

Check Sheet

Company Name: Key Pharmaceuticals
Permit Number: AC 13-128475
PSD Number: _____
Permit Engineer: _____

Application:

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

Cross References:

- AC 13-129899
-
-

Intent:

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

Final Determination:

- Final Determination
- Signed Permit
- BACT Determination
- Other

Post Permit Correspondence:

- Extensions/Amendments/Modifications
- Other



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

*original copy is in
this file
kkw*

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

Dear Mr. Fancy:

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

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

Sincerely,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

I. Goldman - WPB
P. Wong. Miami - DEEM
Willard Hanks
B. Thomas / CH Fancy } Copies furnished
by company per
JWH 10/27/87 *(initials)*

DER
OCT 27 1987
BAQM

PM
3-17-87
Miami, FL

CM: P-043-539-333



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

Telex: 808235

DER

MAR 19 1987

BAQM

March 17, 1987

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

RE: PERMIT NO. AC 13-128475

Dear Mr. Fancy:

Key Pharmaceuticals is in receipt of the above referenced permit. All conditions set forth in the permit are acceptable to Key Pharmaceuticals. The permit is therefore accepted in full.

Should you have any questions please contact me at (305) 654-2240.

Sincerely,

A handwritten signature in cursive script that reads "Thomas W. Flachmeyer".

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

Willard has a copy. WH 3-19-87

P 408 531 171
 RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
 NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to Mr. James R. Confroy	
Street and No.	
P.O., State and ZIP Code	
Postage	\$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt Showing to whom and Date Delivered	
Return Receipt Showing to whom, Date, and Address of Delivery	
TOTAL Postage and Fees	\$
Postmark or Date 3/5/87	

PS Form 3800, Feb. 1982

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.

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

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

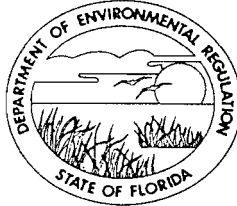
4. Type of Service:	Article Number
<input type="checkbox"/> Registered <input type="checkbox"/> Insured	P 408 531 171
<input checked="" type="checkbox"/> Certified <input type="checkbox"/> COD	
<input type="checkbox"/> Express Mail	

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

- Signature — Addressee
X
- Signature — Agent
X *James R. Confroy*
- Date of Delivery
MAR 10 1987
- Addressee's Address (ONLY if requested and fee paid)

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

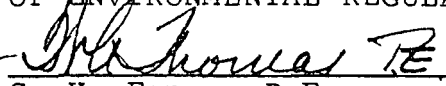
February 27, 1987

Enclosed is Permit Number AC 13-128475 to Key Pharmaceuticals, Inc. which authorizes the manufacture of six lots per year of Drug 0420 tablets at your pharmaceutical plant 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. Fancy, P.E.
Deputy Chief
Bureau of Air Quality
Management

Copies furnished to:

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

CERTIFICATE OF SERVICE

This is to certify that this NOTICE OF PERMIT and all copies were mailed before the close of business on March 5, 1987 to the listed persons.

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

Patricia G. Adams
Clerk

March 5, 1987
Date

Final Determination

Key Pharmaceuticals, Inc.
Miami, Florida
Dade County

Manufacture of Drug 0420 Tablets
File No: AC 13-128475

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

February 25, 1987

Final Determination

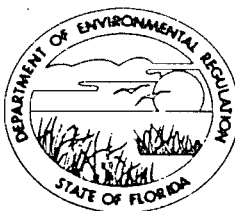
The Technical Evaluation and Preliminary Determination for the manufacture of Drug 0420 tablets by Key Pharmaceuticals, Inc. in Miami, Dade County, Florida facility was distributed on January 26, 1987. Copies of the evaluation were available for public inspection at Dade County's Department of Environmental Resources Management, and the department's offices in West Palm Beach and Tallahassee. The Notice of Proposed Agency Action on the permit application was published in The Miami News on January 29, 1987.

No comments were submitted on the proposed project. 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 13-128475
Expiration Date: December 31, 1987
County: Dade
Latitude/Longitude: 25° 56' 03" N
80° 11' 42" W
Project: Manufacture of Drug 0420

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

Authorization to manufacture 6 lots per year (approximately 517 lbs/lot) of Drug 0420 tablets with existing pan coating, granulation, wet sizing, drying, dry sizing, blending, compression, and packaging process equipment which uses dust collectors to control air pollution. This equipment is located at the pharmaceutical plant at 50 NW 176 Street, Miami, Florida. The UTM coordinates of this plant are zone 17, 579.9 km E and 2868.4 km N.

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

Attachments:

1. Application to Construct Air Pollution Sources, DER form 17-1.202(1), received December 8, 1986.
2. Key Pharmaceuticals, Inc. letter dated December 12, 1986.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-128475
Expiration Date: December 31, 1987

GENERAL CONDITIONS:

1. The terms, conditions, requirements, limitations, and restrictions set forth herein are "Permit Conditions" and as such are binding upon the permittee and enforceable pursuant to the authority of Sections 403.161, 403.727, or 403.859 through 403.861, Florida Statutes. The permittee is hereby placed on notice that the department will review this permit periodically and may initiate enforcement action for any violation of the "Permit Conditions" by the permittee, its agents, employees, servants or representatives.
2. This permit is valid only for the specific processes and operations applied for and indicated in the approved drawings or exhibits. Any unauthorized deviation from the approved drawings, exhibits, specifications, or conditions of this permit may constitute grounds for revocation and enforcement action by the department.
3. As provided in Subsections 403.087(6) and 403.722(5), Florida Statutes, the issuance of this permit does not convey any vested rights or any exclusive privileges. Nor does it authorize any injury to public or private property or any invasion of personal rights, nor any infringement of federal, state or local laws or regulations. This permit does not constitute a waiver of or approval of any other department permit that may be required for other aspects of the total project which are not addressed in the permit.
4. This permit conveys no title to land or water, does not constitute state recognition or acknowledgement of title, and does not constitute authority for the use of submerged lands unless herein provided and the necessary title or leasehold interests have been obtained from the state. Only the Trustees of the Internal Improvement Trust Fund may express state opinion as to title.
5. This permit does not relieve the permittee from liability for harm or injury to human health or welfare, animal, plant or aquatic life or property and penalties therefore caused by the construction or operation of this permitted source, nor does it allow the permittee to cause pollution in contravention of Florida Statutes and department rules, unless specifically authorized by an order from the department.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-128475
Expiration Date: December 31, 1987

GENERAL CONDITIONS:

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

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

- a. Having access to and copying any records that must be kept under the conditions of the permit;
- b. Inspecting the facility, equipment, practices, or operations regulated or required under this permit; and
- c. Sampling or monitoring any substances or parameters at any location reasonably necessary to assure compliance with this permit or department rules.

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

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

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

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-128475
Expiration Date: December 31, 1987

GENERAL CONDITIONS:

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

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

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

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

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

13. This permit also constitutes:

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

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

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

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-128475
Expiration Date: December 31, 1987

GENERAL CONDITIONS:

- b. The permittee shall retain at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation), copies of all reports required by this permit, and records of all data used to complete the application for this permit. The time period of retention shall be at least three years from the date of the sample, measurement, report or application unless otherwise specified by department rule.
- c. Records of monitoring information shall include:
 - the date, exact place, and time of sampling or measurements;
 - the person responsible for performing the sampling or measurements;
 - the date(s) analyses were performed;
 - the person responsible for performing the analyses;
 - the analytical techniques or methods used; and
 - the results of such analyses.

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

SPECIFIC CONDITIONS:

1. Production shall not exceed 6 lots of Drug 0420 (approximately 517 lbs/lot) in any calendar year without prior approval of the department (Bureau of Air Quality Management).
2. Production of these drugs is limited to 312 hours per calendar year unless additional operation time is approved by the department (BAQM).
3. Visible emissions from the process equipment and dust collectors for this operation shall not exceed 5 percent opacity as determined by Method 9 which is described in 40 CFR 60, Appendix A.

PERMITTEE:
Key Pharmaceuticals, Inc.

