Check Sheet

Company Name: Key Pharmaceuticals
Permit Number: AC. 13-100437
PSD Number:
Permit Engineer:

Application:

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

Cross References:

- [ ]
- [ ]
- [ ]

Intent:

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

Final Determination:

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

Post Permit Correspondence:

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

SCHERING CORPORATION
50 NORTHWEST 176TH STREET
MIAMI, FL 33169

Dep#1637

7027

55-1
212

DECEMBER 12 19 86

PAY TO THE ORDER OF DEPARTMENT OF ENVIRONMENTAL REGULATION $ 100.00

ONE HUNDRED 00/100 DOLLARS

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

FOR PERMIT(QUINIDINE BISALFATE)

[redacted]

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

RECEIPT FOR APPLICATION FEES AND MISCELLANEOUS REVENUE

No. 76140

Received from Key Pharmaceuticals Date Dec. 16, 1986

Address 50 N.W. 176 Street Miami, FL 33169 Dollars $ 100.00

Applicant Name & Address Same as above

Source of Revenue

Revenue Code 001031

Application Number AC 13-128475

By Patricia B. Adams

PS Form 3811, July 1983 447-845

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

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

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

3. Article Addressed to:
Mr. Thomas W. Flachmeyer
Key Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, Florida 33169-1307

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

Article Number
P 408 531 145

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature – Addressee
X

6. Signature – Agent
X

7. Date of Delivery

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

DOMESTIC RETURN RECEIPT

P 408 531 145

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to Mr. Thomas Flachmeyer	
Street and No.	
P.O., State and ZIP Code	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt Showing to whom and Date Delivered	
Return Receipt Showing to whom, Date, and Address of Delivery	
TOTAL Postage and Fees	$
Postmark or Date 1/28/87	

PS Form 3800, Feb. 1982

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 22, 1987

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

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

Dear Mr. Flachmeyer:

Re: Modification of Conditions
Permit No. AC 13-100437

The department has reviewed your January 9, 1987, letter requesting the permit to construct No. 2 and No. 3 Fluidized Bed Coating Units be extended to allow additional time to complete the construction of the third fluidized bed coating unit. This request is approved and the expiration date of permit No. AC 13-100437 is changed from April 1, 1987 to July 1, 1987.

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

Sincerely,

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

HLR/ks

cc: I. Goldman
P. Wong

attachment

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

Telex: 808235

DER

JAN 16 1987

BAQM

January 9, 1987

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

RE: CONSTRUCTION PERMIT AC 13-100437

Dear Mr. Hanks:

Key Pharmaceuticals, Inc. would like to request an extension of the expiration date for the above referenced permit. The request is to extend the permit's expiration date from April 1, 1987 to July 1, 1987. The extension has been necessitated due to a delay in the completion of construction of the third fluidized bed coating unit.

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

Very truly yours,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

State of Florida
DEPARTMENT OF ENVIRONMENTAL REGULATION

Interoffice Memorandum

FOR ROUTING TO OTHER THAN THE ADDRESSEE

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

RECEIVED
JAN 21 1987
DIRECTOR - PROGRAMS

TO: Howard L. Rhodes, Director

FROM: C. H. Fancy, Deputy Chief, BAQM

DATE: January 22, 1987

SUBJ: Modifications of Conditions

Attached for your approval and signature is a letter that will extend the expiration date of a construction permit issued to Key Pharmaceuticals, Inc. The extension will allow the permittee additional time to complete the phased construction of the third unit. The bureau recommends this extension be approved.

CHF/WH/s

attachment

DER
JAN 22 1987
BAQM

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

Telex: 808235

January 9, 1987

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

RE: CONSTRUCTION PERMIT AC 13-100437

Dear Mr. Hanks:

Key Pharmaceuticals, Inc. would like to request an extension of the expiration date for the above referenced permit. The request is to extend the permit's expiration date from April 1, 1987 to July 1, 1987. The extension has been necessitated due to a delay in the completion of construction of the third fluidized bed coating unit.

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

Very truly yours,

Thomas W. Flachmeyer, Manager
Environmental Engineering and
Waste Management

TWF/db

State of Florida
DEPARTMENT OF ENVIRONMENTAL REGULATION

INTEROFFICE MEMORANDUM

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

TO: Stephanie Brooks

THRU: Bill Thomas BT

FROM: Willard Hanks wmh

DATE: June 10, 1986

SUBJ: Key Pharmaceuticals (AC 13-116005)

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

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

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

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

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

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

WH/ks

State of Florida
DEPARTMENT OF ENVIRONMENTAL REGULATION

Interoffice Memorandum

FOR ROUTING TO OTHER THAN THE ADDRESSEE

To: _____ Locyn: _____
To: _____ Locyn: _____
To: _____ Locyn: _____
From: _____ Date: _____

TO: Willard Hanks

FROM: Stephanie S. Brooks Stephanie S Brooks

DATE: April 11, 1986

RE: Key Pharmaceuticals AC 13-116005

The SEFD had the following comments:

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

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

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

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

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

SSB:js:j2

DER
APR 16 1986
BAQM

P 408 532 007

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to Mr. Allen F. Gant	
Street and No.	
P.O., State and ZIP Code	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt Showing to whom and Date Delivered	
Return Receipt Showing to whom, Date, and Address of Delivery	
TOTAL Postage and Fees	$
Postmark or Date	

5/20/86

PS Form 3800, Feb. 1982

PS Form 3811, July 1983

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

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

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

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

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

Article Number
P 408 532 007

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature – Addressee
X

6. Signature – Agent
X Bradley

7. Date of Delivery

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

DOMESTIC RETURN RECEIPT

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

May 15, 1986

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

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

Dear Mr. Gant:

Re: Modification of Conditions/Permit No. AC 13-100437

The department is in receipt of Mr. Steve J. Goodstein's letter requesting that the permit to construct No. 2 and No. 3 fluidized bed coating units be extended to allow additional time to install the No. 3 Glatt unit and that the allowable emissions from these units be reduced from 40 to 35 TPY VOC to comply with Consent Order OGC Case No. 84-0644.

