM ***
(METERS)

100.0, 200.0, 300.0, 400.0, 500.0,

*** RADIAL ANGLES OF POLAR GRID SYSTEM ***

(DEGREES)

10.0,	20.0,	30.0,	40.0,	50.0,	60.0,	70.0,	80.0,	90.0,	100.0,
110.0,	120.0,	130.0,	140.0,	150.0,	160.0,	170.0,	180.0,	190.0,	200.0,
210.0,	220.0,	230.0,	240.0,	250.0,	260.0,	270.0,	280.0,	290.0,	300.0,
310.0,	320.0,	330.0,	340.0,	350.0,	360.0,				

*** PREDICTION OF CHLOROFORM CONCENTRATION FROM THEO-DUR COATING ***

*** SOURCE DATA ***

SOURCE NUMBER	TYPE	WAKE	NUMEER PART. CATS.	EMISSION RATE TYPE=0,1 (GRAMS/SEC) TYPE=2 (GRAMS/SEC) *PER METER**2	X (METERS)	Y (METERS)	BASE ELEV. (METERS)	HEIGHT (METERS)	TEMP. TYPE=0 (DEG.K); VERT.DIM TYPE=1 (METERS)	EXIT VEL. TYPE=0 (M/SEC); HORZ.DIM TYPE=1,2 (METERS)	DIAMETER TYPE=0 (METERS)	BLDG. HEIGHT TYPE=0 (METERS)	BLDG. LENGTH TYPE=0 (METERS)	BLDG. WIDTH TYPE=0 (METERS)
1	0	0	0	.49560E+01	.0	.0	.0	12.50	294.26	17.78	.49	.00	.00	.00

* CALM HOURS (=1) FOR DAY 30 *	0	0	0	1	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
* CALM HOURS (=1) FOR DAY 31 *	1	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
* CALM HOURS (=1) FOR DAY 32 *	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 33 *	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
* CALM HOURS (=1) FOR DAY 34 *	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 38 *	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
* CALM HOURS (=1) FOR DAY 42 *	0	0	1	0	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 43 *	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
* CALM HOURS (=1) FOR DAY 44 *	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0
* CALM HOURS (=1) FOR DAY 46 *	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
* CALM HOURS (=1) FOR DAY 98 *	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 144 *	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
* CALM HOURS (=1) FOR DAY 154 *	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1
* CALM HOURS (=1) FOR DAY 155 *	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	1	1	0	0	1	0
* CALM HOURS (=1) FOR DAY 156 *	0	1	1	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 157 *	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 158 *	0	1	0	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 161 *	1	1	1	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
* CALM HOURS (=1) FOR DAY 162 *	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
* CALM HOURS (=1) FOR DAY 163 *	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 167 *	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
* CALM HOURS (=1) FOR DAY 170 *	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 173 *	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 175 *	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 177 *	1	0	0	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 181 *	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 185 *	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 188 *	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 190 *	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 191 *	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	1
* CALM HOURS (=1) FOR DAY 192 *	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 202 *	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
* CALM HOURS (=1) FOR DAY 205 *	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 206 *	1	1	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 207 *	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 208 *	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 212 *	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 213 *	1	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 226 *	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
* CALM HOURS (=1) FOR DAY 228 *	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
* CALM HOURS (=1) FOR DAY 229 *	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1	1	0
* CALM HOURS (=1) FOR DAY 257 *	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
* CALM HOURS (=1) FOR DAY 258 *	1	1	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 290 *	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 324 *	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 336 *	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 341 *	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 347 *	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 354 *	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
* CALM HOURS (=1) FOR DAY 359 *	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY 360 *	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

'N'-DAY
365 DAYS
SGROUP# 1

*** PREDICTION OF CHLOROFORM CONCENTRATION FROM THED-DUR COATING ***

* 365-DAY AVERAGE CONCENTRATION (MICROGRAMS/CUBIC METER) *

* FROM ALL SOURCES *
* FOR THE RECEPTOR GRID *

* MAXIMUM VALUE EQUALS 30.97375 AND OCCURRED AT (300.0, 270.0) *

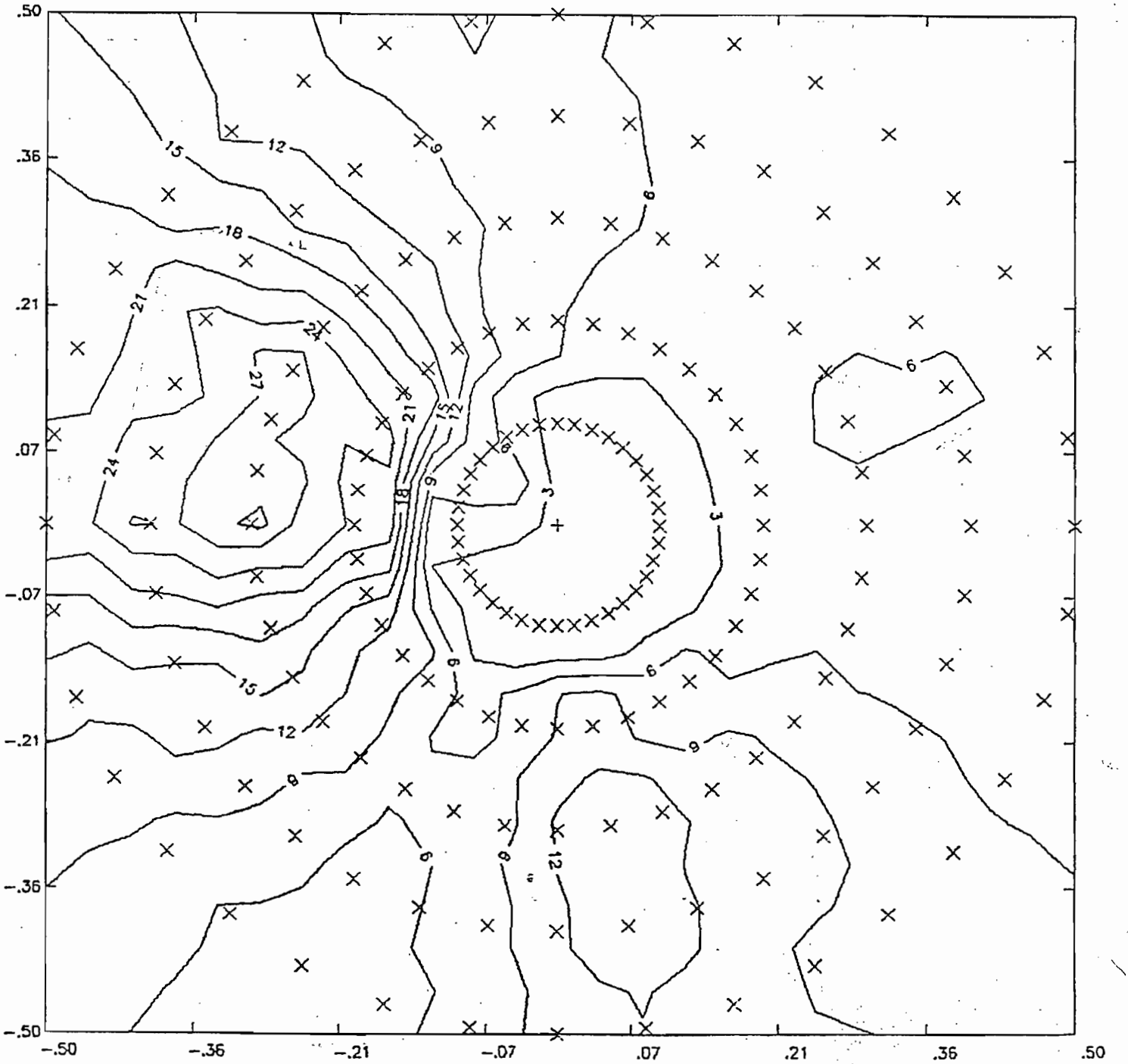
DIRECTION / (DEGREES) /	RANGE (METERS) 100.0	200.0	300.0	400.0	500.0
360.0 /	1.89820	6.37148	8.22518	7.80522	6.82512
350.0 /	2.69612	6.81973	7.51847	6.65236	5.58408
340.0 /	3.90226	9.22694	10.10018	9.07092	7.73827
330.0 /	5.07283	11.91424	12.77490	11.33270	9.59585
320.0 /	6.56874	15.76640	16.51608	14.30373	11.88103
310.0 /	8.36513	21.72767	23.04934	19.85044	16.38482
300.0 /	9.14254	26.30050	28.60753	24.66458	20.29366
290.0 /	7.13447	23.33661	26.52357	23.07166	19.00880
280.0 /	4.97090	23.30781	28.72748	25.49052	21.16315
270.0 /	3.93317	24.26729	30.97375	27.64419	22.98353
260.0 /	3.50492	19.75758	23.92210	20.73079	16.90616
250.0 /	2.98780	15.11902	17.73450	15.17552	12.28816
240.0 /	2.44317	12.84536	15.06727	12.88913	10.44414
230.0 /	1.98743	10.17420	11.65320	9.86633	7.95095
220.0 /	1.51815	7.70057	8.77519	7.40982	5.95848
210.0 /	1.03271	4.85898	5.72846	5.00122	4.12152
200.0 /	1.11899	4.94981	6.47926	6.03376	5.18855
190.0 /	1.49097	6.66900	8.64279	7.94433	6.74150
180.0 /	1.81733	9.32723	12.48082	11.62899	9.96654
170.0 /	1.83023	10.35752	14.49696	13.77050	11.92200
160.0 /	1.69447	8.76508	12.58415	12.25586	10.80744
150.0 /	1.72241	7.71812	10.28579	9.79692	8.55781
140.0 /	1.57425	6.88618	9.66924	9.51140	8.48394
130.0 /	1.43703	5.38383	7.56715	7.55144	6.83579
120.0 /	1.34448	4.73612	6.40393	6.26770	5.57680
110.0 /	1.13763	3.67778	4.76366	4.59788	4.07178
100.0 /	1.03877	3.02267	3.81041	3.68513	3.28705
90.0 /	1.08875	3.72128	4.97231	4.82464	4.27415
80.0 /	1.13059	4.15528	5.78419	5.73478	5.16946
70.0 /	1.23280	4.91483	6.54553	6.26222	5.50807
60.0 /	1.26599	4.62218	5.97932	5.68210	4.98161
50.0 /	1.24308	4.00334	5.27026	5.15287	4.62350
40.0 /	1.33254	3.91266	5.09275	4.99207	4.48766
30.0 /	1.23705	3.82998	5.11139	4.98238	4.43181
20.0 /	1.30681	4.39529	5.85356	5.64403	4.98121
10.0 /	1.47640	4.87402	6.33085	6.04874	5.31832