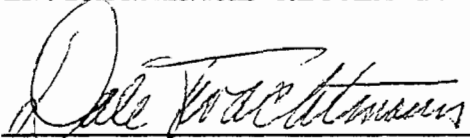
Permit Number: AC 13-128475
Expiration Date: December 31, 1987

SPECIFIC CONDITIONS:

4. Volatile organic compounds emission from this process, as determined by a raw material balance, shall be calculated on a daily basis and not exceed 0.45 TPY.
5. This process shall not cause, suffer, allow or permit the discharge of air pollutants which cause or contribute to an objectionable odor.
6. These drugs shall not be manufactured unless the dust collection systems are operating properly.
7. The permittee shall submit a report within 90 days prior to the expiration of this permit verifying that manufacturing of Drug 0420 did not exceed the limits specified in this permit. The permittee may continue to operate in compliance with all terms of this construction permit until its expiration date.
8. The permittee shall submit an application for the permit to operate to the department (Southeast Florida District) 90 days prior to the expiration of this permit if it is planned to manufacture additional lots of Drug 0420 with the existing equipment.

Issued this 25 day of Feb., 1987

STATE OF FLORIDA DEPARTMENT OF
ENVIRONMENTAL REGULATION



Dale Twachtmann, Secretary

___ pages attached

State of Florida
DEPARTMENT OF ENVIRONMENTAL REGULATION



Interoffice Memorandum

TO: Dale Twachtmann
THRU: Howard Rhodes *HR*
FROM: Clair Fancy *CF*
DATE: February 25, 1987
SUBJ: Approval of Air Construction Permit

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

RECEIVED
FEB 25 1987

Office of the Secretary

Attached for your approval and signature is one air construction permit to Key Pharmaceuticals, Inc. to authorize the manufacture of Drug 0420 tablets at the applicant's 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 April 18, 1987.

The bureau recommends your approval and signature.

CF/ks

Attachment



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

February 4, 1987

DER
FEB 9 1987
BAQM

Mr. C.H. Fancy, Deputy Chief
Bureau of Air Quality Management
State of Florida, Dept. of Env. Reg.
2600 Blainstone Road
Twin Towers Building
Tallahassee, FL 32301-8241

Re: Construction Permit AC13-128475

Dear Mr. Fancy:

As per the construction permit requirements, the public notice announcement for the above-referred permit was placed in the legal section of the Miami News on January 29th, 1987. Therefore, the fourteen (14) day public notice period should end February 14, 1987.

Attached please find a copy of the notice plus a 3 page copy of the original page of the notice. Key Pharmaceuticals personnel has received the draft permit. There are no objections to the conditions of the permit. The permit is accepted in full.

Very truly yours,

Thomas W. Flachmeyer

Thomas W. Flachmeyer
Manager, Environmental Engineering/
Waste Managemesnt

TWF:11c

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

Front Office Manager

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...

January 29, 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.....29.....

day of Jan..... A.D. 19.....87.....

My commission expires.....*Doreen*.....

NOTARY PUBLIC STATE OF FLORIDA
MY COMMISSION EXP. SEP 25, 1988
BONDED THRU GENERAL INS. UNB...



<p>STATE OF FLORIDA Department of Environmental Regulation Notice of Intent The Department gives notice of its intent to issue a permit to Key Pharmaceuticals, Inc. to manufacture 6 lots per year (approximately 517 lbs/lot) of Drug 0420 tablets with existing pan coating, granulation, wet sizing, drying, dry sizing, blending, compression, and packaging process equipment which uses dust collectors to control air pollution. This equipment is located at the pharmaceutical plant at 50 N.W. 176 Street, Miami, Dade County, Florida. 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 determination (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 Department's Office of General Counsel, 2600 Blair Stone Road, Twin Towers Office Building, Tallahassee.</p>	<p>Florida 32399-2400, within fourteen (14) days of publication of this notice. Failure to file a petition within this time period constitutes a waiver of any right such person has to request an administrative determination (hearing) under Section 120.57, Florida Statutes. If a petition is filed, the administrative hearing process is designed to formulate agency action. Accordingly, the Department's final action may be different from the proposed agency action. Therefore, persons who may not wish to file a petition may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Rule 28-5.207, Florida Administrative Code, at least five (5) days before the final hearing and be filed with the hearing officer if one has been assigned at the Division of Administrative Hearings, Department of Administration, 2009 Apalachee Parkway, Tallahassee, Florida 32301. If no hearing officer has been assigned, the petition is to be filed with the Department's Office of General Counsel, 2600 Blair Stone Road, Tallahassee, Florida 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 Bureau of Air Quality Management 2600 Blair Stone Road, Tallahassee, Florida 32399-2400</p>	<p>Dept of Environmental Regulation Southeast Florida District 3301 Gun Club Road, West Palm Beach, Florida 33402 Dade County Dept of Environmental Resources Management 801 S.W. 3rd Avenue Miami, Florida 33130 Any persons 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. Jan 29, 1987 Ad No: 751-315N</p>
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P 408 531 141
 RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
 NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to Mr. Thomas W. Flachmeyer	
Street and No.	
F.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 1-26-87	

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.

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

3. Article Addressed to:
 Mr. Thomas W. Flachmeyer
 Key Pharmaceuticals, Inc.
 50 Northwest 176th Street
 Miami, Florida

4. Type of Service:	Article Number
<input type="checkbox"/> Registered <input type="checkbox"/> Insured <input checked="" type="checkbox"/> Certified <input type="checkbox"/> COD <input type="checkbox"/> Express Mail	P 408 531 141

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

5. Signature - Addressee
 X

6. Signature - Agent
 X *Thomas W. Flachmeyer*

7. Date of Delivery
 JAN 29 A.M.

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 23, 1987

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Mr. James R. Confroy
Vice President 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 manufacture 6 lots per year of Drug 0420 tablets at your pharmaceutical plant in Miami, Dade County, Florida.

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

Sincerely,

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

CHF/pa

Attachments

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

State of Florida
Department of Environmental Regulation
Notice of Intent

The Department gives notice of its intent to issue a permit to Key Pharmaceuticals, Inc. to manufacture 6 lots per year (approximately 517 lbs/lot) of Drug 0420 tablets with existing pan coating, granulation, wet sizing, drying, dry sizing, blending, compression, and packaging process equipment which uses dust collectors to control air pollution. This equipment is located at the pharmaceutical plant at 50 N.W. 176th Street, Miami, Dade County, Florida. 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 determination (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 Department's Office of General Counsel, 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 petition within this time period constitutes a waiver of any right such person has to request an administrative determination (hearing) under Section 120.57, Florida Statutes.

If a petition is filed, the administrative hearing process is designed to formulate agency action. Accordingly, the Department's final action may be different from the proposed agency action. Therefore, persons who may not wish to file a petition may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Rule 28-5.207, Florida Administrative Code, at least five (5) days before the final hearing and be filed with the hearing officer if one has been assigned at the Division of Administrative Hearings, Department of Administration, 2009, Apalachee Parkway, Tallahassee, Florida 32301. If no hearing officer has been assigned, the petition is to be filed with the Department's Office of General Counsel, 2600 Blair Stone Road, Tallahassee, Florida 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
Bureau of Air Quality Management
2600 Blair Stone Road
Tallahassee, Florida 32399-2400

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

Dade County Dept. of Environmental
Resources Management
801 S.W. 3rd Avenue
Miami, Florida 33130

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

BEFORE THE STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

In the Matter of
Application for Permit by:

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

DER File No. AC-13-128475

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 December 16, 1986, to the Department of Environmental Regulation for a permit to manufacture 6 lots per year of Drug 0420 tablets at the applicant's facility 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.

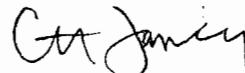
Pursuant to Section 403.815, F.S. and DER Rule 17-103.150, FAC, you (the applicant) are required to publish at your own expense the enclosed Notice of Proposed Agency Action on permit application. The notice must be published one time only in a section of a major local newspaper of general circulation 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:

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

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 Jan. 26, 1987.