This request is acceptable to the department and the construction permit is modified as noted below.

Expiration Date

From: February 28, 1986
To: April 1, 1987

Specific Condition No. 1

From: The permittee must satisfy the requirements of Consent Order OGC No. 84-0644, or the No. 2 and No. 3 fluid bed coating units (Glatt No. 2 and No. 3) shall not be operated. Glatt No. 2 shall not be operated more than 90 days prior to installation of permanent air pollution control equipment. The applicant shall provide documentation to the department demonstrating that total VOC emissions during this 90 day period from Glatt No. 2 has not exceeded 10 tons. Combined emissions from Glatts Nos. 2 and 3, before and after the installation of permanent pollution control equipment, shall not exceed 40 tons

of VOC in any consecutive 12 month period. (Consent Order OGC Case No. 84-0644 15(c) and 15(d) and (e)).

To: The permittee must satisfy the requirements of Consent Order OGC Case No. 84-0644, or the Nos. 2 and 3 Fluid Bed Coating Units (Glatt Nos. 2 and 3) shall not be operated. Glatt No. 2 shall not be operated more than 90 days prior to installation of permanent air pollution control equipment. The applicant shall provide documentation to the department demonstrating that total VOC emissions during this 90 day period from Glatt No. 2 has not exceeded 10 tons. Combined emissions from Glatts Nos. 1, 2, and 3, before and after the installation of permanent air pollution control equipment, shall not exceed 35 tons of VOC in any consecutive 12 month period. (Consent Order OGC Case No. 84-0644 15(c) and 15(d) and (e)).

Specific Conditions No. 6

From: 6. Upon obtaining an operating permit, the applicant will be required to submit annual reports on the actual operation from the facility. These reports will include, as a minimum: the amount of solvents used by inventory control, total hours of operation of the Glatts No. 1, No. 2, and No. 3, and emission test reports for particulate matter (if required by the department), and visible emissions. A compliance test using Method 25 or other methods approved by the department will be required as the initial acceptance test to verify the emission factors for VOC. Inventory control can be used, thereafter, to verify emissions of VOC. However, in the case of any doubt with the emission factors, the department may request a test by Reference Method 25, 40 CFR 60, Appendix A.

To: When Glatts Nos. 2 or 3 begin commerical operation, the applicant shall submit annual reports for the facility. These reports will include, as a minimum: the amount of solvents used as determined by inventory control, total hours of operation of the Glatts No. 1, No. 2, and No. 3, and emission test reports for particulate matter (if required by the department), and visible emissions. A compliance test using EPA Method 18 or other methods approved by the department will be required as the initial acceptance test to verify the emission factors for methanol. Inventory control can be used, thereafter, to

verify emissions of VOC. However, in the case of any doubt with the emission factors, the department may request a test by Reference Method 18, 40 CFR 60, Appendix A.

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

Sincerely,

Victoria J. Tschinkel
Secretary

VJT/ks

cc: Isidore Goldman
Patrick Wong

State of Florida
DEPARTMENT OF ENVIRONMENTAL REGULATION

Interoffice Memorandum

FOR ROUTING TO OTHER THAN THE ADDRESSEE

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

TO: Victoria J. Tschinkel

FROM: Clair Fancy

DATE: May 15, 1986

SUBJECT: Modifications of Conditions

Attached for your approval and signature is a letter that will extend the expiration date and lower the allowable emissions listed in the construction permit that was issued to Key Pharmaceuticals, Inc. The extension will allow time for the applicant to complete construction and the lower allowable emissions are needed for the facility to comply with Consent Order OGC Case No. 84-0644.

The Bureau recommends these modifications be approved.

WH/ps

attach: Permit Modifications letter

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

May 8, 1986

Mr. Stephen J. Goodstein, Manager
Environmental Engineering
Key Pharmaceuticals, Inc.
50 NW 176th Street
Miami, Florida 33169-1307

Dear Mr. Goodstein:

Re: AC 13-100437 and AO 13-114316

The Bureau has reviewed your March 27 letter. Our response to your inquiry, in the same order they were presented in the letter, follows:

1. The official test method for VOC pollutants specified in the regulations and the permit issued to Key Pharmaceuticals is Method 25, Determination of Total Gaseous Nonmethane Organic Emission of Carbon. It is described in 40 CFR 60, Appendix A.

It is our understanding that you would like to substitute NIOSH Method S59 for Method 25. The department proposes to authorize the use of EPA Method 18 on this source. Method 18 is an approved procedure which allows the use of the NIOSH 2000 test to determine methanol emissions. A NIOSH 2000 test is similar to a NIOSH S59 test.