*** PREDICTION OF CHLOROFORM CONCENTRATION FROM THEO-DUR COATING ***

* SECOND HIGHEST 24-HOUR AVERAGE CONCENTRATION (MICROGRAMS/CUBIC METER) *
* FROM ALL SOURCES *
* FOR THE RECEPTOR GRID *

* MAXIMUM VALUE EQUALS 164.01950 AND OCCURRED AT (300.0, 300.0) *

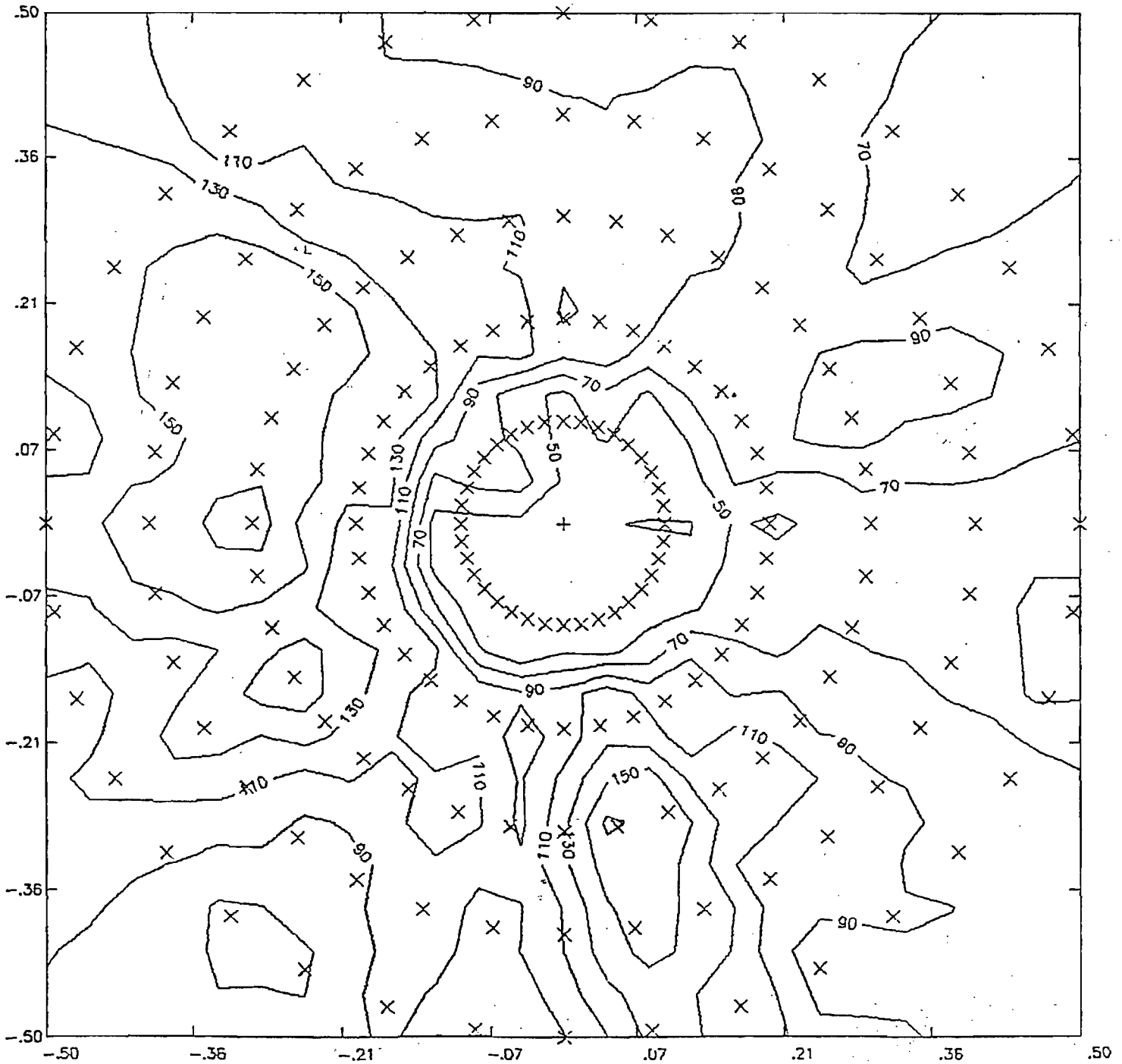
DIRECTION / (DEGREES) /	RANGE (METERS) 100.0	200.0	300.0	400.0	500.0
360.0 /	25.77890D(157, 1)	77.86879 (178, 1)	98.90290D(175, 1)	86.50933D(175, 1)	73.78970 (81, 1)
350.0 /	36.26937 (231, 1)	94.73946 (50, 1)	111.85680 (50, 1)	88.35709D(177, 1)	68.48013D(177, 1)
340.0 /	52.76203 (84, 1)	79.87283 (92, 1)	107.47720 (82, 1)	100.91460 (83, 1)	86.42561 (105, 1)
330.0 /	58.86999D(158, 1)	97.55176 (143, 1)	115.22870 (92, 1)	100.44600 (92, 1)	91.76845 (83, 1)
320.0 /	70.14852D(158, 1)	103.90060 (93, 1)	124.47440 (92, 1)	109.83800 (92, 1)	90.18528 (92, 1)
310.0 /	73.70905 (159, 1)	127.41780D(347, 1)	153.21840 (1, 1)	144.86380 (1, 1)	123.77060 (1, 1)
300.0 /	89.79990D(188, 1)	134.12500D(228, 1)	164.01950D(354, 1)	154.13430 (37, 1)	131.08850 (37, 1)
290.0 /	63.64613D(188, 1)	131.89690 (236, 1)	159.72540 (235, 1)	146.13350 (346, 1)	125.61790 (346, 1)
280.0 /	45.03123D(213, 1)	124.76110 (102, 1)	155.28930 (308, 1)	140.30560 (308, 1)	115.49950 (334, 1)
270.0 /	31.64696 (171, 1)	125.05900 (358, 1)	158.05810 (358, 1)	140.59230 (361, 1)	122.95100 (361, 1)
260.0 /	35.88337 (97, 1)	111.04150 (242, 1)	143.54430 (329, 1)	129.35530 (329, 1)	108.18790 (329, 1)
250.0 /	33.53561 (171, 1)	100.50520D(258, 1)	118.28250 (300, 1)	109.25680 (300, 1)	92.13998 (300, 1)
240.0 /	33.98550 (51, 1)	109.56870 (295, 1)	117.42990 (295, 1)	99.04275 (333, 1)	80.01402 (333, 1)
230.0 /	33.87750D(225, 1)	108.94610 (295, 1)	127.23530 (295, 1)	106.05840 (296, 1)	84.34147 (295, 1)
220.0 /	24.10836D(226, 1)	82.90133 (109, 1)	92.62426 (109, 1)	77.61685 (312, 1)	62.12368 (312, 1)
210.0 /	25.87064 (234, 1)	66.10669 (278, 1)	73.43089 (278, 1)	60.22556 (278, 1)	51.61577 (352, 1)
200.0 /	22.59447 (77, 1)	71.43428 (274, 1)	99.58863 (274, 1)	94.46539 (165, 1)	83.07870 (162, 1)
190.0 /	31.08567 (311, 1)	69.18552 (275, 1)	78.44536 (275, 1)	65.18288 (275, 1)	51.69660 (275, 1)
180.0 /	38.50553 (339, 1)	95.33174 (339, 1)	121.89860 (343, 1)	105.00160 (343, 1)	86.56078 (313, 1)
170.0 /	40.79558 (338, 1)	112.08510 (338, 1)	138.62770 (352, 1)	137.24270 (352, 1)	120.84490 (352, 1)
160.0 /	35.12901 (338, 1)	101.34930 (56, 1)	125.93160 (292, 1)	116.49560 (292, 1)	99.12106 (292, 1)
150.0 /	33.05357D(42, 1)	84.27691 (56, 1)	101.80790 (56, 1)	91.48893 (40, 1)	73.57776 (40, 1)
140.0 /	39.18452D(257, 1)	100.59350D(42, 1)	108.84000D(42, 1)	88.96875D(42, 1)	77.21381D(257, 1)
130.0 /	37.30411D(42, 1)	70.58805D(42, 1)	78.54404 (55, 1)	64.32024 (55, 1)	57.20100 (12, 1)
120.0 /	29.50157 (17, 1)	52.27423D(173, 1)	65.84967 (55, 1)	65.25773 (290, 1)	58.79294 (290, 1)
110.0 /	24.62548 (272, 1)	45.38386 (48, 1)	58.47215 (48, 1)	50.77725 (48, 1)	41.54554 (78, 1)
100.0 /	24.44445 (76, 1)	52.07681D(206, 1)	53.16151 (272, 1)	50.97808D(206, 1)	42.45293D(205, 1)
90.0 /	22.60242 (71, 1)	42.30128 (71, 1)	53.52744 (114, 1)	53.99813 (114, 1)	49.70357 (290, 1)
80.0 /	30.53682 (193, 1)	62.24703D(192, 1)	71.78111 (147, 1)	75.79958 (147, 1)	69.74171 (147, 1)
70.0 /	43.35773 (193, 1)	70.97707 (88, 1)	88.06049 (86, 1)	90.43614 (193, 1)	85.24084D(193, 1)
60.0 /	36.33711 (158, 1)	84.27481 (89, 1)	94.82048D(192, 1)	78.52534 (89, 1)	62.78126 (185, 1)
50.0 /	25.50958D(167, 1)	63.61117 (147, 1)	64.82210 (147, 1)	55.39653 (89, 1)	53.77065D(34, 1)
40.0 /	25.80616D(167, 1)	59.02155 (203, 1)	71.72465D(167, 1)	73.28054D(167, 1)	61.96109 (210, 1)
30.0 /	29.44156D(225, 1)	47.30084D(157, 1)	64.46386 (89, 1)	65.76306D(202, 1)	61.14427D(202, 1)
20.0 /	21.32938D(225, 1)	90.71099D(156, 1)	109.25540D(156, 1)	100.53870D(156, 1)	86.13049D(156, 1)
10.0 /	29.13077 (178, 1)	79.55431 (178, 1)	84.35829 (179, 1)	71.44655D(156, 1)	64.75759D(156, 1)



ANNUAL AVERAGE CHLOROFORM CONCENTRATIONS (UG/M3)

+ – SOURCE LOCATION

× – RECEPTOR LOCATION



PEAK 24-HOUR CHLOROFORM CONCENTRATIONS (UG/M3)

+ – SOURCE LOCATION

× – RECEPTOR LOCATION

State of Florida
DEPARTMENT OF ENVIRONMENTAL REGULATION

Interoffice Memorandum

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

TO: Dale Twachtmann

THRU: Howard Rhodes

FROM: Clair Fancy

DATE: November 3, 1987

SUBJ: Amendment of a Construction Permit

RECEIVED
NOV 9 1987
Office of the Secretary

Attached for your approval and signature is a letter that will amend a construction permit issued for a carbon adsorption system at Key Pharmaceutical, Inc. in Miami, Dade County, Florida. The amendment, which results in a slight decrease in permitted VOC emissions, will allow the company more flexibility in production. There is no controversy associated with this amendment. The Bureau recommends this request be approved.

CHF/WH/s

Federal Express Mr Teachmeyer's copy.
New Account 0531-0749-8
Old Account 1227-2916-8

Hand Delivered
10/30/87

File Copy

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

Telex: 808235

October 29, 1987

DER
OCT 30 1987
BAQM

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

Dear Mr. Fancy:

Reference: Permit No. AC 13-129899

In response to Mr. Willard Hanks' request, Key Pharmaceuticals, Inc. has modeled the Chloroform emissions from the Pan Coating process proposed under the above referenced permit. The model utilized for this is the Industrial Source Complex Short Term (ISCST) model. This model takes into account not only the specific parameters of the source, but also the meteorological data for the location of the source. The meteorological data utilized in this model is data supplied by Trinity Consultants taken from actual National Weather Service data for the greater Miami area. The model predicts the average annual ground level concentration of a particular contaminant. The source parameters utilized in this model area as follows:

MODEL	ISCST
STACK HEIGHT	40'
STACK DIAMETER	1.6'
EMISSION FLOW RATE	7,000 acfm
STACK GAS TEMP	70 ^{o}F
EMISSION LOADING	39.3 LB/HR

Utilizing the above parameters the model predicts an average concentration of Chloroform of 31 micrograms per cubic meter. This information can be compared to the following standards.

OSHA Ceiling (29 CFR 1910.1000)	240,000 $\mu g/m^3$
TLV of Amer. Conf. Gov. Ind Hyg. (1981)	50,000 $\mu g/m^3$
New York State Guideline AAL *	167 $\mu g/m^3$
Key concentration modeled	31 $\mu g/m^3$

* AAL: Acceptable ambient level equal to the annual average ambient concentration not to be exceeded at any off-site receptor.

The model utilized by Key Pharmaceuticals, Inc. predicts a concentration that is 18.5% of the allowable levels under the New York State AAL Guidelines. This is well within the requirements set forth by the State of New York for toxic air emissions.

11/2

[redacted]

FYI

Thanks!

Key Pharmaceuticals, Inc. is of the opinion that this data supports the application letter of October 26, 1987, and that these emissions are in compliance with all Florida regulations.

In addition, Key Pharmaceuticals, Inc. would like to be authorized to utilize Ethyl Acetate as one of the solvents permitted under the VOC emissions.

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

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF

cc: Mr. Patrick Wong
Ms. Stephanie Brooks

ISCST (DATED 86322)
AN AIR QUALITY DISPERSION MODEL IN
SECTION I. GUIDELINE MODELS
IN UNAMAP (VERSION 6) JULY 86.
SOURCE: FILE 6 ON UNAMAP MAGNETIC TAPE FROM NTIS.

SERIAL NUMBER 5257 SOLD TO SCHERING PLOUGH CORPORATION
RUN BEGAN ON 10-30-87 AT 05:58:07

*** PREDICTION OF CHLOROFORM CONCENTRATION FROM THEO-DUR COATING ***

*** METEOROLOGICAL DAYS TO BE PROCESSED ***
(IF=1)

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1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1 1 1 1 1
1 1 1 1 1 1 1 1 1 1   1 1 1 1 1 1
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*** UPPER BOUND OF FIRST THROUGH FIFTH WIND SPEED CATEGORIES ***
(METERS/SEC)

1.54, 3.09, 5.14, 8.23, 10.80,

*** WIND PROFILE EXPONENTS ***

STABILITY CATEGORY	WIND SPEED CATEGORY 1	2	3	4	5	6
A	.15000E+00	.15000E+00	.15000E+00	.15000E+00	.15000E+00	.15000E+00
B	.15000E+00	.15000E+00	.15000E+00	.15000E+00	.15000E+00	.15000E+00
C	.20000E+00	.20000E+00	.20000E+00	.20000E+00	.20000E+00	.20000E+00
D	.25000E+00	.25000E+00	.25000E+00	.25000E+00	.25000E+00	.25000E+00
E	.30000E+00	.30000E+00	.30000E+00	.30000E+00	.30000E+00	.30000E+00
F	.30000E+00	.30000E+00	.30000E+00	.30000E+00	.30000E+00	.30000E+00

*** VERTICAL POTENTIAL TEMPERATURE GRADIENTS ***
(DEGREES KELVIN PER METER)

STABILITY CATEGORY	WIND SPEED CATEGORY 1	2	3	4	5	6
A	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00
B	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00
C	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00
D	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00	.00000E+00
E	.20000E-01	.20000E-01	.20000E-01	.20000E-01	.20000E-01	.20000E-01
F	.35000E-01	.35000E-01	.35000E-01	.35000E-01	.35000E-01	.35000E-01

*** PREDICTION OF CHLOROFORM CONCENTRATION FROM THEO-DUR COATING ***

X,Y-COORDINATES OF THE CENTER OF THE POLAR RECEPTOR GRID (METERS) = (0., 0.)

*** RANGES OF POLAR GRID SYSTEM ***
(METERS)

100.0, 200.0, 300.0, 400.0, 500.0,

*** RADIAL ANGLES OF POLAR GRID SYSTEM ***

(DEGREES)

10.0,	20.0,	30.0,	40.0,	50.0,	60.0,	70.0,	80.0,	90.0,	100.0,
110.0,	120.0,	130.0,	140.0,	150.0,	160.0,	170.0,	180.0,	190.0,	200.0,
210.0,	220.0,	230.0,	240.0,	250.0,	260.0,	270.0,	280.0,	290.0,	300.0,
310.0,	320.0,	330.0,	340.0,	350.0,	360.0,				

*** PREDICTION OF CHLOROFORM CONCENTRATION FROM THEO-DUR COATING ***

*** SOURCE DATA ***

SOURCE NUMBER	TYPE	WAKE	NUMBER PART. CATS.	EMISSION RATE TYPE=0,1 (GRAMS/SEC) TYPE=2 (GRAMS/SEC) *PER METER**2	X (METERS)	Y (METERS)	BASE ELEV. (METERS)	HEIGHT (METERS)	TEMP. TYPE=0 (DEG.K); VERT.DIM TYPE=1 (METERS)	EXIT VEL. TYPE=0 (M/SEC); HORZ.DIM TYPE=1,2 (METERS)	DIAMETER TYPE=0 (METERS)	BLDG. HEIGHT TYPE=0 (METERS)	BLDG. LENGTH TYPE=0 (METERS)	BLDG. WIDTH TYPE=0 (METERS)
1	0	0	0	.43560E+01	.0	.0	.0	12.50	294.26	17.78	.43	.00	.00	.00

* CALM HOURS (=1) FOR DAY	30	*	0	0	0	1	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
* CALM HOURS (=1) FOR DAY	31	*	1	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
* CALM HOURS (=1) FOR DAY	32	*	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	33	*	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
* CALM HOURS (=1) FOR DAY	34	*	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	38	*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
* CALM HOURS (=1) FOR DAY	42	*	0	0	1	0	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	43	*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
* CALM HOURS (=1) FOR DAY	44	*	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0
* CALM HOURS (=1) FOR DAY	46	*	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
* CALM HOURS (=1) FOR DAY	98	*	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	144	*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
* CALM HOURS (=1) FOR DAY	154	*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1
* CALM HOURS (=1) FOR DAY	155	*	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1	1	0	1	1	0	0	1	0	0
* CALM HOURS (=1) FOR DAY	156	*	0	1	1	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	157	*	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	158	*	0	1	0	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	161	*	1	1	1	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
* CALM HOURS (=1) FOR DAY	162	*	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
* CALM HOURS (=1) FOR DAY	163	*	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	167	*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	
* CALM HOURS (=1) FOR DAY	170	*	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	173	*	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	175	*	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	177	*	1	0	0	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	181	*	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	185	*	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	188	*	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	190	*	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	191	*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	1
* CALM HOURS (=1) FOR DAY	192	*	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	202	*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
* CALM HOURS (=1) FOR DAY	205	*	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	206	*	1	1	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	207	*	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	208	*	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	212	*	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	213	*	1	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	226	*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
* CALM HOURS (=1) FOR DAY	228	*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
* CALM HOURS (=1) FOR DAY	229	*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1	1
* CALM HOURS (=1) FOR DAY	257	*	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
* CALM HOURS (=1) FOR DAY	258	*	1	1	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	290	*	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	324	*	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	336	*	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	341	*	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	347	*	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	354	*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
* CALM HOURS (=1) FOR DAY	359	*	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* CALM HOURS (=1) FOR DAY	360	*	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