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

Patricia G. Adams Jan. 26, 1987
Clerk Date

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

28-5.15 Requests for Formal and Informal Proceedings

- (1) Requests for proceedings shall be made by petition to the agency involved. Each petition shall be printed, typewritten or otherwise duplicated in legible form on white paper of standard legal size. Unless printed, the impression shall be on one side of the paper only and lines shall be double spaced and indented.
- (2) All petitions filed under these rules should contain:
 - (a) The name and address of each agency affected and each agency's file or identification number, if known;
 - (b) The name and address of the petitioner or petitioners;
 - (c) All disputed issues of material fact. If there are none, the petition must so indicate;
 - (d) A concise statement of the ultimate facts alleged, and the rules, regulations and constitutional provisions which entitle the petitioner to relief;
 - (e) A statement summarizing any informal action taken to resolve the issues, and the results of that action;
 - (f) A demand for the relief to which the petitioner deems himself entitled; and
 - (g) Such other information which the petitioner contends is material.

DER1985 RULES OF ADMINISTRATIVE PROCEDURE -- NON-RULEMAKING 17-103

of General Counsel, 2600 Blair Stone Road, Tallahassee, Florida 32301. Failure to petition to intervene within the allowed time frame constitutes a waiver of any right such person has to an administrative determination (hearing) under Section 120.57, F.S.

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

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

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

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

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

(6) Failure to publish any notice of application, notice of proposed agency action, or notice of agency action required by the Department shall be an independent basis for the denial of a permit.
Specific Authority: 120.53, 403.0876, 403.815, F.S. Law Implemented: 120.53, F.S.
History: New 9-20-79, Amended 4-28-81, Transferred from 17-1.62 and Amended 6-1-84.

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

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

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

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

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

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

occurs.

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

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

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

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

(c) any notices issued or published; and

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

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

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

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

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

Implemented: 120.53; F.S.

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

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

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

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

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

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

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

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

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

Technical Evaluation
and
Preliminary Determination

Key Pharmaceuticals, Inc.
Miami, Florida
Dade County

Manufacture of Drug 0420 Tablets
File No: AC 13-128475

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

January 21, 1987

I. Application

A. Applicant

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

B. Request

Mr. Thomas Flachmeyer, Manager of Environmental Engineering and Waste Management for Key Pharmaceuticals, Inc., submitted an application for permit to construct dated December 8, 1986, for the manufacture of 6 lots of Drug 0420 tablets. Data gathered during the manufacture of these lots will be used for research and production scale-up. The application was considered complete on receipt of their December 12, 1986, letter (December 16, 1986).

C. Project and Location

Key Pharmaceuticals, Inc. has requested permission to manufacture 3162 lbs/yr of Drug 0420 tablets at their existing pharmaceutical plant (SIC 2834) located at 50 N.W. 176th Street, Miami, Dade County, Florida. The UTM coordinates of this plant are zone 17, 579.9 km E and 2868.4 km N. The tablets will be made with existing pan coating, granulating, drying, sizing, compression, and packaging equipment. An existing dust collection system will be used to control the particulate matter emissions from the process. The drug will be manufactured for research and development purposes during a 7-month period in 1987.

D. Air Pollutant Emissions

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

The process equipment is vented to a 4000 CFM Torit TD 2300 dust collector that is estimated to be 99 percent efficient and a 7500 cfm depth filter that is estimated to be 80 percent efficient in capturing particulate matter. The applicant estimated that less than 1 pound of particulate matter will be emitted during the 312 hours/year these tablets will be manufactured.

Isopropanol, acetone, and ethyl acetate are used in manufacturing the drug. It is estimated that 372 lbs/year of isopropanol, 150 lbs/year of acetone, and 378 pounds/year of ethyl acetate will be used to manufacture the 3162 pounds of tablets.

No VOC pollution control equipment will be installed on the process and all of the volatile organic compounds will escape to the atmosphere. The VOC emissions from this process are estimated to be 9.3 pounds/hour and 0.45 tons/year.

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

Source	Present	Proposed
Glatts	35.00	35.00
GUANIDINE	0.08	0.08
QUINORA	0.88	0.88
Drug 0420	0.00	0.45
Total	35.96	36.41

* Potential PM emissions will increase by a total of less than +0.01 TPY from the Drug 0420 tablet manufacturing process. Other processes at this plant emit VOC.

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

II. Rule Applicability

A. State Regulations

The proposed project, manufacturing of Drug 0420 tablets, is subject to preconstruction review under the provisions of Chapter 403, Florida Statutes, and Chapter 17-2, Florida Administrative Code.

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

Pharmaceutical plants are classified as chemical process plants which are listed on Table 500-1, Major Facility Categories (list of 28). The plant is a major facility (17-2.100) because the potential emissions of 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.

Higher emission would subject this operation to review under other regulations.

B. Federal Regulations

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

III. Technical Evaluation

Dust generated by handling the ingredients used to make the tablets will be captured by a dust collector or a depth filter. The applicant estimates that less than 1.4 lbs/year of particulate matter will escape to the atmosphere from this operation. The process weight table would allow up to 0.25 lbs/hr (78 pounds per year) of particulate matter emissions from this operation. However, emissions at this rate from these operations would be economically prohibitive to the company. The department will specify a surrogate emission standard of 5 percent opacity, as authorized by 17-2.700(1)(d)6., instead of a particulate matter standard for these operations. Less than 0.45 TPY of VOC will be used to manufacture the tablets. All of the VOC's will evaporate and escape to the atmosphere. Air pollution control equipment is not justified for this low of a rate of VOC emissions.

IV. Air Quality Analysis

The manufacture of the proposed products will not result in a significant net emissions increase as set forth in Rule 17-2.500(2)(e)2., FAC. Therefore, no air quality analysis is required by the regulation. Modeling shows that the concentration of VOC in the atmosphere as a result of the manufacture of the tablets will be less than 1 percent of the recommended Threshold Limit Values-Time Weighted Average concentration (TLV-TWA). Although the department has not established ambient air quality standards for these compounds, other states have set standards of 1-2 percent of the TLV-TWA. Based on the analysis,

the department has reasonable assurance that the emissions of compounds from this process will not endanger public health.

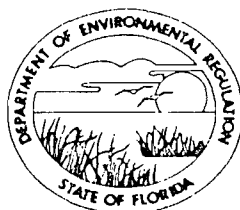
V. Conclusion

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

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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



BOB MARTINEZ
GOVERNOR

DALE TWACHTMANN
SECRETARY

PERMITTEE:

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

Permit Number: AC 13-128475
Expiration Date: December 31, 1987
County: Dade
Latitude/Longitude: 25° 56' 03" N
80° 11' 42" W
Project: Manufacture of Drug 0420

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

Authorization to manufacture 6 lots per year (approximately 517 lbs/lot) of Drug 0420 tablets with existing pan coating, granulation, wet sizing, drying, dry sizing, blending, compression, and packaging process equipment which uses dust collectors to control air pollution. This equipment is located at the pharmaceutical plant at 50 NW 176 Street, Miami, Florida. The UTM coordinates of this plant are zone 17, 579.9 km E and 2868.4 km N.

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

Attachments:

1. Application to Construct Air Pollution Sources, DER form 17-1.202(1), received December 8, 1986.
2. Key Pharmaceuticals, Inc. letter dated December 12, 1986.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-128475
Expiration Date: December 31, 1987

GENERAL CONDITIONS:

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

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

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

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

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

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-128475
Expiration Date: December 31, 1987

GENERAL CONDITIONS:

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

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

- a. Having access to and copying any records that must be kept under the conditions of the permit;
- b. Inspecting the facility, equipment, practices, or operations regulated or required under this permit; and
- c. Sampling or monitoring any substances or parameters at any location reasonably necessary to assure compliance with this permit or department rules.

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

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

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

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-128475
Expiration Date: December 31, 1987

GENERAL CONDITIONS:

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

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

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

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

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

13. This permit also constitutes:

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

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

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

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-128475
Expiration Date: December 31, 1987

GENERAL CONDITIONS:

- b. The permittee shall retain at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation), copies of all reports required by this permit, and records of all data used to complete the application for this permit. The time period of retention shall be at least three years from the date of the sample, measurement, report or application unless otherwise specified by department rule.
- c. Records of monitoring information shall include:
 - the date, exact place, and time of sampling or measurements;
 - the person responsible for performing the sampling or measurements;
 - the date(s) analyses were performed;
 - the person responsible for performing the analyses;
 - the analytical techniques or methods used; and
 - the results of such analyses.