Rule 17-2.700(3), FAC, Exceptions and Approval of Alternate Procedures and Requirements, describes the information needed to apply for an alternate test method. Please submit a written request as specified in the regulations if you want to use an alternate method instead of Method 18 or 25. If the request is approved by the department, the alternate test method can be substituted for the official one required by the regulations.

2. The construction permit for Glatt Nos. 2 and 3 and the state regulations (Rule 17-2.700(2)(a)1., FAC) requires one test prior to applying for a permit to operate. Rule 17-2.700(2)(a)3., FAC, requires another test prior to renewal of a permit to operate (generally, every five years). Rule 17-2.700(2)(b), FAC, authorizes the department to require special compliance tests when, after investigation, it has good reason to believe the source is not in compliance with the emissions standard.

Between required tests, the construction permits for Glatt Nos. 2 and 3 allows the use of inventory records to determine the compliance status.

3. The Bureau proposes to allow commercial operation of the Glatt units under an extended stage construction permit (AC 13-100437) if the units are in compliance with the regulations. The compliance test by Method 18, unless an alternate method is requested and approved, should be made during the operations having the highest potential to emit VOC. In this situation, the highest potential to emit is when all 3 Glatt units are in operation. During the interim commercial operations that will occur prior to the installation of Glatt No. 3, the department requests a methanol test be conducted on the scrubber serving the Glatt units to provide you with assurance that the scrubber is meeting the design specifications, and to provide the department with assurance that the emission standards are not being violated.

4. The Bureau is in the process of recommending to the Secretary that your construction permit for Glatt Nos. 2 and 3 (AC 13-100437) be extended until April, 1987.

5. By copy of this letter, we are informing the Southeast District of the status of the construction permitting activities of these sources. The District should not issue an operation permit for the Glatt units until Key Pharmaceutical submits a compliance test report to complete the application for permit to operate.

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

Sincerely,

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

CHF/WH/s

cc: I. Goldman
P. Wong

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

Cable: KEYPHARM
Telex: 808235

March 27, 1986

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

RE: AC-13-100437 and AO-13-114316

Dear Mr. Fancy:

In a recent telephone conversation with Willard Hanks of your office, the question of exactly how the referenced Glatt 1 - 3 operating permit will be handled has still not been determined. Due to this, testing as requested from the West Palm Beach DER office has not been done. Furthermore, there is an additional question on how the testing will be performed.

The construct permit will probably be extended until April, 1987, as stated by Willard Hanks, for the addition of Glatt 3. However, the vehicle that allows operation of Glatts 1 and 2 is the question. Will it be an interim or restricted operating permit, or something else?

Testing of the air effluent can be performed. The question is as to the method. Enviropact, Inc. has been contacted to establish a suitable method. As methanol is the only component to be looked at, it is their suggestion to use a method other than EPA method 25 or 25-A. Their recommendation is to use NIOSH method S-59 (copy is attached). The methodology can be discussed with their lab manager, Larry Korn at 305-620-1700 or one of the owners, John Tostanoski. Based on discussions between Enviropact personnel, Isidore Goldman and Stephanie Brooks (of the DER West Palm Beach Office) and Willard Hanks, the determination of the proper test method is to be made by your office.

Therefore, I am requesting the following from your office:

1. Determine which test method is suitable to test the single VOC pollutant methanol.
2. Determine the test frequency of No. 1.
3. Determine the vehicle that will allow Glatts 1 and 2 to operate until Glatt 3 is installed and operating without having to submit another contract permit.
4. Extension of the Operating Permit to April, 1987, as previously requested (see my letter to you of February 13, 1986).
5. Discussions with the West Palm Beach office to make sure they know the status of the above.

If there are any questions, please contact me.

Very truly yours,

KEY PHARMACEUTICALS, INC.

Stephen J. Goodstein, Manager
Environmental Engineering and
Waste Management

SJG/db

attachments

W. Smyth

R.A. Franke

R. Quinlan

T. Flachmeyer

Stephanie Brooks (West Palm Beach DER)

Isidore Goldman (West Palm Beach DER)

Methyl Alcohol

Analyte:	Methyl Alcohol	Method No.: S59
Matrix:	Air	Range: 140-540 mg/cu m
OSHA Standard:	200 ppm (260 mg/cu m)	Precision ($\overline{CV_T}$): 0.070
Procedure:	Adsorption on silica gel, desorption with water, GC	Validation Date: 1/17/75

1. Principle of the Method

1.1 A krown volume of air is drawn through a silica gel tube to trap the organic vapors present.

1.2 The silica gel in the tube is transferred to a small, stoppered sample container and the analyte is desorbed with water.

1.3 An aliquot of the desorbed sample is injected into a gas chromatograph.

1.4 The area of the resulting peak is determined and compared with areas obtained from the injection of standards.

2. Range and Sensitivity

2.1 This method was validated over the range of 140-540 mg/cu m at an atmospheric temperature and pressure of 25 C and 748 mm Hg, using a nominal 5-liter sample. Under the conditions of sample size (5 liters) the probable range of this method is 25-900 mg/cu m at a detector sensitivity that gives nearly full deflection on the strip chart recorder for a 4-mg sample. The method is capable of measuring much smaller amounts if the desorption efficiency is adequate. Desorption efficiency must be determined over the range used.