*** PREDICTION OF CHLOROFORM CONCENTRATION FROM THEO-DUR COATING ***

* 365-DAY AVERAGE CONCENTRATION (MICROGRAMS/CUBIC METER) *

* FROM ALL SOURCES *
* FOR THE RECEPTOR GRID *

* MAXIMUM VALUE EQUALS 30.97375 AND OCCURRED AT (300.0, 270.0) *

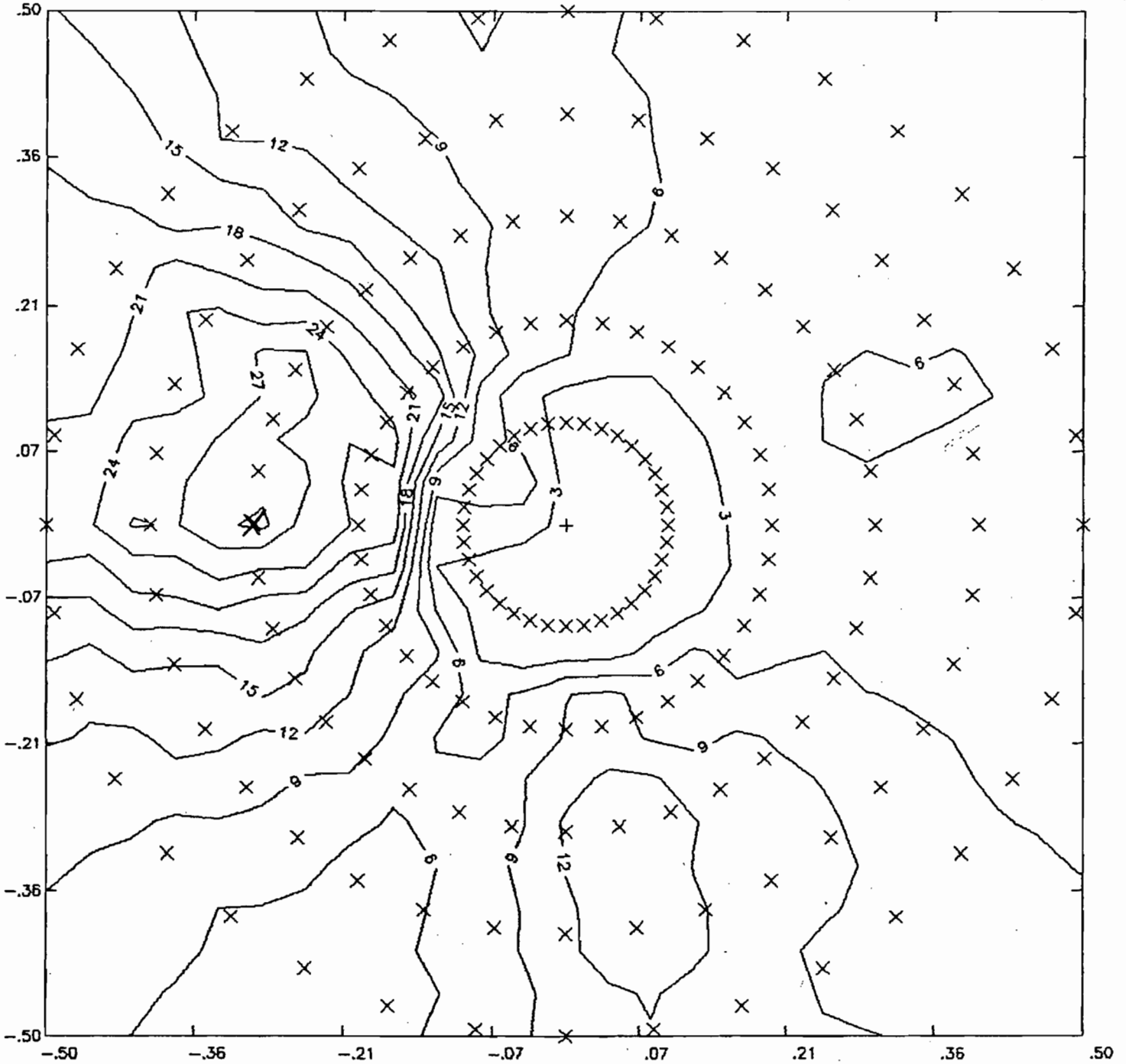
DIRECTION / (DEGREES) /	RANGE (METERS) 100.0	200.0	300.0	400.0	500.0
360.0 /	1.89820	6.37148	8.22518	7.80522	6.82512
350.0 /	2.69612	6.81973	7.51847	6.65236	5.58408
340.0 /	3.90226	9.22694	10.10018	9.07092	7.73827
330.0 /	5.07283	11.91424	12.77490	11.33270	9.59685
320.0 /	6.56874	15.76640	16.51608	14.30373	11.88103
310.0 /	8.36513	21.72767	23.04984	19.85044	16.38482
300.0 /	9.14254	26.30050	28.60753	24.66458	20.29366
290.0 /	7.13447	23.33661	26.52357	23.07166	19.00880
280.0 /	4.97090	23.30781	28.72748	25.49052	21.16315
270.0 /	3.93317	24.26729	30.97375	27.64419	22.98353
260.0 /	3.50492	19.75758	23.92210	20.73079	16.90616
250.0 /	2.98780	15.11902	17.73450	15.17552	12.28816
240.0 /	2.44317	12.84536	15.06727	12.88913	10.44414
230.0 /	1.98743	10.17420	11.65320	9.86633	7.95095
220.0 /	1.51815	7.70057	8.77519	7.40982	5.95848
210.0 /	1.09271	4.85898	5.72846	5.00122	4.12152
200.0 /	1.11899	4.94981	6.47926	6.03376	5.18855
190.0 /	1.49097	6.66900	8.64279	7.94433	6.74150
180.0 /	1.81733	9.32723	12.48062	11.62899	9.96654
170.0 /	1.83023	10.35752	14.49696	13.77050	11.92200
160.0 /	1.69447	8.76508	12.58415	12.25586	10.80744
150.0 /	1.72241	7.71812	10.28579	9.79692	8.55781
140.0 /	1.57425	6.88618	9.66924	9.51140	8.48394
130.0 /	1.43703	5.38383	7.56715	7.56144	6.83579
120.0 /	1.34448	4.73612	6.40393	6.26770	5.57680
110.0 /	1.13763	3.67778	4.76386	4.59788	4.07178
100.0 /	1.03877	3.02267	3.81041	3.68513	3.28705
90.0 /	1.08875	3.72128	4.97231	4.82464	4.27415
80.0 /	1.13059	4.15528	5.78419	5.73478	5.16946
70.0 /	1.23280	4.91483	6.54553	6.26222	5.50807
60.0 /	1.26699	4.62218	5.97932	5.68210	4.98161
50.0 /	1.24308	4.00334	5.27026	5.15287	4.62350
40.0 /	1.33254	3.91266	5.09275	4.99207	4.48766
30.0 /	1.23705	3.82998	5.11139	4.98238	4.43181
20.0 /	1.30681	4.39629	5.85356	5.64403	4.98121
10.0 /	1.47640	4.87402	6.33085	6.04874	5.31832

*** PREDICTION OF CHLOROFORM CONCENTRATION FROM THEO-DUR COATING ***

* SECOND HIGHEST 24-HOUR AVERAGE CONCENTRATION (MICROGRAMS/CUBIC METER) *
* FROM ALL SOURCES *
* FOR THE RECEPTOR GRID *

* MAXIMUM VALUE EQUALS 164.01950 AND OCCURRED AT (300.0, 300.0) *

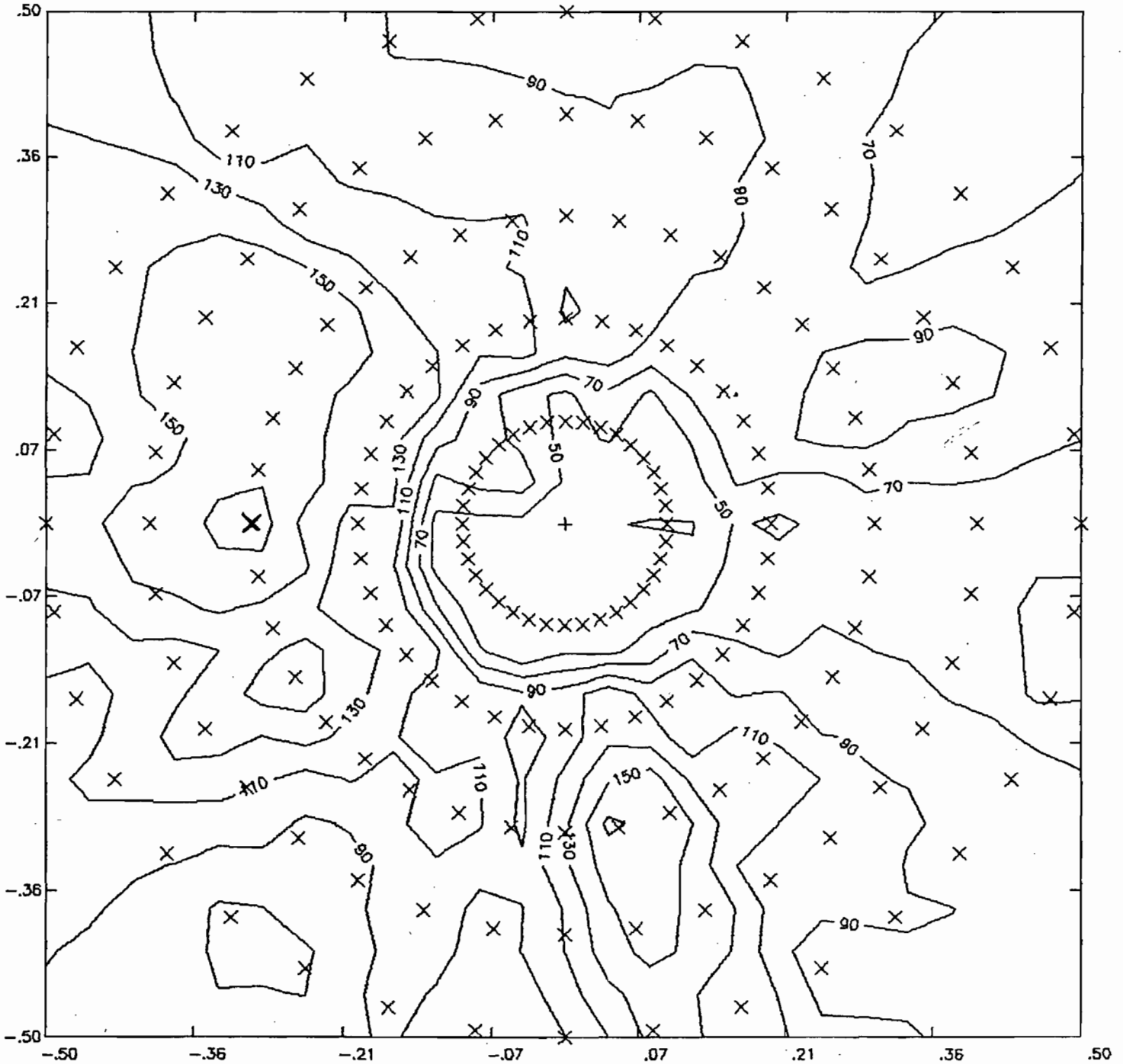
DIRECTION / (DEGREES) /	RANGE (METERS) 100.0	200.0	300.0	400.0	500.0
360.0 /	25.77890C(157, 1)	77.86879 (178, 1)	98.90390C(175, 1)	86.50933C(175, 1)	73.78970 (81, 1)
350.0 /	36.26937 (231, 1)	94.73946 (50, 1)	111.85680 (50, 1)	88.35709C(177, 1)	68.48013C(177, 1)
340.0 /	52.76203 (84, 1)	79.87283 (92, 1)	107.47720 (82, 1)	100.91460 (83, 1)	86.42561 (105, 1)
330.0 /	58.86999C(158, 1)	97.55176 (143, 1)	115.22870 (92, 1)	100.44600 (92, 1)	91.76945 (83, 1)
320.0 /	70.14862C(158, 1)	103.90060 (93, 1)	124.47440 (92, 1)	109.83800 (92, 1)	90.18628 (92, 1)
310.0 /	73.70905 (159, 1)	127.41780C(347, 1)	153.21840 (1, 1)	144.86380 (1, 1)	123.77060 (1, 1)
300.0 /	69.79990C(188, 1)	134.12500C(228, 1)	164.01950C(354, 1)	154.13430 (37, 1)	131.08850 (37, 1)
290.0 /	63.64613C(188, 1)	131.89690 (236, 1)	159.72540 (235, 1)	146.13350 (346, 1)	125.61790 (346, 1)
280.0 /	45.03123C(213, 1)	124.76110 (102, 1)	155.28930 (308, 1)	140.30960 (308, 1)	115.49950 (334, 1)
270.0 /	31.64696 (171, 1)	125.05900 (358, 1)	158.05810 (358, 1)	140.69230 (361, 1)	122.95100 (361, 1)
260.0 /	35.88337 (97, 1)	111.04190 (242, 1)	143.54430 (320, 1)	129.35530 (320, 1)	108.18790 (320, 1)
250.0 /	33.53561 (171, 1)	100.60520C(258, 1)	118.28250 (300, 1)	109.25680 (300, 1)	92.13998 (300, 1)
240.0 /	33.98650 (51, 1)	109.56870 (295, 1)	117.42990 (295, 1)	99.04275 (333, 1)	80.01402 (333, 1)
230.0 /	33.87760C(226, 1)	108.94610 (296, 1)	127.23530 (296, 1)	106.06840 (296, 1)	84.34147 (296, 1)
220.0 /	24.10836C(226, 1)	82.90133 (109, 1)	92.62426 (109, 1)	77.61685 (312, 1)	62.12368 (312, 1)
210.0 /	25.87064 (234, 1)	66.10669 (278, 1)	73.43089 (278, 1)	60.22566 (278, 1)	51.51677 (252, 1)
200.0 /	22.59447 (77, 1)	71.43428 (274, 1)	99.52863 (274, 1)	94.46539 (165, 1)	83.07870 (166, 1)
190.0 /	31.08567 (311, 1)	69.15552 (275, 1)	78.44636 (275, 1)	65.18288 (275, 1)	51.69660 (275, 1)
180.0 /	38.50593 (339, 1)	95.33174 (339, 1)	121.89860 (343, 1)	105.00160 (343, 1)	86.56078 (313, 1)
170.0 /	40.79658 (338, 1)	112.06510 (338, 1)	138.62770 (352, 1)	137.24270 (352, 1)	120.84490 (352, 1)
160.0 /	35.12901 (338, 1)	101.34930 (56, 1)	125.93160 (292, 1)	116.49560 (292, 1)	99.12106 (292, 1)
150.0 /	33.05357C(42, 1)	84.27691 (56, 1)	101.80790 (56, 1)	91.48283 (40, 1)	73.57776 (40, 1)
140.0 /	39.18452C(257, 1)	100.59350C(42, 1)	102.64000C(42, 1)	88.96875C(42, 1)	77.21381C(257, 1)
130.0 /	37.30411C(42, 1)	70.56805C(42, 1)	75.54404 (55, 1)	64.32024 (55, 1)	57.20100 (12, 1)
120.0 /	29.50157 (17, 1)	52.27423C(173, 1)	65.84987 (55, 1)	65.26773 (280, 1)	58.79284 (280, 1)
110.0 /	24.62648 (272, 1)	45.38386 (48, 1)	58.47215 (48, 1)	50.77725 (48, 1)	41.54554 (78, 1)
100.0 /	24.44445 (76, 1)	52.07661C(206, 1)	53.16151 (272, 1)	50.97802C(206, 1)	42.49293C(206, 1)
90.0 /	22.60242 (71, 1)	42.30128 (71, 1)	58.52744 (114, 1)	53.99813 (114, 1)	49.70327 (280, 1)
80.0 /	30.53682 (193, 1)	62.24703C(192, 1)	71.78111 (147, 1)	75.79958 (147, 1)	69.74171 (147, 1)
70.0 /	43.36772 (193, 1)	70.07707 (88, 1)	88.08049 (88, 1)	90.43614 (193, 1)	85.24084C(192, 1)
60.0 /	36.33711 (168, 1)	84.27481 (89, 1)	94.83048C(192, 1)	78.52534 (89, 1)	62.78126 (126, 1)
50.0 /	26.60968C(167, 1)	63.61117 (147, 1)	64.82210 (147, 1)	55.39663 (89, 1)	53.77065C(34, 1)
40.0 /	25.80616C(167, 1)	59.02165 (203, 1)	71.72465C(167, 1)	73.28054C(167, 1)	61.96109 (210, 1)
30.0 /	29.44196C(226, 1)	47.30084C(157, 1)	64.46386 (89, 1)	66.76306C(202, 1)	61.14427C(202, 1)
20.0 /	21.32938C(226, 1)	90.71099C(156, 1)	109.29540C(156, 1)	100.53870C(156, 1)	86.13049C(156, 1)
10.0 /	29.13077 (178, 1)	79.55431 (178, 1)	84.35828 (178, 1)	71.44665C(156, 1)	64.75759C(156, 1)