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

SPECIFIC CONDITIONS:

1. Production shall not exceed 6 lots of Drug 0420 (approximately 517 lbs/lot) in any calendar without prior approval of the department (Bureau of Air Quality Management).
2. Production of these drugs is limited to 312 hours per calendar year unless additional operation time is approved by the department (BAQM).
3. Visible emissions from the process equipment and dust collectors for this operation shall not exceed 5 percent opacity as determined by Method 9 which is described in 40 CFR 60, Appendix A.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-128475
Expiration Date: December 31, 1987

SPECIFIC CONDITIONS:

4. Volatile organic compounds emission from this process, as determined by a raw material balance, shall be calculated on a daily basis and not exceed 0.45 TPY.
5. This process shall not cause, suffer, allow or permit the discharge of air pollutants which cause or contribute to an objectionable odor.
6. These drugs shall not be manufactured unless the dust collection systems are operating properly.
7. The permittee shall submit a report within 90 days prior to the expiration of this permit verifying that manufacturing of Drug 0420 did not exceed the limits specified in this permit. The permittee may continue to operate in compliance with all terms of this construction permit until its expiration date.
8. The permittee shall submit an application for the permit to operate to the department (Southeast Florida District) 90 days prior to the expiration of this permit if it is planned to manufacture additional lots of Drug 0420 with the existing equipment.

Issued this _____ day of _____, 19____

STATE OF FLORIDA DEPARTMENT OF
ENVIRONMENTAL REGULATION

Howard L. Rhodes, P.E.
Director, Division of Environmental
Programs

_____ pages attached

Key Pharmaceuticals, Inc
Drug 0420

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

*** TITLE OF SOURCE # 1 ***

*** TEST OF MPTPLU ***

))INPUT PARAMETERS((

OPTIONS

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

METEOROLOGY

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

RECEPTOR HEIGHT = .00 (M)

SOURCE

EMISSION RATE = 4.91E-01 (G/SEC) 3.9 lb/hr
STACK HEIGHT = 3.35 (M)
EXIT TEMP. = 294.11 (K)
EXIT VELOCITY = 25.87 (M/SEC)
STACK DIAM. = .30 (M)
VOLUME FLOW = 1.89E+00 (M**3/SEC)

))CALCULATED PARAMETERS((

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

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

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

*** WIND SPEED AT 10.0 METER HEIGHT IS GIVEN HERE ***
STABILITY WIND SPEED MAX CONC DIST OF MAX PLUME HT
(M/SEC) (UG/CU M) (KM) (M)
6 1.00 2.7083E+02 .700 16.2

**** CORRESPONDING SPATIAL DISTRIBUTION ****

DISTANCE (KM)	CONCENTRATION (UG/M**3)
.1	6.6792E-07
.2	2.7245E+00
.3	5.4340E+01
.5	2.2376E+02
.7	2.7083E+02
1.0	2.3406E+02
1.5	1.6403E+02
2.0	1.1909E+02

	TLV ppm	mg/m ³	ug/m ³	1% ug/m ³
Isopropyl alcohol	400	980	980 x 10 ³	9800
Acetone	1000	2400	2400 x 10 ³	24000
Ethyl Acetate	400	1400	1400 x 10 ³	14000

$$\frac{C_1}{T_1} + \frac{C_2}{T_2} + \frac{C_3}{T_3} = \frac{264}{980 \times 10^3} + \frac{111}{2400 \times 10^3} + \frac{271}{1400 \times 10^3}$$

$$= 2.7 \times 10^{-4} + 4.6 \times 10^{-5} + 1.9 \times 10^{-4}$$

$$\approx 5.1 \times 10^{-4}$$

∴ Threshold value not exceeded

1% TLV

$$= \frac{264}{9800} + \frac{111}{24000} + \frac{271}{14000}$$

$$= 0.03 + 0.005 + 0.02 = 0.055$$

∴ 1% Threshold value not exceeded

3.0	7.3107E+01
5.0	3.8948E+01
7.0	2.5382E+01
10.0	1.6255E+01
15.0	9.7497E+00
20.0	6.9330E+00
30.0	4.2871E+00
50.0	2.4026E+00

*** SPATIAL DISTRIBUTION OF WORST CONDITIONS ***

(CUMULATED FOR THE LAST 1 SOURCE(S))

DISTANCE (KM)	MAX CONC (UG/M**3)	STABILITY	WIND (M/S)
.1	2.0529E+02	4	10.00
.2	1.6910E+02	5	5.00
.3	1.8248E+02	5	2.00
.5	2.2376E+02	6	1.00
.7	2.7083E+02	6	1.00
1.0	2.3406E+02	6	1.00
1.5	1.6403E+02	6	1.00
2.0	1.1909E+02	6	1.00
3.0	7.3107E+01	6	1.00
5.0	3.8948E+01	6	1.00
7.0	2.5382E+01	6	1.00
10.0	1.6255E+01	6	1.00
15.0	9.7497E+00	6	1.00
20.0	6.9330E+00	6	1.00
30.0	4.2871E+00	6	1.00
50.0	2.4026E+00	6	1.00

Stop - Program terminated.

C>8

Bad command or file name

C>7

Bad command or file name



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

December 8, 1986

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

Dear Mr. Fancy:

Key Pharmaceuticals, Inc. has recently relocated one of its major products, THEO-DUR, to Puerto Rico. As of November 30, 1986, all THEO-DUR manufacturing activities have ceased at the Miami location.

To ensure further operations at the Miami locations several products are currently being considered for scale-up and clinical trials. For this effort, enclosed please find a Permit Application to manufacture six (6) research-to-production scale-up and clinical lot of Drug 0420. These six lots represent the initial trial in bringing this product to a production size effort and preparing data for Food and Drug Administration submittals. The drug is a life saving medication for cardiac patients.

The total added emissions for this scale-up effort is less than one half of one ton of non-attainment Volatile Organic Compounds. This addition will not significantly increase the total emissions at the plant site.

In conjunction with the effort to find new products, Key is currently committed to the development of state of the art emission control systems for VOC emissions. But as you are aware, the evaluation of technology, design, permitting, and installation of such systems is a lengthy procedure. Representatives from Key will be meeting with Willard Hanks and Bill Thomas, of your department, the week of December 8, 1986, to discuss emission control options currently being considered for existing and new production efforts.

Please process the attached permit as soon as possible. If there are any questions, please contact me.

Very truly yours,

Thomas W. Flachmeyer, Manager
 Environmental Engineering and
 Waste Management

TWF/db

attachment

RECEIVED
 DER-MAIL ROOM
 1986 DEC 16 AM 11:06

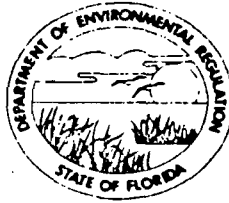
1031

AC 13-128475

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

SOUTHEAST FLORIDA
DISTRICT

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



DER

BOB GRAHAM
GOVERNOR
VICTORIA J. TSCHINKEL
SECRETARY

DEC 16 1986

ROY DUKE
DISTRICT MANAGER

BAQM

APPLICATION TO OPERATE/CONSTRUCT AIR POLLUTION SOURCES

SOURCE TYPE: AIR POLLUTION New¹ Existing¹

APPLICATION TYPE: Construction Operation Modification

COMPANY NAME: KEY PHARMACEUTICALS, INC. COUNTY: DADE

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

SOURCE LOCATION: Street 50 NW 176 STREET City MIAMI

UTM: East 57987 North 2868445

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

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

APPLICANT ADDRESS: 50 NW 176 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: 12/8/86 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)

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
JOHN N. WELLS, P.E.)

Name (Please Type)

KEY PHARMACEUTICALS, INC.

Company Name (Please Type)

50 NW 176 STREET, MIAMI, FL 33169

Mailing Address (Please Type)

Florida Registration No. 33917

Date: 12/8/86

Telephone No. 305-654-2200

SECTION II: GENERAL PROJECT INFORMATION

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

THE PROJECT ENTAILS THE MANUFACTURING OF PRODUCTION SIZE LOTS OF DRUG 0420

FOR RESEARCH PURPOSES AND CLINICAL STUDIES. THE TABLETS ARE MADE BY GRANULATING AND PAN COATING ACTIVE PLUS EXCIPIENTS WITH ACETONE, ISOPROPRANOL, AND ETHYL ACETATE FOLLOWED BY DRYING, SIZING, COMPRESSION, AND PACKAGING OPERATIONS.