2.2 The upper limit of the range of the method is dependent on the adsorptive capacity of the silica gel tube. This capacity varies with the concentration of the analyte and other substances in the air. The first section of the silica gel tube was found to hold 5.6 mg of the analyte when a test atmosphere of 540 mg/cu m of the analyte in dry air was sampled at 0.2 liters per minute for 52 minutes. Breakthrough occurred at this time,

i.e., the concentration of the analyte in the effluent was 5% of that in the influent. (The silica gel tube consists of two sections of silica gel separated by a section of urethane foam. See Section 6.2.) If a particular atmosphere is suspected of containing a large amount of contaminant, a smaller sampling volume should be taken.

3. Interference

3.1 When the amount of water in the air is so great that condensation actually occurs in the tube, organic vapors will not be trapped efficiently.

3.2 When two or more compounds are known or suspected to be present in the air, such information, including their suspected identities, should be transmitted with the sample.

3.3 It must be emphasized that any compound which has the same retention time as the specific compound under study at the operating conditions described in this method is an interference. Retention time data on a single column cannot be considered as proof of chemical identity.

3.4 If the possibility of interference exists, separation conditions (column packing, temperature, etc.) must be changed to circumvent the problem.

4. Precision and Accuracy

4.1 The Coefficient of Variation ($\overline{CV}_T$) for the total analytical and sampling method in the range of 140 to 540 mg/cu m was 0.063. This value corresponds to a standard deviation of 16.5 mg/cu m at the OSHA standard level. Statistical information and details of the validation and experimental test procedures can be found in Reference 11.2.

4.2 The average values obtained using the overall sampling and analytical method were 8.9% lower than the "true" value at the OSHA standard level.

4.3 The above data are based on validation experiments using the internal standard method. (Reference 11.2)

5. Advantages and Disadvantages of the Method

5.1 The sampling device is small, portable, and involves no liquids. Interferences are minimal, and most of those which do occur can be eliminated by altering chromatographic conditions. The tubes are analyzed by means of a quick, instrumental method. The method can also be used for the simultaneous analysis of two or more compounds suspected to be present in the same sample by simply changing gas chromatographic conditions from isothermal to a temperature-programmed mode of operation.

5.2 One disadvantage of the method is that the amount of sample which can be taken is limited by the number of milligrams that the tube will hold before overloading. When the sample value obtained for the backup section of the silica gel tube exceeds 25% of that found on the front section, the possibility of sample loss exists.

5.3 Furthermore, the precision of the method is limited by the reproducibility of the pressure drop across the tubes. This drop will affect the flow rate and cause the volume to be imprecise, because the pump is usually calibrated for one tube only.

6. Apparatus

6.1 A calibrated personal sampling pump whose flow can be determined accurately (±5%) at the recommended flow rate, (Reference 11.3)

6.2 Silica gel tubes: glass tube with both ends flame sealed, 7 cm long with a 6-mm O.D. and a 4-mm I.D., containing 2 sections of 20/40 mesh silica gel separated by a 2-mm portion of urethane foam. The absorbing section contains 100 mg of silica gel, the backup section 50 mg. A 3-mm portion of urethane form is placed between the outlet end of the tube and the backup section. A plug of silylated glass wool is placed in front of the absorbing section. The pressure drop across the tube must be less than one inch of mercury at a flow rate of 1 liter per minute.

6.3 Gas chromatograph equipped with a flame ionization detector.

6.4 Column (10-ft x 1/8-in. stainless steel) packed with 10% FFAP on 80/100 Chromosorb W-AW.

6.5 An electronic integrator or some other suitable method for determining peak size areas.

6.6 Two-milliliter glass sample containers with glass stoppers or Teflon®-lined caps. If an automatic sample injector is used, the sample injector vials can be used.

6.7 Microliter syringes: 10-µl, and other convenient sizes for making standards.

6.8 Pipets: 1.0-ml delivery type.

6.9 Volumetric flasks: 10 ml or convenient sizes for making standard solutions.

7. Reagents

7.1 Eluent: Distilled water.

7.2 Methyl Alcohol (reagent grade).

7.3 Purified nitrogen.

7.4 Prepurified hydrogen.

7.5 Filtered compressed air.

8. Procedure

8.1 Cleaning of Equipment. All glassware used for the laboratory analysis should be detergent washed and thoroughly rinsed with tap water and distilled water.

8.2 Calibration of Personal Pumps. Each personal pump must be calibrated with a representative silica gel tube in the line. This will minimize errors associated with uncertainties in the sample volume collected.

8.3 Collection and Shipping of Samples

8.3.1 Immediately before sampling, break the ends of the tube to provide an opening at least one-half the internal diameter of the tube (2 mm).

8.3.2 The smaller section of silica gel is used as a back-up and should be positioned nearest the sampling pump.

8.3.3 The silica gel tube should be placed in a vertical direction during sampling to minimize channeling through the silica gel.

8.3.4 Air being sampled should not be passed through any hose or tubing before entering the silica gel tube.

8.3.5 A maximum sample size of 5 liters is recommended. Sample at a flow of 0.20 liters per minute or less. The flow rate should be known with an accuracy of at least ±5%.

8.3.6 The temperature and pressure of the atmosphere being sampled should be recorded. If the pressure reading is not available the elevation should be recorded.

8.3.7 The silica gel tubes should be capped with the supplied plastic caps immediately after sampling. Under no circumstances should rubber caps be used.

8.3.8 One tube should be handled in the same manner as the sample tube (break, seal, and transport), except that no air is sampled through this tube. This tube should be labeled as a blank.