ANNUAL AVERAGE CHLOROFORM CONCENTRATIONS (UG/M3)

\+ – SOURCE LOCATION

× – RECEPTOR LOCATION



PEAK 24-HOUR CHLOROFORM CONCENTRATIONS (UG/M3)

+ - SOURCE LOCATION

× - RECEPTOR LOCATION

Hand Delivered File Copy

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

Telex: 808235

October 26, 1987

DER
OCT 27 1987
BAQM

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

RE: Permit No. AC 13-129899

Dear Mr. Fancy:

Key Pharmaceuticals, Inc. is currently in a position that requires a realignment of production activities. In light of this Key Pharmaceuticals, Inc. is requesting a modification to the above referenced permit. The specific modification request is as follows:

Drop from the permit

1) Two (2) Perforated Pan Coaters - 2,190 lots

2) Six (6) Coating Pans - 128 lots of QUINEL-DUR

This reduction in production equipment capacity will result in an allowable emission reduction of 0.03771 tons per year particulates, 15.49 tons per year of VOC's and 65.67 tons per year of Methylene Chloride. The solvents included in the VOC emission reduction use Acetone, Isopropyl Alcohol, Methanol and Ethyl Acetate.

As a trade off, Key Pharmaceuticals, Inc. is requesting permission to manufacture 160 lots of THEO-DUR 100 in 6 Coating Pans per year. This process will result in an annual emission of 0.01529 tons of particulate and 12.06 tons per year of VOC's. The VOC's involved in this process are Acetone, Isopropyl Alcohol, Diethyl Phthalate and Chloroform. As indicated in the original permit application the emissions from the Coating Pans will be controlled by the Carbon Adsorption/Solvent Recovery System once it come on line after July of 1988 or will cease.

This request, therefore, results in a net allowable emission decrease of the following:

	CURRENT ALLOWABLE 1987 (T/Y)	PROPOSED ALLOWABLE 1987 (T/Y)	NET DECREASE (T/Y)
PARTICULATE	0.09859	0.07616	0.02242
VOC	53.64	50.20	3.44
METHYLENE CHLORIDE	370.51	304.84	65.67

It should be noted that Dade County is a non-attainment area for Ozone and that this request will result in a decrease in permitted levels of VOC's in Dade County.

Key Pharmaceuticals, Inc. trusts that this request will receive your department's timely attention.

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

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

I. Goldman
P. Wong - DERM
Willard Hanks
Bill Thomas/CHP
} copies furnished by company per WH / 10/27/87 mm

DER
OCT 27 1987
BAQM

P 274 007 727

RECEIPT FOR CERTIFIED MAIL

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

Sent to James R. Confroy Key Pharmaceuticals, Inc.	
Street and No. 50 N.E. 176th Street	
P.O., State and ZIP Code Miami, Florida 33169	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt showing to whom and Date Delivered	
Return Receipt showing to whom, Date, and Address of Delivery	
TOTAL Postage and Fees	$
Postmark or Date Mailed: 07/22/87 Permit: AC 13-129899	

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

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

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

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

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

4. Type of Service:
☐ Registered ☐ Insured
☒ Certified ☐ COD
☐ Express Mail

Article Number: P 274 007 727

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature - Addressee
X

6. Signature - Agent
X

7. Date of Delivery
JUL 27 1987

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

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

File

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION
NOTICE OF PERMIT

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

July 21, 1987

Enclosed is construction permit No. AC 13-129899 to Key Pharmaceuticals, Inc., which authorizes the modification of the carbon adsorption and solvent recovery system to serve existing, permitted, and new process equipment at your existing facility in Miami, Dade County, Florida. This permit is issued pursuant to Section 403, Florida Statutes.

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

Executed in Tallahassee, Florida.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL REGULATION

For C. H. Thomas

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

Copy furnished to:

I. Goldman, SE District
P. Wong, DERM
J. Wells, P.E.

Final Determination

Key Pharmaceuticals, Inc.
Miami, Florida
Dade County

Modify the Carbon Adsorption and Solvent Recovery System by Constructing Six Coating and Three Drying/Curing Rooms with Ancillary Equipment

Permit Number: AC 13-129899

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

July 16, 1987

Final Determination

Key Pharmaceuticals, Inc. submitted an application for permit to construct (modify) a carbon adsorption and solvent recovery system to include the control of the emissions from 6 existing coating pans and 3 existing drying rooms at their pharmaceutical plant located at 50 N.W. 176th Street, Miami, Dade County, Florida, on January 26, 1987.

The application was reviewed by the Bureau and the Technical Evaluation and Preliminary Determination was distributed on June 5, 1987. The public notice of the Department's Intent to Issue the permit was published in the Miami News on June 18, 1987. Copies of the Technical Evaluation and Preliminary Determination were available for public inspection at Dade County's Department of Environmental Resources Management in Miami and the Department of Environmental Regulation's offices in West Palm Beach and Tallahassee.

No written comments on the Department's intent were submitted to the Bureau. The final action of the Department will be to issue the permit to construct as proposed in the Technical Evaluation and Preliminary Determination.

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

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

Permit Number: AC 13-129899
Expiration Date: January 1, 1989
County: Dade
Latitude/Longitude: 25° 56' 03" N
80° 11' 42" W
Project: Modify the Carbon Adsorption & Solvent Recovery System by Constructing 6 Coating Pans & 3 Drying/Curing Rooms with Ancillary Equipment

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

Authorization to construct 6 coating pans and 3 drying/curing rooms with ancillary equipment and connect this process equipment to the 90% efficient carbon adsorption/solvent recovery system that controls the emissions from four fluid bed processors (Glatt) and two Perforated Pan Coating Units (PPCU). This equipment will be located at the pharmaceutical plant at 50 N.W. 176th Street, Miami, Dade County, Florida. The UTM coordinates of this plant are zone 17, 579.9 km E and 2868.4 km N.

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

Attachments:

1. Key's Application for 6 Coating Pans, 3 Drying Rooms received by BAQM on January 26, 1987.

2. DER's letter of January 28, 1987.

3. Key's letter dated April 16, 1987.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129899
Expiration Date: January 1, 1989

GENERAL CONDITIONS:

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

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

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

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

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

GENERAL CONDITIONS:

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

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

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

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

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

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

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

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

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

GENERAL CONDITIONS:

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

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

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

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

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

13. This permit also constitutes:

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

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

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

GENERAL CONDITIONS:

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

c. Records of monitoring information shall include:

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

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

SPECIFIC CONDITIONS:

1. Until the carbon adsorption/solvent recovery system are able to control the air pollutant emissions from the pan coating process, the permittee shall limit production from this process to 128 lots in 1987 and 128 lots in 1988.

2. Production after the carbon adsorption/solvent recovery system is placed in service shall not exceed the following without prior approval of the Department (BAQM):

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

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129899
Expiration Date: January 1, 1989

SPECIFIC CONDITIONS:

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

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

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

Pan Coating Process - 2,190 lots/year

Each pan coating process lot uses approximately 909 lbs of solids (excipients) and 166 lbs/VOC solvents (ethyl acetate, acetone, and isopropanol).

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

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

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

4. The carbon adsorption/solvent recovery system shall remove a minimum of 90% of the solvents emitted by the process equipment during the process cycle. Compliance with this standard shall be determined using the data from the continuous monitors on the inlet and discharge of the carbon adsorbers.

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

Unit	Methylene Chloride lb/hr	lb/day	TPY	VOC lb/hr	lb/day	TPY	PM lb/hr	TPY
Glatt No. 1	20.9	271.2	49.5	1.9	25.0	4.6		
Glatt No. 2	26.7	465.6	85.0	2.5	43.2	7.9		
Glatt No. 3	26.7	465.6	85.0	2.5	43.2	7.9		
Glatt No. 4	26.7	465.6	85.0	2.5	43.2	7.9		
PPCU No. 1	20.0	180.0	32.8	3.0	27.1	4.9	0.1*	0.23*
PPCU No. 2	20.0	180.0	32.8	3.0	27.1	4.9		
Pan Coat. Process	0	0	0	6.98	99.4	18.13	0.5	1
Total	141.0	2028.0	370.1	22.08	308.2	53.23	0.6	1.23

* Net emissions from Glatt and PPCU units.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129899
Expiration Date: January 1, 1989

SPECIFIC CONDITIONS:

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

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

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

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

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

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

7. The construction shall reasonably conform to the plans and schedule submitted in the application. This permit may replace permit No. AC 13-129893. If the permittee is unable to complete construction on schedule, he must notify the Department in writing 60 days prior to the expiration of the construction permit and submit a new schedule and request for an extension of the construction permit. (FAC Rule 17-4.09)

8. To obtain a permit to operate, the permittee must demonstrate compliance with the conditions of the construction permit and submit a complete application for an operating permit, including the application fee, along with test results and Certificate of Completion, to the Department's district office or their designated agent 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 Rules 17-4.22 and 17-4.23)

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129899
Expiration Date: January 1, 1989

SPECIFIC CONDITIONS:

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

STATE OF FLORIDA DEPARTMENT OF
ENVIRONMENTAL REGULATION

Dale Twachtmann, Secretary

State of Florida
DEPARTMENT OF ENVIRONMENTAL REGULATION

Interoffice Memorandum

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

TO: Dale Twachtmann

THRU: Howard Rhodes

FROM: Clair Fancy for CHF

DATE: July 16, 1987

SUBJ: Approval of Air Construction Permit

Attached for your approval and signature is one air construction permit to authorize the modification of a carbon adsorption and solvent recovery system at Key Pharmaceuticals, Inc. facility in Miami, Dade County, Florida. There have been no controversies regarding this permit.

Day 90, after which the permit would be issued by default, is August 27, 1987.

The Bureau recommends your approval and signature.

CF/ks

attachment

PM
7/6/87
Miami, FL

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

Telex: 808235

DER

JUL 8 1987

BAQM

July 6, 1987

Mr. C. H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality Management
State of Florida
Department of Environmental Regulation
2600 Blairstone Road
Tallahassee, Florida 32399-2400

Dear Mr. C.H. Fancy:

Re: Permit AC 13-128475

This letter is to inform you that Key Pharmaceuticals Inc. intends to let the above referenced permit expire on December 31, 1987. A report will be issued as to operating hours and solvents used for the calender year of 1987 in the first quarter of 1988.

The equipment permitted in the above referenced permit will also be permitted thru permit AC13-129899.

Should you have any questions or comments, please don't hesitate to call me at (305) 654-2200.

Sincerely,

KEY PHARMACEUTICALS, INC.

Thomas W. Flachmeyer

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/msa

cc: Willard Hanks 7-8-87

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

Telex: 808235

DER

JUL 1 1987

BAQM

June 29, 1987

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

RE: PERMIT NO. AC 13-129899

Dear Mr. Fancy:

Key Pharmaceuticals, Inc. is in receipt of the Technical Evaluation and Preliminary Determination for the above referenced DER permit. The Public Notice for this permit was published in the legal section of the Miami News on June 18, 1987. Documentation concerning this publication has been enclosed for your records.

The conditions set forth in the draft permit are acceptable to Key Pharmaceuticals, Inc..

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

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

attachment

CC: Willard Hanna
Isidore Goldman - FDER - West Palm Beach, S.E. FL
Patrick Wong - DERM
Fancy / Thomas

all above delivered
on July 1, 1987

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

MIAMI'S FOR ME

MIAMI JUN 29 '87 FLA.

U.S. POSTAGE ≡ 0.22 METER 8210890

KEY

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

THE MIAMI NEWS
A COX NEWSPAPER

PUBLISHED DAILY
MIAMI — DADE — FLORIDA

STATE OF FLORIDA
COUNTY OF DADE:

Before the undersigned authority personally appeared

Ann Martula

who on oath says that he/she is

Custodian of Records

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

June 18, 1987

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

Ann Martula

Sworn to and subscribed before me this 19th day of June A.D. 19 87

My commission expires Lynette M Beard

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

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

The Department of Environmental Regulation gives notice of its intent to issue a permit to Key Pharmaceuticals, Inc. to modify the carbon adsorption and solvent recovery system by constructing 6 coating pans and 3 drying rooms at their existing pharmaceutical plant located at 50 N.W. 176th Street, Miami, Dade County, Florida. The modification will increase volatile organic compounds emissions by 18.13 TPY. A determination of best available control technology (BACT) was not required.

Persons whose substantial interests are affected by the Department's proposed permitting decision may petition for an administrative proceeding (hearing) in accordance with Section 120.57, Florida Statutes. The petition must conform to the requirements of Chapters 17-103 and 28-5, Florida Administrative Code, and must be filed (received) in the Office of General Counsel of the Department at 2600 Blair Stone Road, Twin Towers Office Building, Tallahassee, Florida 32399-2400, within fourteen (14) days of publication of this notice. Failure to file a request for hearing within this time period shall constitute a waiver of any right such person may have to request an administrative determination (hearing) under Section 120.57, Florida Statutes.