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

Start of Construction DEC'86

Completion of Construction DEC'86

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

NO POLLUTION CONTROL SYSTEMS OTHER THAN THE PRESENT DUST COLLECTORS WILL BE ADDED. AS THE TOTAL EFFLUENT OF VOC FOR THIS PRODUCT IS LESS THAN 1 TON/YEAR, SUCH ADDITION TO PRESENT EMISSIONS DO NOT WARRANT CONTROL EQUIPMENT.

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

(1) CONSENT ORDER OGC CASE NO. 83-0373

(2) PERMIT TO CONSTRUCT FOR MANUFACTURING OF GUANIDINE AND QUINORA AC 13-115383

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

E. Requested permitted equipment operating time: hrs/day _____; days/wk _____; wks/yr _____; if power plant, hrs/yr _____; if seasonal, describe: LESS THAN 312 HRS/YEAR
ONLY 6 LOTS ARE SCHEDULED. EACH LOT TAKES LESS THAN 52 HOURS WHERE SOLVENTS ARE
EMITTED. THE LOTS WILL BE MANUFACTURED BETWEEN DECEMBER, 1986 AND AUG, 1987.

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

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

- H. Do "Reasonably Available Control Technology" (RACT) requirements apply to this source? NO
- a. If yes, for what pollutants? _____
- b. If yes, in addition to the information required in this form, any information requested in Rule 17-2.650 must be submitted.

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

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

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

Description	Contaminants		Utilization * Rate - lbs/hr	Relate to Flow Diagram
	Type	% Wt		
ISOPROPNOL	VOC	100	1.55	" A "
ACETONE	VOC	100	0.625	" A "
ETHYL ACETATE	VOC	100	1.575	" A "

* BASED ON ALL SOLVENTS BEING USED IN 40 HOURS.

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

1. Total Process Input Rate (lbs/hr): 10.14

2. Product Weight (lbs/hr): 10.03

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

** BASED ON 52 HOURS PER LOT.

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	< 0.010	0.001	N / A	N / A	0.0079		" A "
ISOPROPNOL	3.8***	0.186	N / A	N / A	0.186		" A "
ACETONE	1.6***	0.075	N / A	N / A	0.075		" A "
ETHYL ACETATE	3.9***	0.189	N / A	N / A	0.189		" A "

¹*** BASED ON ALL SOLVENTS USED IN 16 HOURS.
See Section V, Item 2.

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

³Calculated from operating rate and applicable standard.

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

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

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	PARTICULATES	80%	1 MICRON OR LARGER	SUPPLIER'S DESIGN
TORIT TD-2300	PARTICULATES	99+%	1 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 waste generated and method of disposal.

APPROXIMATELY 0.8 TONS OF PARTICULATES WILL BE GENERATED AS WASTE DURING THIS PROJECT.
ALL PARTICULATE WASTE WILL BE DRUMMED OFF & DISPOSED OF IN AN OFF-SITE APPROVED DISPOSAL
SITE.

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

Stack Height: OFF ROOM - ABOUT 11 ft. Stack Diameter: 12" x 12" ft.
 Gas Flow Rate: 4000 SCFM DSCFM Gas Exit Temperature: 70 °F.
 Water Vapor Content: ~ 50 TO 60% RH % Velocity: 67 FPS

SECTION IV: INCINERATOR INFORMATION

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

Description of Waste _____

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

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

Manufacturer _____

Date Constructed _____ Model No. _____

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

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

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

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

Type of pollution control device: Cyclone Wet Scrubber Afterburner
 Other (specify) _____

Brief description of operating characteristics of control devices: _____

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

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

SECTION V: SUPPLEMENTAL REQUIREMENTS

Please provide the following supplements where required for this application.

1. Total process input rate and product weight -- show derivation [Rule 17-2.100(127)]
2. To a construction application, attach basis of emission estimate (e.g., design calculations, design drawings, pertinent manufacturer's test data, etc.) and attach proposed methods (e.g., FR Part 60 Methods 1, 2, 3, 4, 5) to show proof of compliance with applicable standards. To an operation application, attach test results or methods used to show proof of compliance. Information provided when applying for an operation permit from a construction permit shall be indicative of the time at which the test was made.
3. Attach basis of potential discharge (e.g., emission factor, that is, AP42 test).
4. With construction permit application, include design details for all air pollution control systems (e.g., for baghouse include cloth to air ratio; for scrubber include cross-section sketch, design pressure drop, etc.)
5. With construction permit application, attach derivation of control device(s) efficiency. Include test or design data. Items 2, 3 and 5 should be consistent: actual emissions = potential (1-efficiency).
6. An 8 1/2" x 11" flow diagram which will, without revealing trade secrets, identify the individual operations and/or processes. Indicate where raw materials enter, where solid and liquid waste exit, where gaseous emissions and/or airborne particles are evolved and where finished products are obtained.
7. An 8 1/2" x 11" plot plan showing the location of the establishment, and points of airborne emissions, in relation to the surrounding area, residences and other permanent structures and roadways (Example: Copy of relevant portion of USGS topographic map).
8. An 8 1/2" x 11" plot plan of facility showing the location of manufacturing processes and outlets for airborne emissions. Relate all flows to the flow diagram.

9. The appropriate application fee in accordance with Rule 17-4.05. The check should be made payable to the Department of Environmental Regulation.
10. With an application for operation permit, attach a Certificate of Completion of Construction indicating that the source was constructed as shown in the construction permit.

SECTION VI: BEST AVAILABLE CONTROL TECHNOLOGY

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

Yes No

Contaminant	Rate or Concentration

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

Yes No

Contaminant	Rate or Concentration

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

Contaminant	Rate or Concentration

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

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

*Explain method of determining

5. Useful Life:

6. Operating Costs:

7. Energy:

8. Maintenance Cost:

9. Emissions:

Contaminant

Rate or Concentration

Contaminant	Rate or Concentration

10. Stack Parameters

a. Height:

ft.

b. Diameter:

ft.

c. Flow Rate:

ACFM

d. Temperature:

°F.

e. Velocity:

FPS

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

1.

a. Control Device:

b. Operating Principles:

c. Efficiency:¹

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:²

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

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

2.

a. Control Device:

b. Operating Principles:

c. Efficiency:¹

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:²

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

¹Explain method of determining efficiency.

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

j. Applicability to manufacturing processes:

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

3.

a. Control Device:

b. Operating Principles:

c. Efficiency:¹

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:²

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

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

4.

a. Control Device:

b. Operating Principles:

c. Efficiency:¹

d. Capital Costs:

e. Useful Life:

f. Operating Cost:

g. Energy:²

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

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

F. Describe the control technology selected:

1. Control Device:

2. Efficiency:¹

3. Capital Cost:

4. Useful Life:

5. Operating Cost:

6. Energy:²

7. Maintenance Cost:

8. Manufacturer:

9. Other locations where employed on similar processes:

a. (1) Company:

(2) Mailing Address:

(3) City:

(4) State:

¹Explain method of determining efficiency.

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

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:¹

Contaminant

Rate or Concentration

(8) Process Rate:¹

b. (1) Company:

(2) Mailing Address:

(3) City:

(4) State:

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:¹

Contaminant

Rate or Concentration

(8) Process Rate:¹

10. Reason for selection and description of systems:

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

SECTION VII - PREVENTION OF SIGNIFICANT DETERIORATION

A. Company Monitored Data

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

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

Other data recorded _____

Attach all data or statistical summaries to this application.