8.3.9 Capped tubes should be packed tightly and padded before they are shipped to minimize tube breakage during shipping.

8.3.10 A sample of the suspected compound should be submitted to the laboratory in glass containers with Teflon®-lined caps. These liquid bulk samples should not be transported in the same container as the silica gel tubes.

8.4 Analysis of Samples

8.4.1 Preparation of Samples. In preparation for analysis, each silica gel tube is scored with a file in front of the first section of silica gel and broken open. The glass wool is removed and discarded. The silica gel in the first (larger) section is transferred to a 2-ml stoppered sample container or automatic sample injector vial. The separating section of foam is removed and discarded; the second section is transferred to another sample container or vial. These two sections are analyzed separately.

8.4.2 Desorption of Samples. Prior to analysis, 1.0 ml of distilled water is pipetted into each sample container. Desorption should be done for 4 hours. Tests indicate that this is adequate if the sample is agitated occasionally during this period. The sample vials should be capped as soon as the water is added to minimize evaporation.

8.4.3 GC Conditions. The typical operating conditions for the gas chromatograph are:

1. 30 ml/min (80 psig) nitrogen carrier gas flow.
2. 30 ml/min (50 psig) hydrogen gas flow to detector.
3. 300 ml/min (50 psig) air flow to detector.
4. 200 C injector temperature.
5. 300 C manifold temperature (detector).
6. 80 C column temperature.

8.4.4 Injection. The first step in the analysis is the injection of the sample into the gas chromatograph. To eliminate difficulties arising from blow back or distillation within the syringe needle, one should employ the solvent flush injection technique. The 10-µl syringe is first flushed with solvent several times to wet the barrel and plunger. Three microliters of solvent are drawn into the syringe to increase the accuracy and reproducibility of the injected sample volume. The needle is removed from the solvent, and the plunger is pulled back about 0.2 µl to separate the solvent flush from the sample with a pocket of air to be used as a marker. The needle is then immersed in the sample, and a 5-µl aliquot is withdrawn, taking into consideration the volume of the needle, since the sample in the needle will be completely injected. After the needle is removed from the sample and prior to injection, the plunger is pulled back 1.2 µl to minimize evaporation of the sample from the tip of the needle. Observe that the sample occupies 4.9-5.0 µl in the barrel of the syringe. Duplicate injections of each sample and standard should be made. No more than a 3% difference in area is to be expected.

An automatic sample injector can be used if it is shown to give reproducibility at least as good as the solvent flush technique.

8.4.5 Measurement of area. The area of the sample peak is measured by an electronic integrator or some other suitable form of area measurement, and preliminary results are read from a standard curve prepared as discussed below (see Section 9).

8.5 Determination of Desorption Efficiency

8.5.1 Importance of determination. The desorption efficiency of a particular compound can vary from one laboratory to another and also from one batch of silica gel to another. Thus, it is necessary to determine at least once the percentage of the specific compound that is removed in the desorption process.

8.5.2 Procedure for determining desorption efficiency. Silica gel equivalent to the amount in the first section of the sampling tube (100 mg) is measured into a 2.0-ml sample container. This silica gel must be the same

type as that used in obtaining the samples and can be obtained from unused silica gel tubes. A known amount of the analyte is injected directly into the silica gel with a 10-µl syringe, and the container is capped. The amount injected is equivalent to that present in a 5-liter sample at the selected level.

At least six tubes at each of three levels (0.5X, 1X, and 2X the standard) are prepared in this manner and allowed to stand for at least overnight to assure complete adsorption of the analyte onto the silica gel. These six tubes are referred to as the samples. A parallel blank tube should be treated in the same manner except that no sample is added to it. The sample and blank tubes are desorbed and analyzed in exactly the same manner as the sampling tube described in Section 8.4.

The weight of analyte found in each tube is determined from the standard curve (Section 9). Desorption efficiency is determined by the following equation:

$$D.E. = \frac{\text{Average Weight (mg) recovered}}{\text{Weight (mg) added}}$$

The desorption efficiency is dependent on the amount of analyte collected on the silica gel. Plot the desorption efficiency versus the weight of analyte found. This curve is used in Section 10.4 to correct for adsorption losses.

9. Calibration and Standards

It is convenient to express concentration of standards in terms of mg/ml of eluent. A series of standards, varying in concentration over the range of interest, is prepared and analyzed under the same GC conditions and during the same time period as the unknown samples. Curves are established by plotting concentrations in mg/ml versus peak area.

Note: Standard solutions should be analyzed at the same time that the sample analysis is done. This will minimize the effect variations of FID response.

10. Calculations

10.1 Read the weights, in mg, corresponding to each peak area (area ratio in case of the internal standard method) from the

standard curve. No volume corrections are needed, because the standard curve is based on mg/ml eluent and the volume of sample injected is identical to the volume of the standards injected.

10.2 Corrections for the blank must be made for each sample.

mg = mg sample - mg blank

where:

mg sample = mg found in front section of sample tube

mg blank = mg found in front section of blank tube

A similar procedure is followed for the backup sections.

10.3 Add the weights present in the front and backup sections of the same sample tube to determine the total weight in the sample.