If a petition is filed, the administrative hearing process is designed to formulate agency action. Accordingly, the Department's final action may be different from the position taken by it in this preliminary statement. Therefore, persons who may not object to the proposed agency action may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Model Rule 28-5.207 at least five (5) days before the final hearing and be filed with the hearing officer if one has been assigned at the Division of Administrative Hearings, Department of Administration, 2009 Apalachee Parkway, Tallahassee, Florida 32399-2400. 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 32399-2400. Failure to petition to intervene within the allowed time frame constitutes a waiver of any right such person has to request a hearing under Section 120.57, Florida Statutes.

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

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

Dept. of Environmental Regulation, Bureau of Air Quality Management, 2600 Blair Stone Road, Tallahassee, Florida 32399-2400

Dade County Department of Environmental Resources Management, Metro Dade Governmental Center, Suite 3110, 111 N.W. 1st Street, Miami, Florida 33128

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

June 18, 1987
Ad. No. 341-340N

File Copy

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

June 5, 1987

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

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

Dear Mr. Confroy:

Attached is one copy of the Technical Evaluation and Preliminary Determination, and proposed permit to modify the carbon adsorption and solvent recovery system by constructing 6 coating pans and 3 drying rooms 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/ks

Attachments

cc: I. Goldman
P. Wong
J. Wells, P.E.

P 408 531 192

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to James R. Confroy Key Pharmaceuticals, Inc.	
Street and No. 50 N.W. 176th Street	
P.O., State and ZIP Code Miami, FL 33169	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt Showing to whom and Date Delivered	
Return Receipt Showing to whom, Date, and Address of Delivery	
TOTAL Postage and Fees	$
Postmark or Date 6/5/87 AC 13-129899	

PS Form 3800, Feb. 1982

UNITED STATES POSTAL SERVICE

OFFICIAL BUSINESS

SENDER INSTRUCTIONS

Print your name, address, and ZIP Code in the space below.

- **Complete items 1, 2, 3, and 4 on the reverse.**
- **Attach to front of article if space permits, otherwise affix to back of article.**
- **Endorse article "Return Receipt Requested" adjacent to number.**

U.S.MAIL

PENALTY FOR PRIVATE USE, $300

RETURN TO

DER

JUN 11 1987

BAQM

Department of Environmental Regulation
(Name of Sender)
Bureau of Air Quality Management
2600 Blair Stone Road
(No. and Street, Apt., Suite, P.O. Box or R.D. No.)
Tallahassee, Florida 32399-2400
(City, State, and ZIP Code)

attn: K. Sholar

PS Form 3811, July 1983 447-845

DOMESTIC RETURN RECEIPT

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

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

1. ☐ Show to whom, date and address of delivery.

2. ☐ Restricted Delivery.

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

4. Type of Service:

☐ Registered ☐ Insured
☒ Certified ☐ COD
☐ Express Mail

Article Number

P 408 531 192

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature – Addressee
X Robert Rose

6. Signature – Agent
X

7. Date of Delivery
JUN 09 1987

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

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 13-129899

INTENT TO ISSUE

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

The applicant, Key Pharmaceuticals, Inc, applied on January 26, 1987, to the Department of Environmental Regulation for a permit to modify the carbon adsorption and solvent recovery system by constructing 6 coating pans and 3 drying rooms at their existing pharmaceutical plant in Miami, Dade County, Florida.

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

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

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

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

Executed in Tallahassee, Florida.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL REGULATION

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

Copies furnished to:

James R. Confroy
Isidore Goldman
Patrick Wong

CERTIFICATE OF SERVICE

The undersigned duly designated deputy clerk hereby certifies that this NOTICE OF INTENT TO ISSUE and all copies were mailed before the close of business on June 5, 1987.

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

R Bruce Potter
Clerk

6/5/87
Date

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

The Department of Environmental Regulation gives notice of its intent to issue a permit to Key Pharmaceuticals, Inc. to modify the carbon adsorption and solvent recovery system by constructing 6 coating pans and 3 drying rooms at their existing pharmaceutical plant located at 50 N.W. 176th Street, Miami, Dade County, Florida. The modification will increase volatile organic compounds emissions by 18.13 TPY. A determination of best available control technology (BACT) was not required.

Persons whose substantial interests are affected by the Department's proposed permitting decision may petition for an administrative proceeding (hearing) in accordance with Section 120.57, Florida Statutes. The petition must conform to the requirements of Chapters 17-103 and 28-5, Florida Administrative Code, and must be filed (received) in the Office of General Counsel of the Department at 2600 Blair Stone Road, Twin Towers Office Building, Tallahassee, Florida 32399-2400, within fourteen (14) days of publication of this notice. Failure to file a request for hearing within this time period shall constitute a waiver of any right such person may have to request an administrative determination (hearing) under Section 120.57, Florida Statutes.

If a petition is filed, the administrative hearing process is designed to formulate agency action. Accordingly, the Department's final action may be different from the position taken by it in this preliminary statement. Therefore, persons who may not object to the proposed agency action may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Model Rule 28-5.207 at least five (5) days before the final hearing and be filed with the hearing officer if one has been assigned at the Division of Administrative Hearings, Department of Administration, 2009 Apalachee Parkway, Tallahassee, Florida 32399-2400. 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 32399-2400. 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:

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

Dept. of Environmental Regulation
Bureau of Air Quality Management
2600 Blair Stone Road
Tallahassee, Florida 32399-2400

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

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

Technical Evaluation
and
Preliminary Determination

Key Pharmaceuticals, Inc.
Miami, Florida
Dade County

Modify the Carbon Adsorption and Solvent Recovery System by Constructing Six Coating and Three Drying/Curing Rooms with Ancillary Equipment

File Number: AC 13-129899

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

June 5, 1987

I. General Information

A. Applicant

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

B. Request

Mr. Thomas Flachmeyer, Manager of Environmental Engineering and Waste Management for Key Pharmaceuticals, Inc., delivered an application for permit to construct six coating pans and three drying rooms on January 26, 1987. In a letter dated April 16, 1987, Key Pharmaceuticals modified the application by proposing to connect the six coating pans and three drying/curing rooms with ancillary equipment to the carbon adsorption and solvent recovery system. The application was considered complete on receipt of the April 16 letter (April 20, 1987).

C. Project and Location

The applicant proposes to reactivate six coating pans and three drying/curing rooms with ancillary equipment that had ceased operation pursuant to Consent Order OGC Case No. 84-0644. Production will be restricted to limit emissions prior to the process being connected to the air pollution control equipment. The emissions from this process will be controlled by the carbon adsorption and solvent recovery system that is under construction (AC 13-129893) when it is placed in service (June 1988). The location of this equipment is at the pharmaceutical plant (SIC 2834) at 50 N.W. 176th Street in Miami, Dade County, Florida. The UTM coordinates of this facility are zone 17, 579.9 km E and 2868.4 km N.

D. Process and Emissions

Batches of solids and VOC solvents (ethyl acetate, acetone, and isopropanol) are mixed, dried, and sized in process equipment that includes six coating pans, three in-process solvent storage carts, three drying/curing rooms, wet sizing equipment, drying equipment, dry sizing equipment, and ancillary equipment. Each lot uses a total of approximately 909 pounds of excipients and 166 pounds of VOC. The emissions (particulate matter and VOC) from the coating pans, sizing and drying equipment, and the rooms are exhausted through an 80^{+} percent efficient depth filter. The disposal filter elements are replaced after two weeks of service and disposed of at an off-site approved facility.

The applicant is requesting permission to produce 128 lots of drugs in 1987 and 1988 (256 lots total) in this process

equipment prior to the availability of the carbon adsorption air pollution control system. Emissions associated with the production of 128 lots per year are 10.6 tons VOC and 0.06 tons particulate matter. As each lot is a batch operation and emissions are not linear, instantaneous emissions are estimated to be as high as 66.8 lbs/hr VOC and 0.50 lbs/hr particulate matter.

The applicant plans to produce up to 2,190 lots of drugs per year with this process equipment after the emissions are controlled with the carbon adsorption system that is under construction. The carbon adsorption system will remove a minimum of 90% of the VOC discharged from the process over an equipment process cycle. Estimated emissions from 2,190 lots of drugs per year are 18.13 TPY VOC and 1 TPY particulate matter. Because of the batch mode of operation, instantaneous emissions are estimated to be as high as 6.7 lbs/hr VOC and 0.50 lbs/hr of particulate matter.

It is noted that additional air pollution controls to protect the carbon adsorption system from particulate matter exist downstream from this process. Thus, the estimate of the particulate matter emissions from the pan coating process are probably high. Because all particulate matter generated by different processes at this facility pass through baghouses prior to being discharged to the atmosphere, the Department may substitute an alternate standard of 5% opacity for the particulate matter standard.

The emissions from the carbon adsorption system, as originally approved and modified by the proposed pan coating process, are summarized below:

	Methylene Chloride		VOC		Particulate Matter	
	lb/hr	TPY	lb/hr max	TPY	lb/hr max	TPY
Original Carbon Adsorption Permit AC 13-129893	141.0	370.1	15.4	38.1	0.1	0.23
Proposed Pan Coating Process AC 13-129899	0	0	6.68	18.13	0.5	1
Total	141.0	370.1	22.08	56.23	0.6	1.23

II. Rule Applicability

A. State Regulations

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

The pharmaceutical plant (SIC 2834) is located in an area designated nonattainment for ozone (Rule 17-2.410, FAC), and attainment for the other criteria pollutants.

Pharmaceutical plants are classified as chemical process plants which are listed on Table 500-1, Major Facility Categories (list of 28). The plant is a major facility (17-2.100) because the potential emissions of exempt VOC presently exceed 100 TPY. It is a minor source for the regulated VOC because these emissions are less than 100 TPY. The increase in emissions resulting from the proposed project is less than the significant emission rate listed in Table 500-2, Regulated Air Pollutants Significant Emission Rates.

The project is not subject to the prevention of significant deterioration regulation (17-2.500) and new source review for nonattainment areas (17-2.510) because the modification does not result in a significant net emissions increase of any criteria pollutant (17-2.500(2)(d)4.a.(ii) and 17-2.510(2)(d)4.a.).

The project will be reviewed under Rule 17-2.520, Sources Not Subject to Prevention of Significant Deterioration or Nonattainment Requirements. Allowable VOC emissions will be based on the requirement for reasonable controls, Rule 17-2.620, FAC, and Consent Order No. 84-0644. Allowable particulate matter emissions shall be based on 17-2.610(1), the process weight table. An alternate standard of no visible emissions will be substituted for the particulate matter standard (17-2.700(3)(d)).

Higher emissions could subject this operation to review under other regulations.

B. Federal Regulations

The proposed project, a minor modification to a major facility, is not subject to review under federal regulations because the modification will not result in a significant net emissions increase of any criteria pollutant.

III. Technical Evaluation

Key Pharmaceuticals, Inc. specified to the manufacturer that the carbon adsorber system be sized to accommodate the pan

coating process and that it reduce VOC emissions by 90 percent. The solvents captured by the carbon adsorption system will be sent to a solvent recovery system which will recycle methylene chloride to the process and dispose of the other VOC solvents recovered by using them as boiler fuel.

Carbon adsorbers are used to control gaseous emissions. Particulate matter harms their performance. Key's carbon adsorber system will have a dust collector ahead of it to remove the particulate matter in order to protect the adsorber. Thus, carbon adsorber systems are not considered to be sources of particulate matter emissions.

IV. Air Quality Analysis

The proposed project will not result in a significant net emissions increase as set fourth in Rule 17-2.500(2)(e)2., FAC. Therefore, no air quality analysis is required by the regulation. Screening model (MPTPLU) results shows that the maximum one hour concentration of methylene chloride and volatile organic compounds in the atmosphere from the proposed emissions will be 1,059 and 166 ug/m^3, respectively. These impacts are less than 2% of the TLV-TWA. Although the Department has not established ambient air quality standards for these compounds, other states have set standards at 1-2% of the TLV-TWA. Based on this analysis, the Department has reasonable assurance that the emissions of the solvents from this process will not endanger public health.

V. Conclusion

Based on the data submitted by the applicant, the Department has concluded that the emissions from the carbon adsorption unit controlling air pollution from four Glatts, two perforated pan coating units, six coating pans and three drying/curing rooms with ancillary equipment will comply with the State's regulations. The Department proposes to issue a construction permit that will authorize the construction of the new process and air pollution control equipment. The General and Specific Conditions in the proposed permit (attached) will assure compliance of the source with the State's air pollution control regulations.

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

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

Permit Number: AC 13-129899
Expiration Date: January 1, 1989
County: Dade
Latitude/Longitude: 25° 56' 03" N
80° 11' 42" W
Project: Modify the Carbon Adsorption & Solvent Recovery System by Constructing 6 Coating Pans & 3 Drying/Curing Rooms with Ancillary Equipment

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

Authorization to construct 6 coating pans and 3 drying/curing rooms with ancillary equipment and connect this process equipment to the 90% efficient carbon adsorption/solvent recovery system that controls the emissions from four fluid bed processors (Glatt) and two Perforated Pan Coating Units (PPCU). This equipment will be located at the pharmaceutical plant at 50 N.W. 176th Street, Miami, Dade County, Florida. The UTM coordinates of this plant are zone 17, 579.9 km E and 2868.4 km N.

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

Attachments:

1. Key's Application for 6 Coating Pans, 3 Drying Rooms received by BAQM on January 26, 1987.

2. DER's letter of January 28, 1987.

3. Key's letter dated April 16, 1987.

GENERAL CONDITIONS:

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

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

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

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

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

GENERAL CONDITIONS:

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

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

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

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

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

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

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

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

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

GENERAL CONDITIONS:

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

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

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

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

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

13. This permit also constitutes:

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

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

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

GENERAL CONDITIONS:

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

c. Records of monitoring information shall include:

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

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

SPECIFIC CONDITIONS:

1. Until the carbon adsorption/solvent recovery system are able to control the air pollutant emissions from the pan coating process, the permittee shall limit production from this process to 128 lots in 1987 and 128 lots in 1988.

2. Production after the carbon adsorption/solvent recovery system is placed in service shall not exceed the following without prior approval of the Department (BAQM):

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

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129899
Expiration Date: January 1, 1989

SPECIFIC CONDITIONS:

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

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

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

Pan Coating Process - 2,190 lots/year

Each pan coating process lot uses approximately 909 lbs of solids (excipients) and 166 lbs/VOC solvents (ethyl acetate, acetone, and isopropanol).

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

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

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

4. The carbon adsorption/solvent recovery system shall remove a minimum of 90% of the solvents emitted by the process equipment during the process cycle. Compliance with this standard shall be determined using the data from the continuous monitors on the inlet and discharge of the carbon adsorbers.