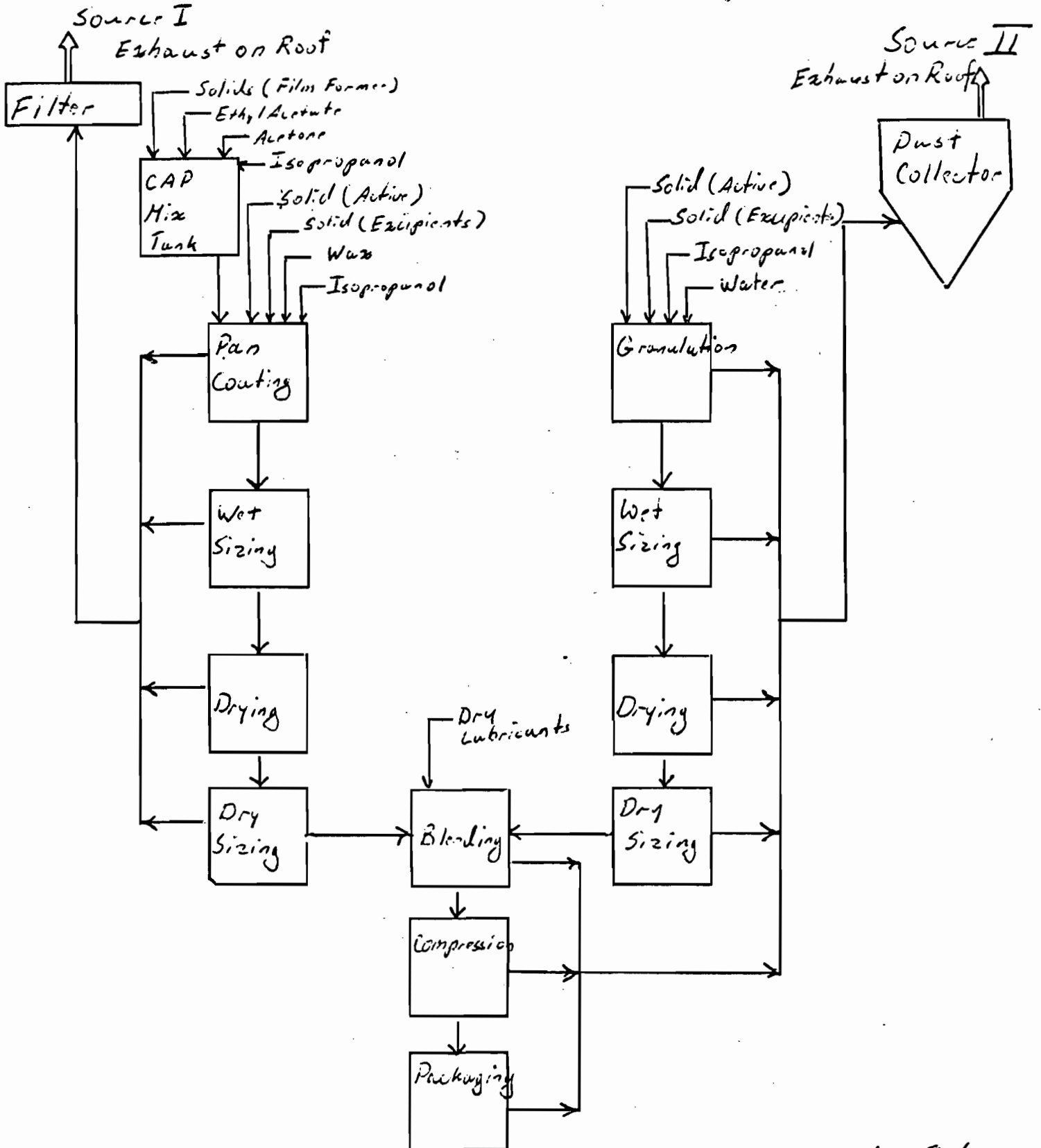
*Specify bubbler (B) or continuous (C).

CUSTOMER Drug 0420

WORK ORDER NO. _____ DATE 12-8-86

PROBLEM STATED Process Flow Sheet "A"

TYPE OF EQUIPMENT R+D scale up and clinical of Drug 0420



J.W. Fleckman
12/8/86

CUSTOMER Drug 0420

WORK ORDER NO. _____ DATE 12-8-86

PROBLEM STATED Emission Calculations

TYPE OF EQUIPMENT R+D scale up and clinical of Drug 0420

I. Particulate

(i) Source I (Pan Counting)

No. of lots - 6
 Weight per lot - 210 lbs
 Total weight per year - 1,260 lbs

Potential Emissions @ $\frac{1}{2}$ of 1% of total weight
 (w/o control) = 6.3 lbs per year

Emission Control 80%

Emissions
 (w control) = 1.26 lb per year

(ii) Source II (Granulation)

No of lots - 6
 weight per lot - 317 lbs
 Total weight per year - 1902 lbs

Potential Emissions @ $\frac{1}{2}$ of 1% of total weight
 (w/o control) = 9.51 lbs per year

Emission Control 99.5%

Emissions
 (w control) = 0.0951 lbs per year

Total Potential Emissions = 15.8 lb per year
 (w/o control) = 0.0079 Tons per year

Total Emissions = 1.36 lb per year
 (w/control) = 0.0007 Tons per year

CUSTOMER Drug 0420

WORK ORDER NO. _____ DATE 12-8-86

PROBLEM STATED Emission Calculations

TYPE OF EQUIPMENT R+D scale up and clinical of Drug 0420

II. VOC

(i) Source I (Pan Coating)

No. of lots	-	6
Weight per lot - Isopropanol	-	31 lbs
Acetone	-	25 lbs
Ethyl Acetate	-	63 lbs
Total weight per year - Isopropanol	-	186 lbs
Acetone	-	150 lbs
Ethyl Acetate	-	378 lbs

VOC Emission Potential = 714 lbs per year

(ii) Source II (Granulation)

No. of lots	-	6
Weight per lot - Isopropanol	-	31 lbs
Total weight per year - Isopropanol	-	186 lbs

VOC Emission Potential = 186 lbs per year

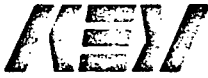
Total VOC Emissions for
Manufacturing

= 900 lbs per year

= 0.45 Tons per year

Calculated by

J.W. Flaherty
Dec 8, 1986



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

Cable: KEYPHARM
Telex: 808235

C E R T I F I C A T E

To Whom It May Concern:

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

Key Pharmaceuticals, Inc.