10.4 Read the desorption efficiency from the curve (Section 8.5.2) for the amount of analyte found in the front section. Divide the total weight by this desorption efficiency to obtain the corrected mg/sample.

$$\text{Corrected mg/sample} = \frac{\text{Total Weight}}{\text{D.E.}}$$

10.5 The concentration of analyte in the air sampled can be expressed in mg per cu m, which is numerically equal to µg per liter of air

$$\text{mg/cu m} = \frac{\text{Corrected mg (Section 10.4) x 1000 (liter/cu m)}}{\text{Air Volume Sampled (liter)}}$$

10.6 Another method of expressing concentration is ppm:

$$\text{ppm} = \text{mg/cu m} \times \frac{24.45}{MW} \times \frac{760}{P} \times \frac{T + 273}{298}$$

where:

P = pressure (mm Hg) of air sampled
T = temperature (C) of air sampled
24.45 = molar volume (liter/mole) at 25 C and 760 mm Hg
MW = molecular weight (g/mole) of analyte
760 = standard pressure (mm Hg)
298 = standard temperature (K)

11. References

11.1 White L. D., et al., "A Convenient Optimized Method for the Analysis of Selected Solvent Vapors in the Industrial Atmosphere," Amer. Ind. Hyg. Assoc. J., 31: 225 (1970).

11.2 "Documentation of NIOSH Validation Tests", Contract No. CDC-99-74-45.

11.3 Final Report, NIOSH Contract No. HSM-99-71-31, "Personal Sampler Pump for Charcoal Tubes, September 15, 1972."

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

Cable: KEYPHARM
Telex: 808235

August 16, 1985

Mr. Willard Hanks
State of Florida Department
of Environmental Regulation
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, Florida 32301-8241

RE: PERMIT NO. AC 13-100437

Dear Willard:

I have reviewed the permit for Key Pharmaceuticals' Project 0410 and find no discrepancies. Therefore, the permit is accepted in its entirety.

If there are any questions, please contact me.

Very truly yours,

KEY PHARMACEUTICALS, INC.

Stephen J. Goodstein

Stephen J. Goodstein, Manager
Environmental Engineering and
Waste Management

SJG/db

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

P 408 530 291

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
NOT FOR INTERNATIONAL MAIL

(See Reverse)

Sent to Mr. Allen F. Gant	
Street and No.	
P.O., State and ZIP Code	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt Showing to whom and Date Delivered	
Return Receipt Showing to whom, Date, and Address of Delivery	
TOTAL Postage and Fees	$
Postmark or Date 7/30/85	

PS Form 3800, Feb. 1982

PS Form 3811, July 1983

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

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

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

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

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

Article Number
P 408 530 291

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature – Addressee
X

6. Signature – Agent
X

7. Date of Delivery

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

DOMESTIC RETURN RECEIPT

50/13/04741

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION
NOTICE OF PERMIT

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

July 30, 1985

Enclosed is Permit Number AC 13-100437 to Key Pharmaceuticals, Inc. to which authorizes the installation of fluidized bed coating units No. 2 and No. 3 at your Miami facility, 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 32301; and by filing a copy of the Notice of Appeal accompanied by the applicable filing fees with the appropriate District Court of Appeal. The Notice of Appeal must be filed within 30 days from the date this permit is filed with the clerk of the Department.

Sincerely,

Willard Hanks

for

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

Enclosure

cc: Art Bolivar
Isidore Goldman
Marvin F. Nathan
Bill Voshell

CERTIFICATION

This is to certify that the foregoing Notice of Permit and all copies requested were mailed before the close of business on July 30, 1985.

for C. H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality
Management
2600 Blair Stone Road
Tallahassee, Florida 32301

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

July 30, 1985
Date

Final Determination

Key Pharmaceuticals, Inc.
No. 2 and No. 3 Fluidized Bed Coating Units

Miami, Dade County, Florida

Permit Number AC 13-100437

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

July 24, 1985

Final Determination

Key Pharmaceuticals, Inc.'s application for permit to construct the No. 2 and No. 3 fluidized bed coating units (Glatts) at their plant located in Miami, Dade County, Florida, has been processed by the Bureau of Air Quality Management. Public Notice of the department's Intent to Issue the construction permit was published in the Miami News on May 23, 1985. Copies of the Technical Evaluation and Preliminary Determination were available for public inspection at the department's offices in West Palm Beach and Tallahassee and the Dade County Department of Environmental Resources Management office in Miami.

Comments on the bureau's evaluation were received from Mr. Goodstein of Key Pharmaceuticals, Inc. and Mr. Isidore Goldman of the Southeast District.

Mr. Goodstein's comments in his letter dated May 16, 1985 clarified the process equipment to be installed under this permit and the operation scenario of the equipment. Both Mr. Goodstein's and Mr. Goldman's comments addressed clarification of temporary emissions.

The bureau is in general agreement with the comments of both parties. The permit has been revised to show it authorizes the construction of two fluidized bed coating units, to specify the maximum process input limits for this equipment and clarify the temporary emissions allowed while the pollution control equipment is being installed.

The final action of the department will be to issue the construction permit with the changes mentioned above.

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

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

Permit Number:AC 13-100437
Expiration Date: February 28, 1986
County: Dade
Latitude/Longitude: 25° 56' 04"N/ 80° 12' 11"W
Project: No. 2 and No. 3 Fluidized Bed Coating Units

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 drawings, plans, and other documents attached hereto or on file with the department and made a part hereof and specifically described as follows:

Construction of No. 2 and No. 3 Fluidized Bed Coating units (Glatts) for intermediate processing prior to tableting at the facility. The maximum input rate to each Glatt unit is 277.2 lb/hr (max. 831.6 lb/hr with 3 Glatt units in operation). The units have a dust collector system and a high efficiency absorber column (scrubber) for control of emissions.