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

Unit	Methylene Chloride			VOC			PM	
	lb/hr	lb/day	TPY	lb/hr	lb/day	TPY	lb/hr	TPY
Glatt No. 1	20.9	271.2	49.5	1.9	25.0	4.6		
Glatt No. 2	26.7	465.6	85.0	2.5	43.2	7.9		
Glatt No. 3	26.7	465.6	85.0	2.5	43.2	7.9		
Glatt No. 4	26.7	465.6	85.0	2.5	43.2	7.9		
PPCU No. 1	20.0	180.0	32.8	3.0	27.1	4.9	0.1*	0.23*
PPCU No. 2	20.0	180.0	32.8	3.0	27.1	4.9		
Pan Coat. Process	0	0	0	6.98	99.4	18.13	0.5	1
Total	141.0	2028.0	370.1	22.08	308.2	53.23	0.6	1.23

* Net emissions from Glatt and PPCU units.

SPECIFIC CONDITIONS:

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

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

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

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

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

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

7. The construction shall reasonably conform to the plans and schedule submitted in the application. This permit may replace permit No. AC 13-129893. If the permittee is unable to complete construction on schedule, he must notify the Department in writing 60 days prior to the expiration of the construction permit and submit a new schedule and request for an extension of the construction permit. (FAC Rule 17-4.09)

8. To obtain a permit to operate, the permittee must demonstrate compliance with the conditions of the construction permit and submit a complete application for an operating permit, including the application fee, along with test results and Certificate of Completion, to the Department's district office or their designated agent 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 Rules 17-4.22 and 17-4.23)

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-129899
Expiration Date: January 1, 1989

SPECIFIC CONDITIONS:

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

STATE OF FLORIDA DEPARTMENT OF
ENVIRONMENTAL REGULATION

Dale Twachtmann, Secretary

MIA 880 119381

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

Telex: 808235

DER

APR 20 1987

BAQM

April 16, 1987

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

RE: PERMIT NO. AC 13-129893

Dear Mr. Fancy:

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

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

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

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

RE: AC 13-129799

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

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

These changes are reflected in Attachment II.

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

Your prompt review of these comments will be appreciated.

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

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

attachments

ATTACHMENT 1

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

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

January 28, 1987

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

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

Dear Mr. Flachmeyer:

Re: 8 Permit Applications for Construction of Various Manufacturing Equipment

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

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

CHF/WH/s

cc: S. Brooks
P. Wong

enclosure

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

No. 76143

RECEIPT FOR APPLICATION FEES AND MISCELLANEOUS REVENUE

Received from Schering Corporation Date Jan. 26, 1987

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

Applicant Name & Address Key Pharmaceuticals, Inc.

Source of Revenue

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

By Patricia G. Adams

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7072

[redacted]

JANUARY 20 1987

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

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

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

FOR PERMIT FEE [redacted] James R Cafferty

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7032

[redacted]

DECEMBER 12 1986

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

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

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

FOR PERMIT (GLATT 4) [redacted] James R Cafferty

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

No 76143

RECEIPT FOR APPLICATION FEES AND MISCELLANEOUS REVENUE

Received from Schering Corporation Date Jan. 26, 1987

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

Applicant Name & Address Key Pharmaceuticals, Inc.

Source of Revenue

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

By Patricia G. Adams

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7072

[redacted]

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FOR PERMIT FEE

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SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7032

[redacted]

DECEMBER 12 1986

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

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

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

FOR PERMIT (GLATT 4)

[redacted] James R Cafferty

ATTACHMENT II

Revisions to Application No. 8

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

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

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

* based on solvents used in 24 hours.

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

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

2. Product Weight (lbs/hr): 62.2

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

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

[1]See Section V, Item 2.

** based on all solvents used in 8 hours.

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

[3]Calculated from operating rate and applicable standard.

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

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

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

E. Fuels

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

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

Fuel Analysis:

Percent Sulfur: _____ Percent Ash: _____

Density: _____ lbs/gal Typical Percent Nitrogen: _____

Heat Capacity: _____ BTU/lb _____ BTU/gal

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

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

Annual Average _____ Maximum _____

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

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

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

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

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

Water Vapor Content: 25 % Velocity: 55.4 FPS

SECTION IV: INCINERATOR INFORMATION

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

Description of Waste _____

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

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

Manufacturer _____

Date Constructed _____ Model No. _____

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

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

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

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

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

[ ] Other (specify) _____

KEY PHARMACEUTICALS
EMISSION CALCULATIONS
PAN COATING AT MAXIMUM PRODUCTION CAPACITY

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

BASIS :

#1 NUMBER OF ACTIVE PAN LOTS : 2190 LOTS

ACTIVE LOT CYCLE TIME : 12 HOURS

ANNUAL OPERATING HOURS : 26280 HOURS

LOT SPECIFICATIONS :

EXCIPIENTS : 247 LBS

VOC : 89 LBS

A. PARTICULATE EMISSIONS

(i) EMISSION POTENTIAL

1/2 OF 1% OF LOT

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

(ii) MAXIMUM INSTANTANEOUS EMISSION POTENTIAL

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

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

(iii) MAXIMUM INSTANTANEOUS EMISSIONS

DEPTH FILTER DESIGN - 80% REMOVAL EFFICIENCY

0.9261 * 0.2 = 0.19 LBS/HOUR

(iv) AVERAGE ANNUAL EMISSIONS

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

B. VOC EMISSIONS

(i) MAXIMUM INSTANTANEOUS EMISSIONS POTENTIAL

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

89 * 6 / 8 = 66.81 LBS/HOUR

(ii) MAXIMUM INSTANTANEOUS EMISSIONS

CONTROL SYSTEM DESIGN 90 %REMOVAL EFFICIENCY

0.1 *66.80653 = 6.68 LBS/HOUR

(iii) AVERAGE ANNUAL EMISSIONS POTENTIAL

89 * 2190 / 2000 = 97.54 TONS/YEAR

(iv) AVERAGE ANNUAL EMISSIONS

CONTROL SYSTEM DESIGN 90 %REMOVAL EFFICIENCY

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

BASIS :

#2 NUMBER OF WAX PAN LOTS : 2190 LOTS

WAX LOT CYCLE TIME : 12 HOURS

ANNUAL OPERATING HOURS : 26280 HOURS

LOT SPECIFICATIONS :

EXCIPIENTS : 662 LBS

VOC : 77 LBS

A. PARTICULATE EMISSIONS

(i) EMISSION POTENTIAL

1/2 OF 1% OF LOT

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

(ii) MAXIMUM INSTANTANEOUS EMISSION POTENTIAL

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

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

(iii) MAXIMUM INSTANTANEOUS EMISSIONS

DEPTH FILTER DESIGN - 80% REMOVAL EFFICIENCY

2.480625 * 0.2 = 0.50 LBS/HOUR

(iv) AVERAGE ANNUAL EMISSIONS

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

B. VOC EMISSIONS

(i) MAXIMUM INSTANTANEOUS EMISSIONS POTENTIAL

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

77 * 6 / 8 = 57.39 LBS/HOUR

(ii) MAXIMUM INSTANTANEOUS EMISSIONS

CONTROL SYSTEM DESIGN 90 %REMOVAL EFFICIENCY

0.1 *57.38512 = 5.74 LBS/HOUR

(iii) AVERAGE ANNUAL EMISSIONS POTENTIAL

77 * 2190 / 2000 = 83.78 TONS/YEAR

(iv) AVERAGE ANNUAL EMISSIONS

CONTROL SYSTEM DESIGN 90 %REMOVAL EFFICIENCY

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

TOTAL EMISSIONS

(i) PARTICULATE

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

(ii) VOC

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

ATTACHMENT III -)

VOC Emission Calculations for Drug 0420

KEY PHARMACEUTICALS
EMISSION CALCULATIONS
PAN COATING OF DRUG 0420

PREPARED BY:
CHECKED BY:

BASIS :

#1 NUMBER OF ACTIVE PAN LOTS : 128 LOTS

ACTIVE LOT CYCLE TIME : 24 HOURS

ANNUAL OPERATING HOURS : 3072 HOURS

LOT SPECIFICATIONS :

EXCIPIENTS : 247 LBS

VOC : 89 LBS

A. PARTICULATE EMISSIONS

(i) EMISSION POTENTIAL

1/2 OF 1% OF LOT

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

(ii) MAXIMUM INSTANTANEOUS EMISSION POTENTIAL

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

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

(iii) MAXIMUM INSTANTANEOUS EMISSIONS

DEPTH FILTER DESIGN - 80% REMOVAL EFFICIENCY

0.9261 * 0.2 = 0.19 LBS/HOUR

(iv) AVERAGE ANNUAL EMISSIONS

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

B. VOC EMISSIONS

(i) MAXIMUM INSTANTANEOUS EMISSIONS

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

89 * 6 / 8 = 66.81 LBS/HOUR

(ii) AVERAGE ANNUAL EMISSIONS

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

BASIS :

#2 NUMBER OF WAX PAN LOTS : 128 LOTS

WAX LOT CYCLE TIME : 24 HOURS

ANNUAL OPERATING HOURS : 3072 HOURS

LOT SPECIFICATIONS :

EXCIPIENTS : 662 LBS

VOC : 77 LBS

A. PARTICULATE EMISSIONS

(i) EMISSION POTENTIAL

1/2 OF 1% OF LOT

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

(ii) MAXIMUM INSTANTANEOUS EMISSION POTENTIAL

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

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

(iii) MAXIMUM INSTANTANEOUS EMISSIONS

DEPTH FILTER DESIGN - 80% REMOVAL EFFICIENCY

2.480625 * 0.2 = 0.50 LBS/HOUR

(iv) AVERAGE ANNUAL EMISSIONS

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

B. VOC EMISSIONS

(i) MAXIMUM INSTANTANEOUS EMISSIONS

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

77 * 6 / 8 = 57.39 LBS/HOUR

(ii) AVERAGE ANNUAL EMISSIONS

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

TOTAL EMISSIONS

(i) PARTICULATE

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

(ii) VOC

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

ATTACHMENT IV

Key Pharmaceuticals, Inc.

50 N.W. 176th Street Facility

VOC Emission Tabulations

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

REGULATED VOC EMISSIONS
(EXCEPT METHYLENE CHLORIDE)

PROPOSED EMISSIONS POTENTIAL
(tons/year)

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

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

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

NON REGULATED VOC EMISSIONS
(METHYLENE CHLORIDE)

PROPOSED EMISSIONS POTENTIAL
(tons/year)

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

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

REGULATED VOC EMISSIONS
(EXCEPT METHYLENE CHLORIDE)

PROPOSED EMISSIONS POTENTIAL
(tons/year)

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

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

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

P 408 531 153

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to Mr. Thomas W. Flachmeyer	
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	1/29/87

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. Thomas W. Flachmeyer
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, FL 33169-1307

4. Type of Service:	Article Number
☐ Registered ☐ Insured ☒ Certified ☒ COD ☐ Express Mail	P 408 531 153

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature — Addressee
X [signature]

6. Signature — Agent
X

7. Date of Delivery

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

DOMESTIC RETURN RECEIPT

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

January 28, 1987

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

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

Dear Mr. Flachmeyer:

Re: 8 Permit Applications for Construction of Various Manufacturing Equipment

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

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

CHF/WH/s

cc: S. Brooks
P. Wong

enclosure

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

Telex: 808235

January 12, 1987

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

RE: KEY PHARMACEUTICALS, INC. PERMIT APPLICATIONS

Dear Mr. Fancy:

Enclosed please find eight (8) Permit Applications for construct of various manufacturing equipment located at Key Pharmaceuticals, Inc. 50 N.W. 176th Street, Miami facility. In the past Key Pharmaceuticals had permitted the manufacturing of specific products regardless of equipment capacity. After several discussions with personnel in your department, Mr. Bill Thomas and Mr. Willard Hanks, it was concluded that it would be more advantageous for Key Pharmaceuticals and less of a burden on State permitting personnel to permit the capacity of specific manufacturing equipment, regardless of product manufactured. Therefore, enclosed are the following permit applications:

APPLICATION #1	3 FLUID BED PROCESS UNITS (GLATT)
APPLICATION #2	1 SOLVENT VAPOR CONTROL & RECOVERY SYSTEM
APPLICATION #3	1 FLUID BED PROCESS UNIT (GLATT)
APPLICATION #4	2 PAN COATING UNITS (ACCELA-COTA)
APPLICATION #5	4 TABLET PRESSES
APPLICATION #6	2 GRANULATION UNITS
APPLICATION #7	1 GRANULATION UNIT
APPLICATION #8	6 COATING PANS

The permitting of these applications will place Key Pharmaceuticals' Miami facility strategically into the manufacturing marketplace. The specific reasoning for each application is as follows:

APPLICATION #1

An increase in production capacity has been achieved. This increase significantly alters the emission potential and emissions of the unit.

APPLICATION #2

Due to the increase in emission for the three Glatt units and the need for 1 to 3 more Glatt units and 2 Accela-Cota units, it has been decided to update the current environmental control system

APPLICATION #3

Due to increased forecast on sales for the K-DUR product a fourth Glatt is needed.

APPLICATION #4

The Accela-Cotas are new process equipment proposed for the facility.

APPLICATION #5

The tablet presses have been permitted for several products. This is to change the permit strategy from products to equipment.

APPLICATION #6

The granulation processes have been permitted for several products. This is to change the permit strategy from products to equipment.

APPLICATION #7

The potential exists that some products which are manufactured by granulation need to be solvent based. Therefore, one granulator is permitted for both solvent and aqueous processing.

APPLICATION #8

These coating pans are part of the equipment that has been shut-down in compliance with Consent Order No. 83-0373. The need has arisen to use these 6 pans for some product scale-up/development work and for small scale production. The permitting of the units will allow Key to more quickly respond to research and development's scale-up requests. Current project utilization is 25% of permitted capacity.

As you can see Key Pharmaceuticals is trying to place this manufacturing facility into a position to develop and start manufacturing a variety of products utilizing a spectrum of manufacturing practices. TABLE I illustrates current permitting strategy and emissions. The table illustrates a significant increase in methylene chloride emission for permit AC 13-100437. As you can see from TABLE II the methylene chloride emissions are significantly reduced once the new control system is implemented. Although the permit applications are submitted as separate applications, Key would be willing to accept a single for for applications 5, 6, and 7. The combination of these applications would lessen the burden on State permitting personnel.