James R. Confrey, Vice President

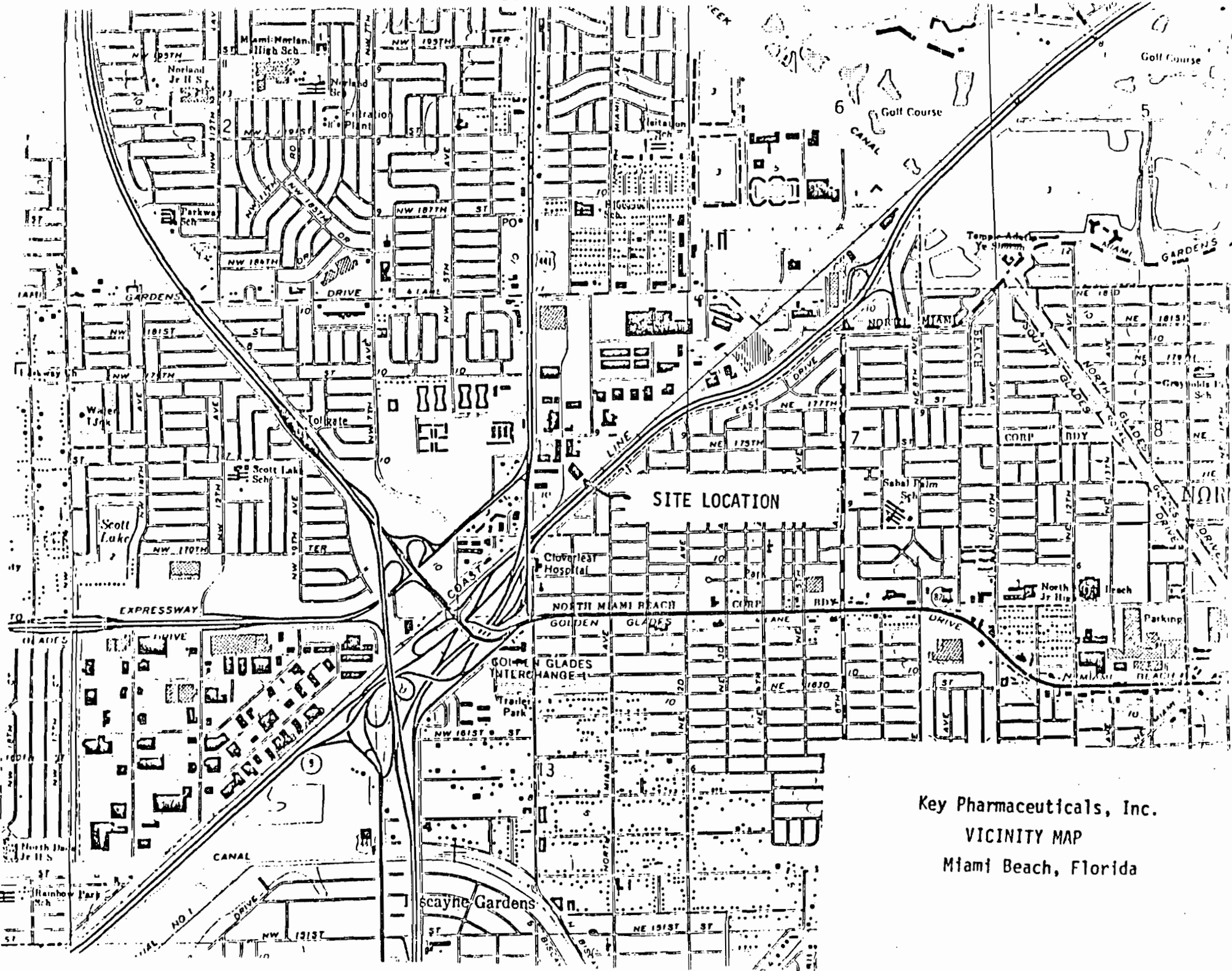
Miami and Puerto Rico Operations

JRC/db

STATE OF FLORIDA
COUNTY OF DADE

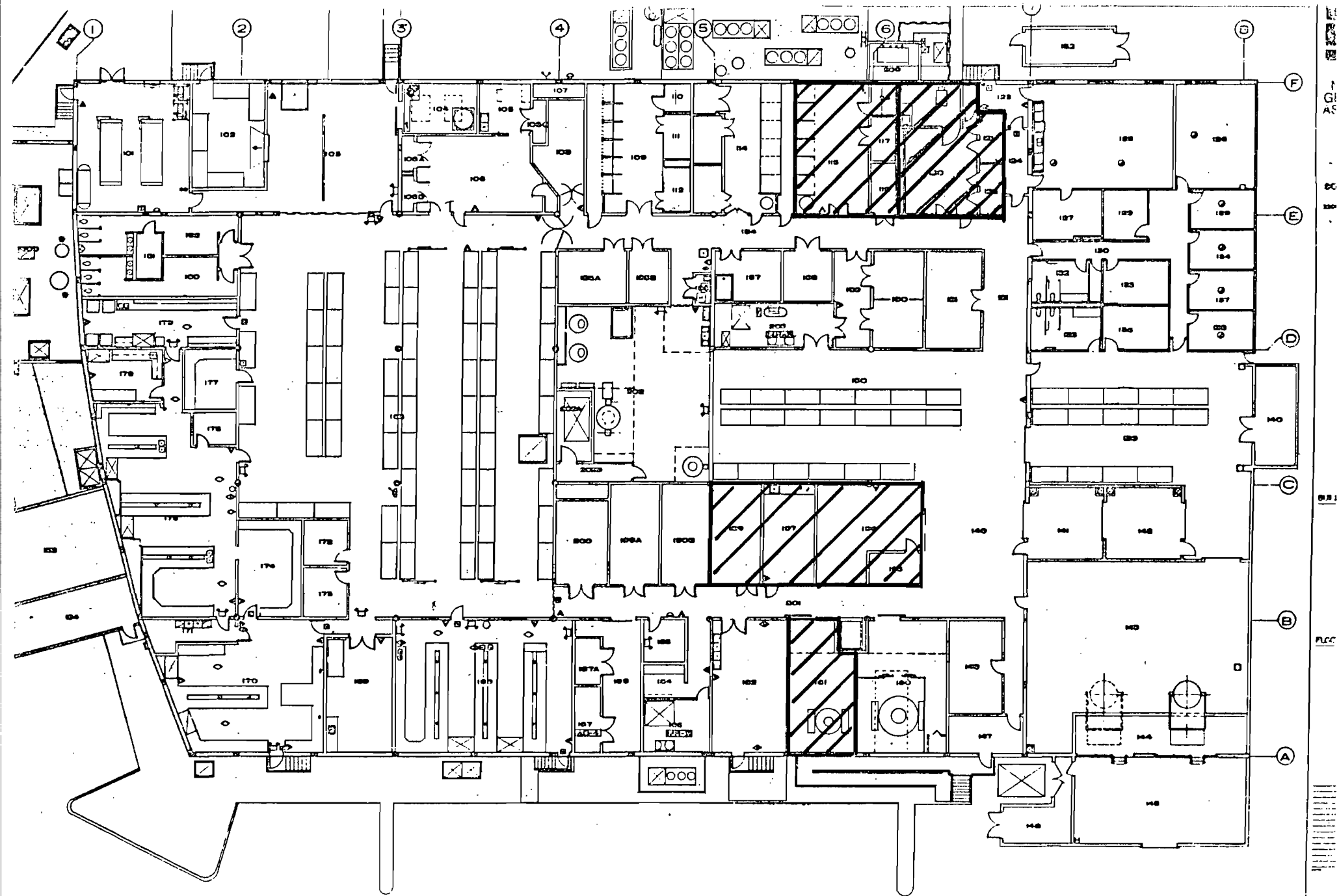
Sworn to and subscribed before me
this 21st day of October A.D. 1986.

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



Key Pharmaceuticals, Inc.
VICINITY MAP
Miami Beach, Florida

BEST AVAILABLE COPY



BUILDING 50

FLOOR PLAN

1/8"

1
GI
AC

BC

100

E

D

100

C

B

FLCC

A

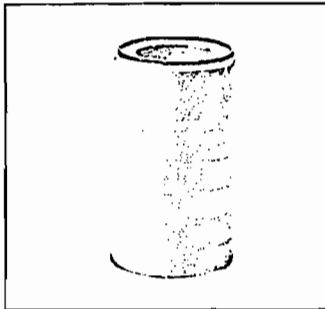


DUST COLLECTORS

FILTER CARTRIDGE SYSTEMS/TD 2300

NEW FILTRATION TECHNOLOGY

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



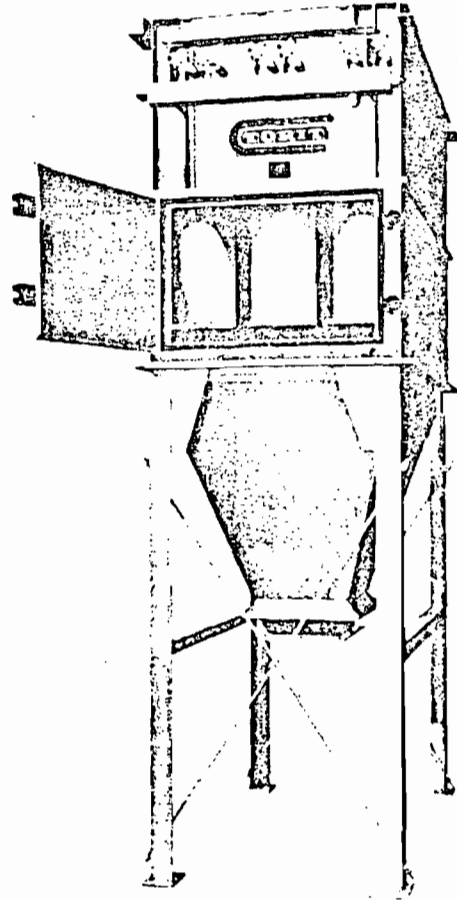
treating large volumes of dust-laden air on a continuing basis: highly efficient filtration; increased filtering area for lower air-to-media ratios; increased ease of maintenance and operation; and substantially decreased collector headroom.