The facility location is bounded on the west by S.R. 441, on the east and south by Interstate Highway 95, and on the north by NW 176th Street in Miami, Dade County, Florida. The UTM coordinates of the site are 17-580.6 east and 2868.5 north.

The construction and operation of the No. 1, No. 2, and No. 3 Glatt shall be in accordance with the (1) application for permit to construct, submitted by Mr. Allen F. Gant on March 1, 1985, and the additional information provided in Mr. Marvin F. Nathan's (2) March 6, 1985 letter and Mr. Stephen J. Goodstein's (3) April 3, 1985 and (4) May 16, 1985 letters. Key Pharmaceuticals, Inc. must also comply with the terms and conditions of the consent order OGC No. 84-0644 issued.

GENERAL CONDITIONS:

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

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

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

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

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

GENERAL CONDITIONS:

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

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

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

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

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

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

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

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

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

GENERAL CONDITIONS:

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

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

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

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

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

13. This permit also constitutes:

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

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

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

GENERAL CONDITIONS:

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

c. Records of monitoring information shall include:

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

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

SPECIFIC CONDITIONS:

1. The permittee must satisfy the requirements of Consent Order OGC Case No. 84-0644 or the No. 2 and No. 3 Fluid Bed Coating Units (Glatt No. 2 and No. 3) shall not be operated. Glatt No. 2 shall not be operated more than 90 days prior to installation of permanent pollution control equipment. Applicant shall provide documentation to the Department demonstrating that total VOC emissions during this 90 day period from Glatt No. 2 has not exceeded 10 tons. Combined emissions from Glatts Nos. 2 and 3 before and after the installation of permanent pollution control equipment shall not exceed 40 tons of VOC in any consecutive 12 month period. (Consent Order OGC Case No. 84-0644 15(c) and 15 (d) and (e))

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-100437
Expiration Date: February 28, 1986

SPECIFIC CONDITIONS:

2. The operating hours shall not exceed 8,400 hours per year.

3. The input rate to the Glatt No. 1, No. 2 and No. 3 shall not exceed 277.2 lb/hr/unit and 831.6 lb/total for the three units.

4. The Glatt No. 1, No. 2, and No. 3 opacity test shall meet all applicable requirements of 40 CFR 60, Appendix A, Reference Method 9. Particulate matter emissions from the scrubber shall not exceed .016 lb/hr, .068 tons/yr, or 5% opacity. The department may require a particulate matter test if visible emissions exceed 5 percent opacity.

5. The applicant will demonstrate compliance with the conditions of this construction permit and the Consent Order OGC case No. 84-0644 and submit a complete application for an operating permit to the Southeast District prior to 90 days before the expiration date of this permit. The applicant may continue to operate in compliance with all terms of the consent order and construction permit until its expiration or until issuance of an operating permit.

6. Upon obtaining an operating permit, the applicant will be required to submit annual reports on the actual operation of the facility. These reports will include, as a minimum: the amount of solvents used by inventory control, total hours of operation of the Glatts No. 1, No. 2, and No. 3, and emission test reports for particulate matter (if required by the department) and visible emissions. A compliance test using Method 25 or other methods approved by the Department will be required as the initial acceptance test to verify the emission factors for VOC. Inventory control can be used, thereafter, to verify emissions of VOC. However, in the case of any doubt with the emission factors, the department may request a test by Reference Method 25, 40 CFR 60, Appendix A.

Issued this 29 day of July, 1985

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL REGULATION

Victoria J. Tschinkel

VICTORIA J. TSCHINKEL, Secretary

State of Florida
DEPARTMENT OF ENVIRONMENTAL REGULATION

Interoffice Memorandum

FOR ROUTING TO OTHER THAN THE ADDRESSEE

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

TO: Victoria J. Tschinkel

FROM: for Clair Fancy BT

DATE: July 25, 1985

SUBJ: Key Pharmaceuticals, Inc.

Attached is the Final Determination and Permit to Construct No. AC 13-100437 which approves the construction of two fluid bed coating units at Key Pharmaceuticals, Inc.'s Miami, Dade County, Florida facility. Public Notice of the department's intent to issue the permit was published in the Miami News on May 23, 1985.

Comments on the Preliminary Determination for this source were submitted by the company and the Southeast District. These comments primarily addressed what process equipment would be added to the plant and the temporary allowable emissions while the air pollution control equipment was being installed.

Based on these comments, minor modifications were made to the proposed permit to construct.

The bureau recommends your approval and signature of the construction permit. Day 90, after which the permit would be issued by default, is August 3, 1985.

CHF/WH/s

HOPPING BOYD GREEN & SAMS
ATTORNEYS AND COUNSELORS
SUITE 420, LEWIS STATE BANK BUILDING
POST OFFICE BOX 6526
TALLAHASSEE, FLORIDA 32314
(904) 222-7500

CARLOS ALVAREZ
BRIAN H. BIBEAU
WILLIAM L. BOYD, IV
PETER C. CUNNINGHAM
WILLIAM H. GREEN
WADE L. HOPPING
RICHARD D. MELSON
WILLIAM D. PRESTON
GARY P. SAMS
ROBERT P. SMITH, JR.