Your cooperation in this matter is greatly appreciated. Should you have any questions, please do not hesitate to call me at 305-654-2240.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

attachments

TABLE I

1987 PERMITTED OR PROPOSED EMISSIONS

PERMIT NO.	METHYLENE CHLORIDE	VOC	PARTICULATE
AC 13-115383		0.95	0.00025
AC 13- 100437			
DEC'86	978	35	0.068
JUN'87	2,195	20.3	0.14
DRUG 0420		0.45	0.001

TABLE II

1988 PROPOSED EMISSIONS

APPLICATION NO.	METHYLENE CHLORIDE	VOC	PARTICULATE
#1	INCLUDED IN APPLICATION #2		
#2	370.1	38.1	0.23
#3	INCLUDED IN APPLICATION #2		
#4	INCLUDED IN APPLICATION #2		
#5			0.2
#6			0.02
#7		30.2	0.006
#8		97.5	0.27

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7030

DECEMBER 12 19 86

PAY TO THE ORDER OF FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATION $ 100.00

ONE HUNDRED AND 00/100---------- DOLLARS

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

FOR PERMIT (GRAN. 1)

[redacted]

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7073

JANUARY 20 19 87

PAY TO THE ORDER OF FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATIONS $ 250.00

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

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

FOR PERMIT FEE

[redacted]

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7070

JANUARY 20 19 87

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

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

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

FOR PERMIT FEE

[redacted]

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7031

[redacted]

DECEMBER 12 19 86

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

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

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

FOR PERMIT (GLATT 1-3)

[redacted]

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7033

[redacted]

DECEMBER 12 1986

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

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

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

FOR PERMIT (GLATT 1-4)

[redacted]

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7071

[redacted]

19

PAY TO THE ORDER OF FLORIDA DEPARTMENT FO ENVIRONMENTAL REGULATIONS $ 100.00

ONE HUNDRED AND 00/100---------- DOLLARS

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

FOR PERMIT FEE

[redacted]

Best Available Copy

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7032

DECEMBER 12 1986

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

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

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

FOR PERMIT (GLATT 4)

[redacted]

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

7072

JANUARY 20 1987

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

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

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

FOR PERMIT FEE

[redacted]

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

No. 76143

RECEIPT FOR APPLICATION FEES AND MISCELLANEOUS REVENUE

Received from Schering Corporation Date Jan. 26, 1987

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

Applicant Name & Address Key Pharmaceuticals Inc.

Source of Revenue AC13-129891 -129892, 129894 -129895, -129897 -129899

Revenue Code 001031 Application Number

By Patricia D. Adams

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

Telex: 808235

January 12, 1987

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

RE: APPLICATION TO CONSTRUCT 1 COATING PAN ROOM (6 COATING PANS).

Dear Mr. Fancy:

Attached please find an "Application to Construct Air Pollution Sources". The application attached is for the construction of a Pan Coating Room at Key Pharmaceuticals, Inc 50 N.W. 176 Street, Miami location. The equipment included is six (6) Coating Pans, 3 in process solvent storage carts, two drying/curing rooms, and ancillary equipment. This application supercedes and replaces the permit application submitted December 8, 1986, for the manufacturing of DRUG 0420. This application is being submitted at this time to allow Key to develop several new drugs and manufacture small quantities of existing pharmaceutical products. As stated in previous applications, Key is trying to permit production equipment rather than product specific manufacturing process. The permit application reflects the manufacturing capacity of the equipment, production forecasts currently project 25% utilization of the equipment for 1987 and 1988. The percent utilization is directly proportional to the reduction of emissions of volatile organic compounds.

Your cooperation in this matter is greatly appreciated. Should you have any questions please do not hesitate to call me at 305-654-2240.

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

attachment

cc: S. Brooks (S.E. Florida District)
P. Wong (DERM Office)

AC 13-129899 rec'd 1/26/87

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

APPLICATION TO OPERATE/CONSTRUCT AIR POLLUTION SOURCES

SOURCE TYPE: AIR POLLUTION [x] New[1] [ ] Existing[1]

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

COMPANY NAME: KEY PHARMACEUTICALS, INC. COUNTY: DADE

Identify the specific emission point source(s) addressed in this application (i.e. Lime Kiln No. 4 with Venturi Scrubber; Peaking Unit No. 2, Gas Fired) 6 COATING PANS, 3 DRYING ROOMS

SOURCE LOCATION: Street 50 N.W. 176TH STREET City MIAMI

UTM: East 57987 North 7868445

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

APPLICANT NAME AND TITLE: JAMES R. CONFROY, VICE PRESIDENT OPERATIONS

APPLICANT ADDRESS: 50 N.W. 176TH STREET, MIAMI, FL 33169

SECTION I: STATEMENTS BY APPLICANT AND ENGINEER

A. APPLICANT

I am the undersigned owner or authorized representative* of KEY PHARMACEUTICALS, INC.

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

*Attach letter of authorization

Signed: James R Confroy

JAMES R. CONFROY, VICE PRESIDENT OPERATIONS
Name and Title (Please Type)

Date: 1/12/87 Telephone No. 305-654-2200

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

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

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

* SEE NOTE PAGE 2

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

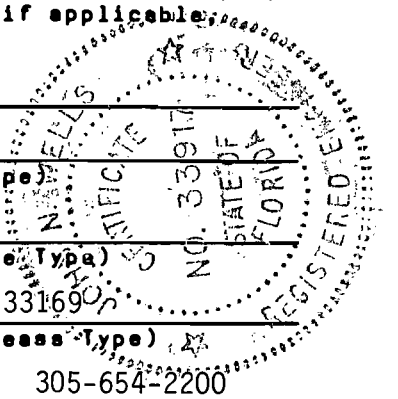
the pollution control facilities, when properly maintained and operated, will discharge an effluent that complies with all applicable statutes of the State of Florida and the rules and regulations of the department. It is also agreed that the undersigned will furnish, if authorized by the owner, the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

Signed John N. Wells, P.E.

JOHN N. WELLS, P.E.
Name (Please Type)

KEY PHARMACEUTICALS, INC.
Company Name (Please Type)

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



Florida Registration No. 33917 **Date:** 1/12/87 **Telephone No.** 305-654-2200

SECTION II: GENERAL PROJECT INFORMATION

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

THE SIX COATING PANS WITH ANCILLARY EQUIPMENT WILL BE UTILIZED DURING THE MANUFACTURING OF VARIOUS SOLID DOSE (TABLET OR CAPSULE) PHARMACEUTICAL PRODUCTS. ROOM VENTILATION IS PROVIDED FOR WITH THIS EQUIPMENT.

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

Start of Construction MAR'87 **Completion of Construction** SEP'87

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

$1,000.00

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

(1) CONSENT ORDER 83-0373 (CLOSED)

(2) PERMIT TO CONSTRUCT FOR MFG GUANIDINE & QUINORA AC 13-115383

(3) PERMIT TO CONSTRUCT FOR MFG K-DUR AC 13-100437

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

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

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

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

a. If yes, for what pollutants?_____

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

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

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

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

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

* BASED ON SOLVENTS USED IN 24 HOURS.

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

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

2. Product Weight (lbs/hr): 62.2

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

Name of Contaminant	Emission[1]		Allowed[2] Emission Rate per Rule 17-2	Allowable[3] Emission lbs/hr	Potential[4] Emission		Relate to Flow Diagram
	Maximum lbs/hr	Actual T/yr			lbs/yr	T/yr	
PARTICULATE	0.94	0.27				1.37	"A"
VOC	66.75 **	97.5				97.5	

[1] See Section V, Item 2. ** BASED ON ALL SOLVENTS USED IN 8 HOURS.

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

[3] Calculated from operating rate and applicable standard.

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

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

Name and Type (Model & Serial No.)	Contaminant	Efficiency	Range of Particles Size Collected (in microns) (If applicable)	Basis for Efficiency (Section V Item 5)
DEPTH FILTER	PARTICULATE	80%	2 MICRON OR LARGER	SUPPLIER'S DESIGN

E. Fuels

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

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

Fuel Analysis:

Percent Sulfur: _____ Percent Ash: _____

Density: _____ lbs/gal Typical Percent Nitrogen: _____

Heat Capacity: _____ BTU/lb _____ BTU/gal

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

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

Annual Average _____ Maximum _____

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

FILTERS ARE REMOVED EVERY 2 WEEKS AND REPLACED. FILTERS ARE DISPOSED OF OFF-SITE AT AN APPROVED FACILITY.

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

Stack Height: ROOF LEVEL 1 ft. Stack Diameter: 2 ft.

Gas Flow Rate: 7000 ACFM _____ DSCFM Gas Exit Temperature: 70 °F.

Water Vapor Content: 50% to 70% RH % Velocity: 37 FPS

SECTION IV: INCINERATOR INFORMATION

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

Description of Waste _____

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

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

Manufacturer _____

Date Constructed _____ Model No. _____

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

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

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

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

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

[ ] Other (specify) _____

Brief description of operating characteristics of control devices: _____

_____

_____

_____

_____

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

_____

_____

_____

_____

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

SECTION V: SUPPLEMENTAL REQUIREMENTS

Please provide the following supplements where required for this application.

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

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

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

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

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

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

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

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

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

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

SECTION VI: BEST AVAILABLE CONTROL TECHNOLOGY

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

[ ] Yes [ ] No

Contaminant	Rate or Concentration

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

[ ] Yes [ ] No

Contaminant	Rate or Concentration

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

Contaminant	Rate or Concentration

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

1. Control Device/System: 2. Operating Principles:

3. Efficiency:* 4. Capital Costs:

*Explain method of determining

5. Useful Life:

6. Operating Costs:

7. Energy:

8. Maintenance Cost:

9. Emissions:

Contaminant	Rate or Concentration

10. Stack Parameters

a. Height: ft.

b. Diameter: ft.

c. Flow Rate: ACFM

d. Temperature: °F.

e. Velocity: FPS

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

1.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

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

2.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

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

j. Applicability to manufacturing processes:

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

3.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

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

4.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Costs:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

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

F. Describe the control technology selected:

1. Control Device:

2. Efficiency:[1]

3. Capital Cost:

4. Useful Life:

5. Operating Cost:

6. Energy:[2]

7. Maintenance Cost:

8. Manufacturer:

9. Other locations where employed on similar processes:

a. (1) Company:

(2) Mailing Address:

(3) City:

(4) State:

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

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

b. (1) Company:

(2) Mailing Address:

(3) City: (4) State:

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

10. Reason for selection and description of systems:

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

SECTION VII - PREVENTION OF SIGNIFICANT DETERIORATION

A. Company Monitored Data

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

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

Other data recorded _____

Attach all data or statistical summaries to this application.

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

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

Cable: KEYPHARM
Telex: 808235

C E R T I F I C A T E

To Whom it May Concern:

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

Key Pharmaceuticals, Inc.

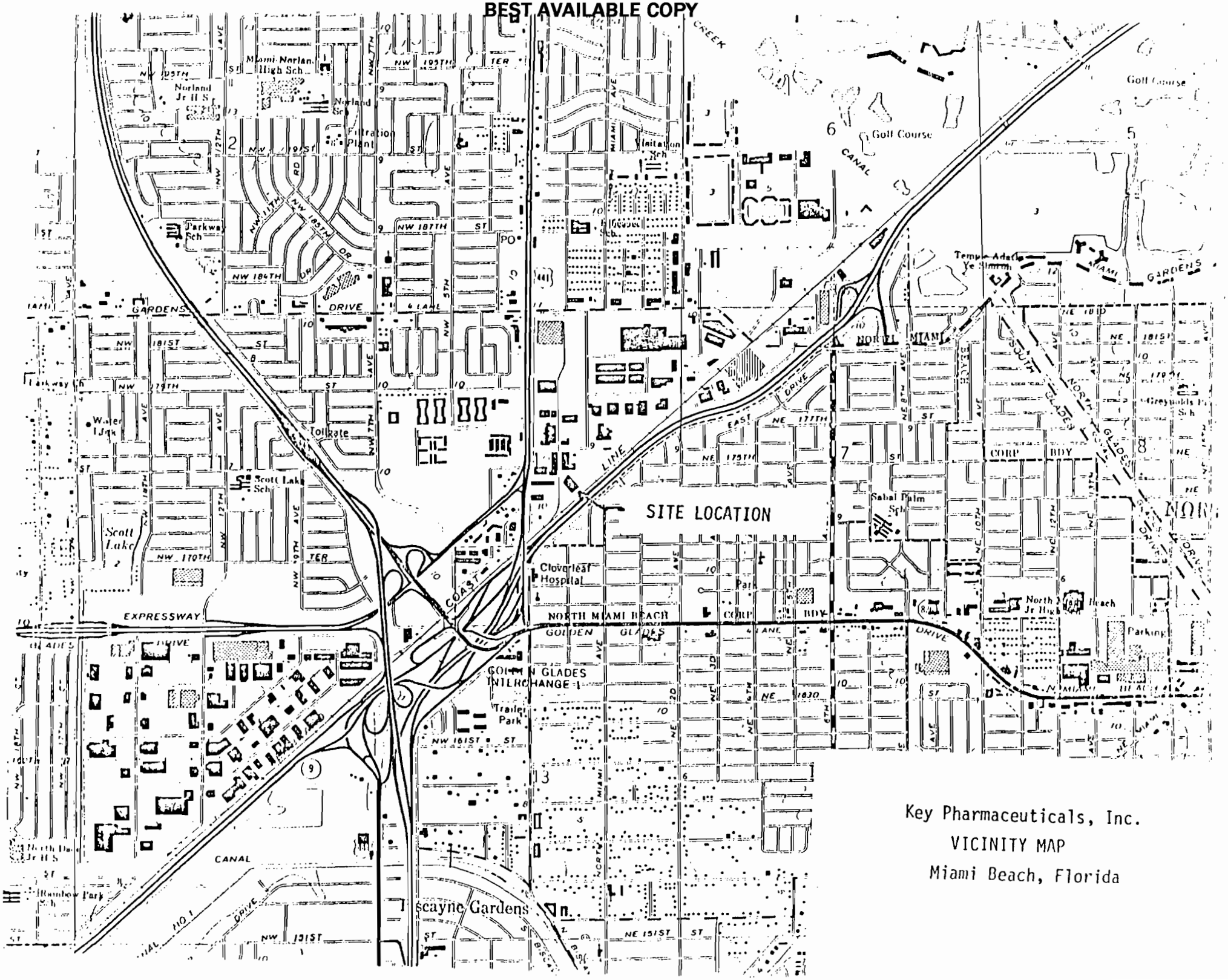
James R. Confroy, Vice President

Miami and Puerto Rico Operations

JRC/db

STATE OF FLORIDA
COUNTY OF DADE
Sworn to and subscribed before me
this 21st day of October A.D. 1986.