EFFECTIVE FINE PARTICLE CONTROL

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

CONTINUOUS PULSE-JET CLEANING

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



EASY-TO-HANDLE FLEXIBILITY

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

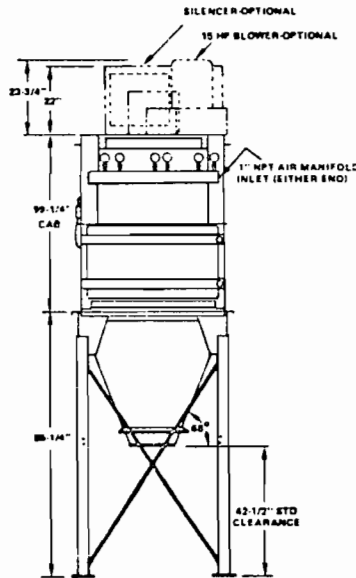
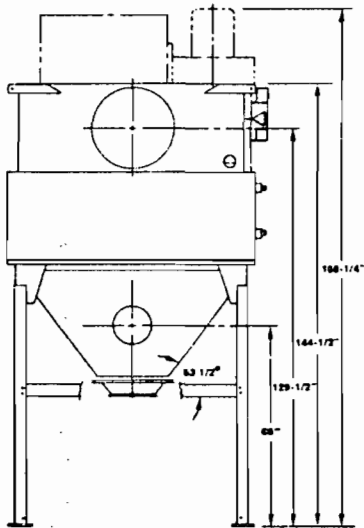
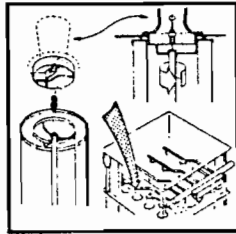
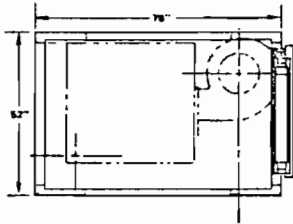
The TD 2300 is delivered to you in major assemblies. The system is available with different blower pack combinations for single-unit or multiple-unit applications. Its hopper can be fitted for 55-gallon drums, or for a rotary air lock adapter. The TD is made with the same high quality TORIT puts into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



DUST COLLECTORS

FILTER CARTRIDGE SYSTEMS, TD 2300

Quick-change feature allows fast cartridge removal and installation.



SPECIFICATIONS

Actual Filter Area2712 sq. ft.
Number of Valves6
Number of Filter Cartridges12
Filter Cartridge	
Dimensions 12 $\frac{3}{4}$ " OD x 8 $\frac{3}{8}$ " ID x 26" long
Number of Hopper Outlets1
Hopper Outlet Size 14 $\frac{1}{4}$ " square
Hopper Size 38 cu. ft.
Shipping Weight est. 2040 lbs.
Wind Load Rating 100 m.p.h.
Seismic Rating Zone 3

Specifications subject to change without notice.

NOTES

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

OPTIONAL EQUIPMENT

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

PERFORMANCE TESTED

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

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



A G E N D A

FOR KEY PHARMACEUTICALS, INC.
AND
STATE OF FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATION

KEY PHARMACEUTICALS, INC. REPRESENTATIVES:

MR. ROBERT A. FRANKE
MR. ERIC MITTLEBERG, PhD
MR. THOMAS W. FLACHMEYER

I SHUTDOWN OF THEO-DUR PRODUCTION (CONSENT ORDER CASE NO. 83-0373)

- A. C.A.P ROOM
- B. THREE COATING PAN ROOMS
- C. TWO GRANULATION ROOMS

II CURRENT PERMITS

- A. QUINORA AND GUANIDINE (VE TEST 12-10-86)
- B. K-DUR (METHOD 18 JAN 7 TO 9, 1987)

III CURRENT APPLICATION

- A. DRUG 0420 - SCALE-UP AND CLINICALS

IV FUTURE CONTROLS

- A. VARA FOR K-DUR 1987-1988
- B. SOLVENT ADSORPTION FOR BLDG 50 1988-1989

non solvent base

V FUTURE PRODUCTS: 1987, 1988, 1989

- A. VOC BASE
- B. AQUEOUS BASE
- C. INCREASED PRODUCTION K-DUR



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

Telex: 808235

December 1, 1986

Ms. Rebecca Moore
Department of Environmental
Regulation Enforcement
3301 Gun Club Road
P.O. Box 3858
West Palm Beach, FL 33402

Dear Ms. Moore:

The final "milestone" to show compliance with Consent Order OGC Case No. 83-0373 was to show the Commercial Scale Production of THEO-DUR product at our new Las Piedras, Puerto Rico plant. As discussed with you on the phone, we agreed that copies of several large invoices would adequately show the sale of THEO-DUR product produced in Puerto Rico and that other correspondence dated November 21 and 25, 1986, would confirm the shutdown and dismantling of unpermitted VOC sources at our Miami plant site.

The attached invoices (6) show shipments and billings totaling more than \$6,000,000 and span the July through October, 1986 time frame.

Should you require additional information, please advise.

Sincerely,

A handwritten signature in cursive script, reading "R. A. Franke", written over a horizontal line.

Robert A. Franke, Director
Engineering

RAF/db

attachments

bcc: J. Confroy
R. Glover
T. Flachmeyer
L. Mulligan
S. Gordon



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

Telex: 808235

November 25, 1986

Ms. Rebecca Moore
Department of Environmental
Regulation Enforcement
3301 Gun Club Road
P.O. Box 3858
West Palm Beach, FL 33402

Dear Ms. Moore:

As a follow-up to my letter to you dated November 21, 1986, all unpermitted sources of VOC's at our Miami facility have already been shutdown and the dismantling procedure has begun.

One change, not affecting the Consent Order but worthy of documentation is that we are going to continue using Granulation Room #1 but without the use of solvents, i.e., the Granulation will be aqueous, therefore not a source of VOC's.

Please call if any additional information is required.

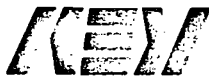
Sincerely,

A handwritten signature in cursive script, reading "R. A. Franke", written over a horizontal line.

Robert A. Franke, Director
Engineering

RAF/db

bcc: J. Confroy
R. Glover
T. Flachmeyer
L. Mulligan
S. Gordon



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

Cable: KEYPHARM
Telex: 808235

November 21, 1986

Ms. Rebecca Moore
Department of Environmental
Regulation Enforcement
3301 Gun Club Road
P.O. Box 3858
West Palm Beach, FL 33402

Dear Ms. Moore:

This is to confirm several phone conversations over the past few days and to confirm that by November 30, 1986, all unpermitted sources of VOC's at our Miami facility will be shutdown and dismantled as per our agreed upon procedure. All unpermitted sources of VOC's will be electrically and pneumatically disabled by terminating the electrical power and the compressed air at electrical disconnects and main air supplies respectively, with all connections to equipment removed. This will be accomplished in the three (3) Coating Pan Rooms and Granulation Room #1 as per Consent Order OCG Case No. 83-0373. All other sources of VOC's at the Miami Plant site have been permitted.

Within the next several days I will forward to you invoices showing that we are commercially selling THEO-DUR product made in our Las Piedras, Puerto Rico facility. This will complete the final "milestone" requirement of the Consent Order and should close Case No. 83-0373.

Should you require additional information, please advise.

Sincerely,

Robert A. Franke, Director
Engineering

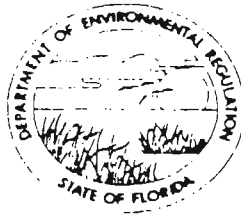
RAF/db

bcc: J. Confroy
R. Glover
T. Flachmeyer
L. Mulligan
S. Gordon

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

SOUTHEAST FLORIDA
DISTRICT

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



BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

ROY DUKE
DISTRICT MANAGER

November 13, 1986

Dade County
AP-Key Pharmaceuticals
Fluid Bed Processors

Mr. Thomas W. Flachmeyer
Manager of Environmental Engineering
Key Pharmaceuticals
50 Northwest 176 Street
Miami, Florida 33169

On 9/23/86, you were notified that your application for a permit was incomplete. The required information necessary to complete your application was itemized (copy attached).

When a permit application is incomplete, all processing of the application is suspended. Pursuant to Section 120.60, Florida Statutes, the Department may deny a permit application if the applicant, after receiving timely notice, fails to correct errors, omission, or supply additional information within a reasonable period of time.

It has been 50 days since we notified you of the deficiencies in your application. Please remember that a permit must be obtained from this Department before you undertake the proposed work.

cc: DERM
Mr. Confroy, V.P.
W. Hanks
S. Neck

Sincerely,

I. Goldman
I. Goldman, P.E.
Supervisor
Air Permitting

Enclosure

Please advise us if:

- You wish to withdraw your application.
- You need additional time to obtain the required information and we will receive the information in approximately ____ days.
- You have questions about our request and you wish to discuss your application with us.

You may check more than one of these items. Please sign and return this cover letter to us within 15 days of the day you receive it.

Application No. AO 13-114316

(Signature)