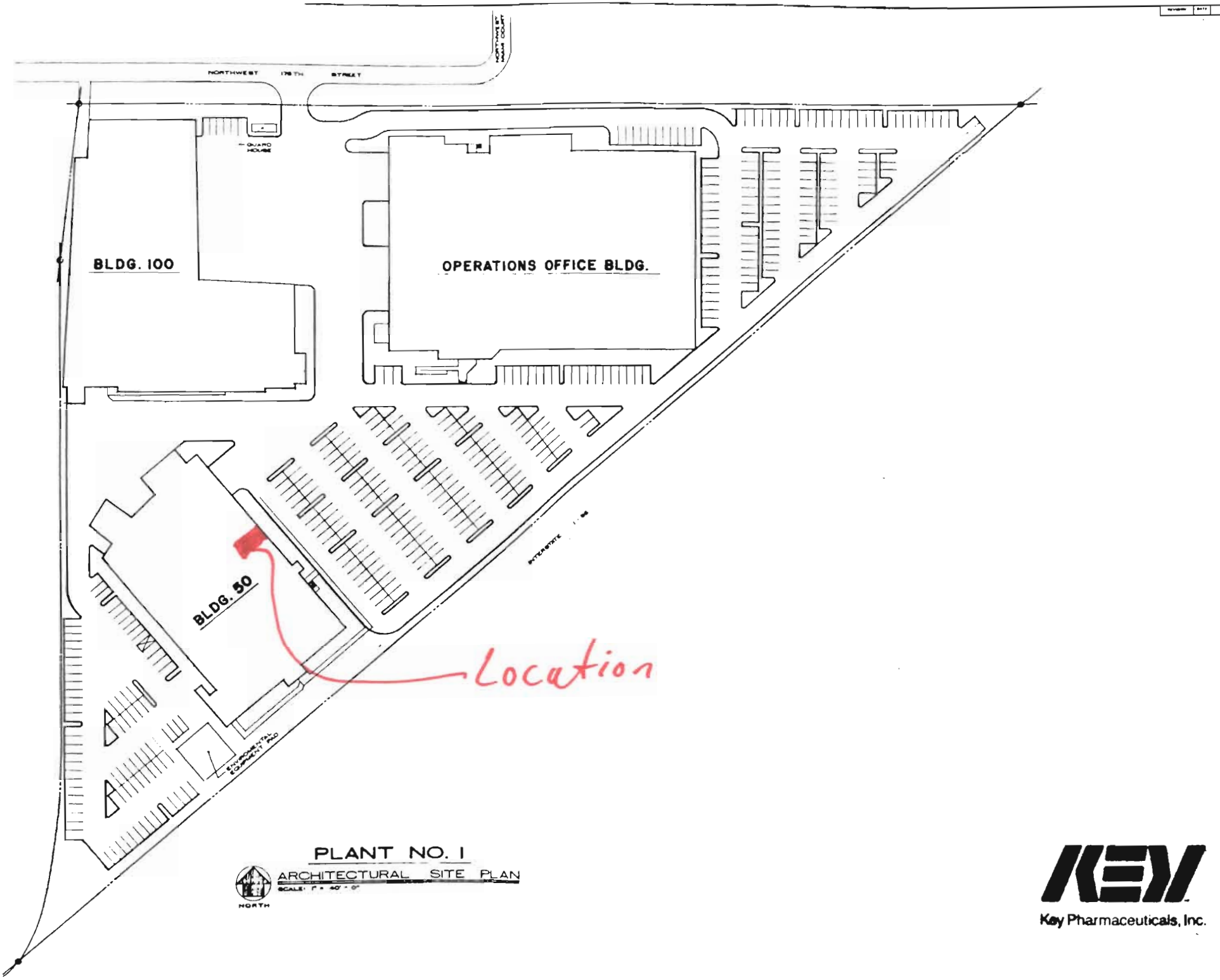
NOTARY PUBLIC STATE OF FLORIDA
MY COMMISSION EXP. DEC 18,1989
BONDED THRU GENERAL INS. UND.



Key Pharmaceuticals, Inc.

VICINITY MAP

Miami Beach, Florida

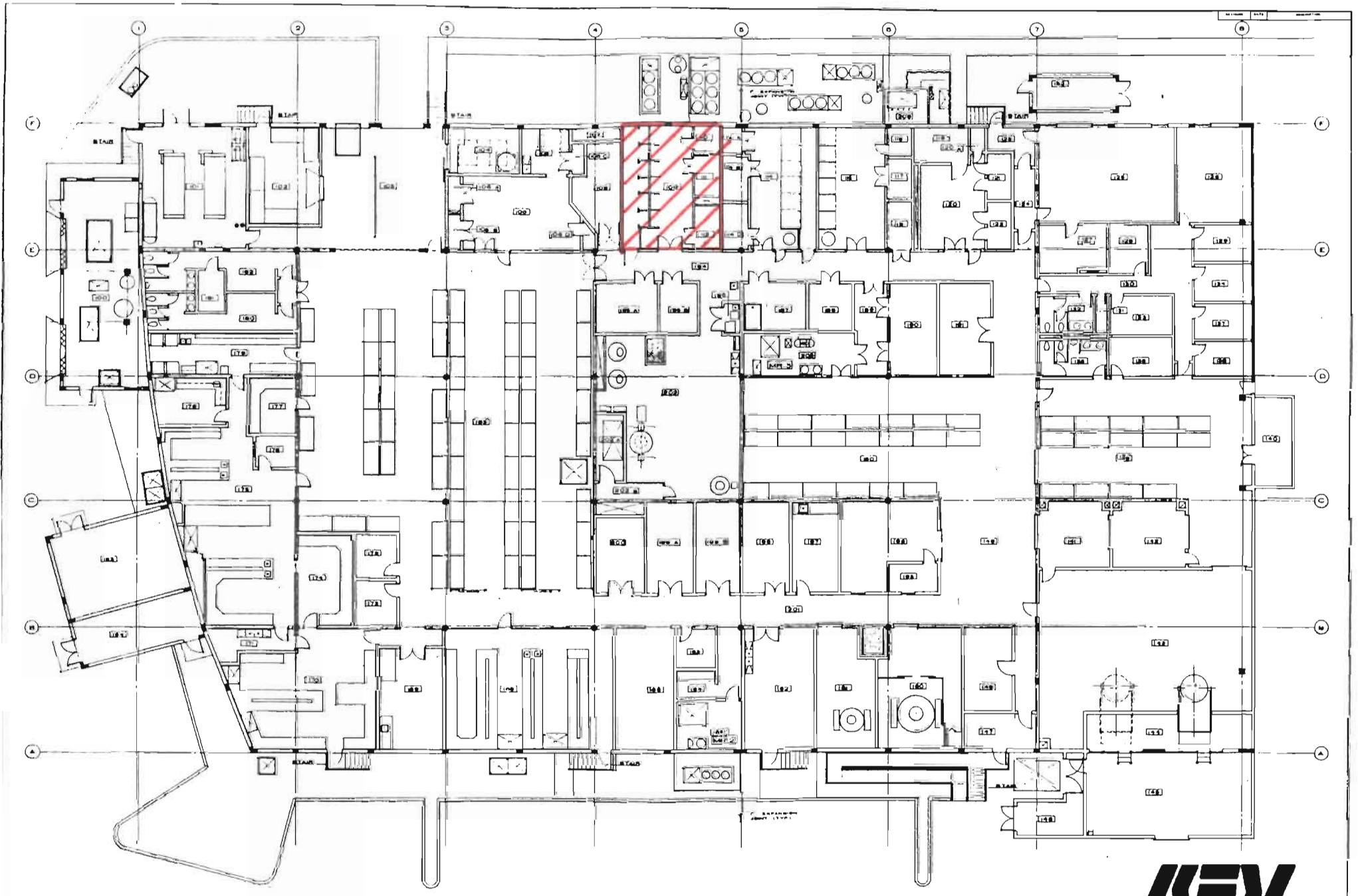


PLANT NO. 1

ARCHITECTURAL SITE PLAN

SCALE: 1" = 40'-0"

Key Pharmaceuticals, Inc.



BUILDING 50 - FLOOR PLAN

Key Pharmaceuticals, Inc.

KEY PHARMACEUTICALS

DESIGN CALCULATIONS

FILE NO. _____

SHEET 1 OF 2

CUSTOMER Pan Coating

WORK ORDER NO. _____ DATE 1-20-87

PROBLEM STATED Emission Calculations

TYPE OF EQUIPMENT 6 Coating Pans

PREPARED BY TWF CHECKED BY _____

Basis:

6 Coating Pans

Lot cycle is 24 hours

Total lots per years is 2190

Lot Specification

Maximum Solids 250 lb

Ethyl Acetate 41 lb

Acetone 36 lb

Isopropanol 12 lb

Maximum Volatile Organic Compounds 89 lb

A Particulate Emissions

(i) Emission Potential

½ of 1% of lot

(0.005)(2190)(250) ÷ (2000) = 1.37 Tons/year

(ii) Max instantaneous emission potential

assuming a pan rotation cycle of 8 hours with all 6 pans on

(250)(6)(0.005) ÷ 8 = 0.94 lb/Hr

KEY PHARMACEUTICALS

DESIGN CALCULATIONS

FILE NO. _____

SHEET 2 OF 2

CUSTOMER Pan Coating

WORK ORDER NO. _____ DATE _____

PROBLEM STATED Emission Calculations

TYPE OF EQUIPMENT _____

PREPARED BY TWF CHECKED BY _____

A Particulate Emissions cont.

(c ii) Max instantaneous emissions

Depth Filter Design - 80% + removal eff.

(0.94)(0.2) = 1.916/Hr

(c v) Average Annual Emissions

(1.37)(0.2) = 0.27 Tons/year

0.063 lb/Hr

B VOC Emissions

(i) Max instantaneous emissions

assuming a pan rotation of 8 hours with all 6 pans on and all solvents used in the 8 hours

(89)(6) ÷ (8) = 66.75 lb/Hr

(ii) Average annual emissions

(89)(2190) ÷ (2000) = 97.5 Ton/year

22.25 lb/Hr

KEY PHARMACEUTICALS

DESIGN CALCULATIONS

FILE NO. _____

SHEET 1 OF 1

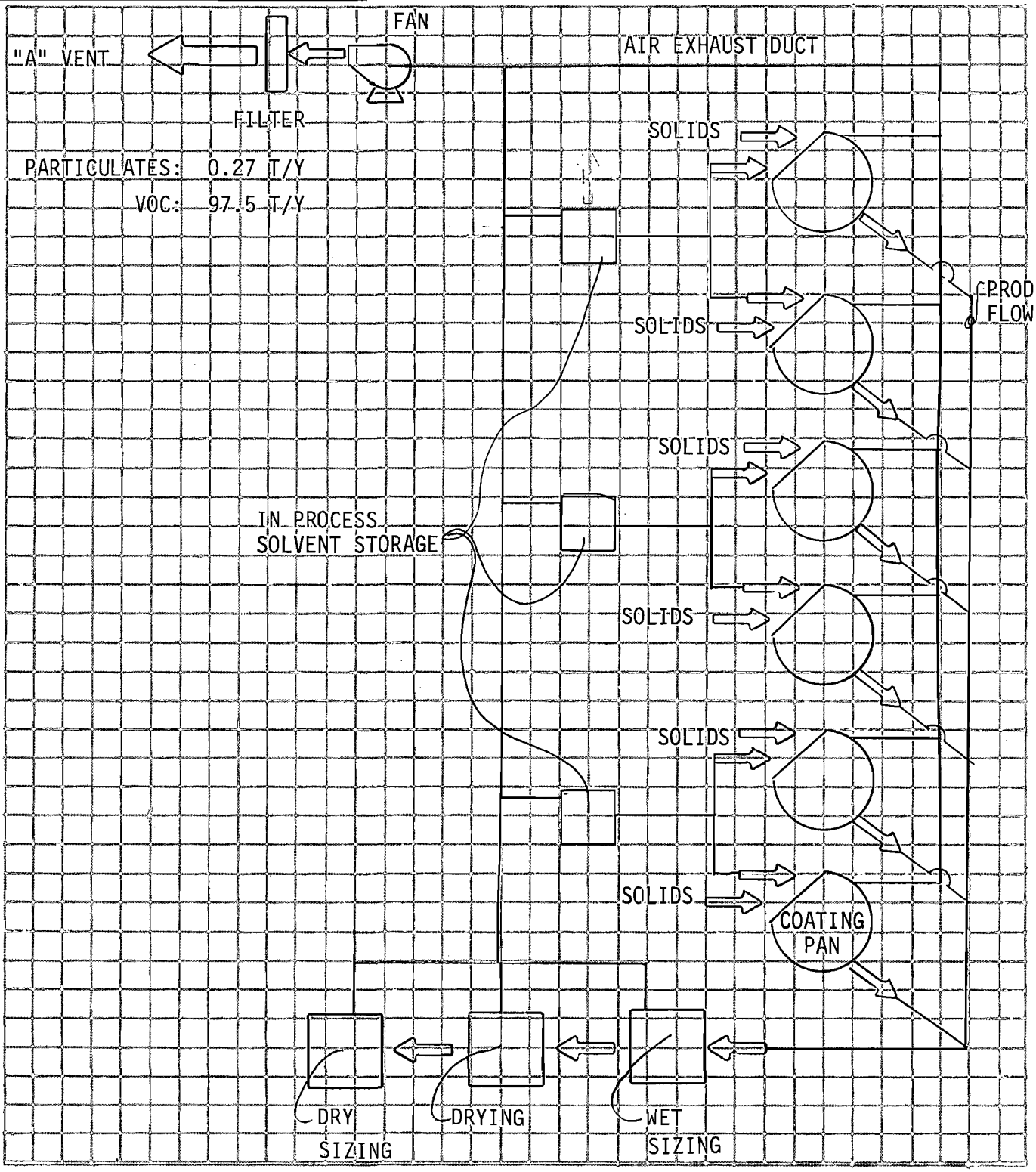
CUSTOMER PAN COATING

WORK ORDER NO. _____ DATE 1/20/87

PROBLEM STATED PROCESS FLOW SHEET

TYPE OF EQUIPMENT 6 COATING PANS

PREPARED BY _____ CHECKED BY _____



Interoffice Memo

From: Eric Borbe

Date: September 8, 1986

To: Tom Flachmeyer

Subject: Facility Parameters THEO-DUR 100 Tablet Production

PURPOSE

This report presents environmental data from Miami facilities where THEO-DUR 100 pellets are coated and compressed. This data is to serve as a comparison with conditions for similar facilities in Puerto Rico.

DATA

DATE	LOCATION	EQUIPMENT	TEST PARAMETER		RESULTS
11/15/84	ROOM 2	PAN EXHAUST AIR	FLOW RATE	6	380 - 410 cfm ✓
10/29/85	ROOM 2	PAN SUPPLY AIR	FLOW RATE		78 - 87 cfm
			TEMP/REL HUMIDITY		70°F / 64%
9/05/86	ROOM 1	PAN SUPPLY AIR	TEMP/REL HUMIDITY		67°F / 68%
9/04/86	ROOM 1	ROOM AIR	TEMP/REL HUMIDITY		64°F / 76%
9/05/86	ROOM 1	ROOM AIR	TEMP/REL HUMIDITY		62°F / 85%
4/21/86	ROOM 2	DRYER AIR	TEMP/REL HUMIDITY		75°F / 37%
			FLOW RATE		1430 cfm
			EXCHANGE RATE		94 cfm ✓
9/04/86	ROOM 1	CART EXHAUST	FLOW RATE	3	1446 cfm ✓
9/05/86	ROOM 197	ROOM AIR	TEMP/REL HUMIDITY		62°F / 67%
		UNIPRESS EXHAUST	FLOW RATE		26.5 cfm
9/04/86	ROOM 1	HOT WAX	TEMP, FROM KETTLE		113°C
			TEMP, AFTER CHLOROFORM		78.9°C
			TEMP, AFTER FIRST PITCHER		72.9°C
			TEMP, BEFORE LAST PITCHER		63.5°C

7000 cfm
RH
50 to 70
Temp 70°F

DISCUSSION

Temperature and relative humidity measurements on 9/04 and 9/05 were taken with a Pacer DH 200 digital hygro-thermometer.

The hot wax temperatures were taken with a Doric Trendicator 410A with Power Pack 406, using a submersible RTD probe.

An IR thermometer was also used for hot wax temperatures. There was no good correlation between IR and RTD.