JAMES S. ALVES
KATHLEEN BLIZZARD
ELIZABETH C. BOWMAN
RICHARD S. BRIGHTMAN
FRANK E. MATTHEWS
STEVEN A. MEDINA
CAROLYN S. RAEPPLE

OF COUNSEL
W. ROBERT FOKES

DER
MAY 30 1985
BAQM

May 28, 1985

RECEIVED
MAY 28
Office of the Secretary

HAND DELIVERED THIS DATE

Victoria J. Tschinkel, Secretary
c/o Mary Smallwood, General Counsel
Department of Environmental Regulation
2600 Blair Stone Road
Tallahassee, Florida 32301

Re: Key Pharmaceuticals, Inc. - Request for Extension of Time Concerning Air Construction Permit No. AC 13-100437

Dear Secretary Tschinkel:

On March 13, 1985, Key Pharmaceuticals, Inc. ("Key") received from the Department its Intent to Issue and Technical Evaluation and Preliminary Determination relating to the above referenced permit. Key's review of those documents led to additional correspondence with the Agency and the publication of a Notice of Proposed Agency Action which was agreeable to both Key and the Department. However, to assure that Key and the Department will retain the legal flexibility to implement the agreed upon changes in the final permit action in this matter, we herewith respectfully request that Key be given an additional twenty-five (25) days within which to request a hearing on the proposed preliminary determination, to and including June 22, 1985. As good cause for the grant of such an extension, Key shows that:

1. There appears to be no disagreement between the Department and Key to this matter.
2. The extension of time is needed to allow the parties to document the agreed upon changes.

I hereby certify that I attempted to reach Bill Thomas of the Bureau of Air Quality Management and Carol Forthman, Assistant General Counsel, unsuccessfully.

Accordingly, I request that you formally extend the time for filing a petition for administrative proceedings regard-

ing Air Construction Permit AC 13-100437 to and including June 22, 1985.

Respectfully submitted,

William H. Green

WHG/gs

cc: Bill Thomas
Carol Forthman, Esquire

Bill
These seem to be the most pertinent communications leading up to request permit

A.F. Gant

R. Quinlan

R.A. Franke

W. Smyth

P. Rothchild

T. Flachmeyer

E. Mittleberg

P. Solazzo (Crawford & Russell)

L. Jack (DERM)

P. Cunninghan (Hopping, Boyd, Green & Sams)

W. Green (Hopping, Boyd, Green & Sams)

Key
Pharmaceuticals,
Inc.

May 24, 1985

Mr. William Thomas
State of Florida Department
of Environmental Regulation
Twin Towers Building
2600 Blair Stone Road
Tallahassee, Florida 32301-8241

RE: Public Notice for Proposed Permit AC 13-100437

Dear Bill:

As prescribed by regulations, the Public Notice for the referenced proposed permit was published in the Legal Notice section of the Miami News. Attached is a copy of that section of the Thursday, May 23, 1985 paper. Therefore, the public comment period will extend from May 23 to June 22, 1985.

Note that the wording in the first two paragraphs of the Public Notice was changed to indicate that two new fluid bed processors (i.e. No. 2 and No. 3) were to be constructed and permitted. This change was discussed and agreed upon by by Willard Hanks and Lillian Jack of your offices. I still would like a formal revised Public Notice sent from your office.

I understand from Lillian that the final permit barring major comments should be available within two weeks after the end of the comment period. This would mean by July 6, 1985.

If there are any questions, please call me immediately.

Very truly yours,

KEY PHARMACEUTICALS, INC.

Stephen J. Goodstein, Manager
Environmental Engineering and
Waste Management

SJG/db

enclosure

BEST AVAILABLE COPY

The Miami News

A1-16 Legal notice

BID NO. 84-85-78

ADVERTISEMENT FOR BIDS

Sealed bids for S.W. 7 STREET SIDEWALK PROJECT B-4503 will be received by the City Manager and the City Clerk of the City of Miami, Florida at 11:00 a.m. on the 13th day of June, 1985, in the City Clerk's Office, first floor of the Miami City Hall, 3500 Pan American Drive, Dinner Key, Miami, Florida 33133, at which time and place they will be publicly opened and read.

Briefly, the projects will consist of constructing decorative brick sidewalks on S.W. 7 Street between 12 Avenue and S.W. 17 Avenues. Construction will include the installation of the brick pavers, brick paver sand base and concrete borders around utility castings.

The engineer's estimate for this project is $165,000.

New requirements will allow the successful low bidder to submit a performance bond in accordance with Resolution No. 84-423, and a bid bond in accordance with Resolution No. 84-873.

For technical questions regarding the plans and specifications please contact William A. Mackey, P.E., Highway Design Engineer at (305) 579-6865.

All bids shall be submitted in accordance with the Instructions to Bidders and Specifications. Plans and specifications may be obtained from the office of the Director, Department of Public Works, 275 N.W. 2 Street, (4th floor), Miami, Florida, on or after May 23, 1985 with a $20 deposit for each set. Deposits will be refunded only upon return of plans and specifications, unmarked and in good condition, within two (2) weeks after the opening of the bids.

Prospective bidders are alerted to the provisions of Ordinance No. 9775 regarding allocation of contracts to minority vendors. Those minority or target area contractors/small businesses interested in submitting bids are advised to contact Contractors Training & Development, Inc. 5800 N.W. 7 Avenue, Suite 212, telephone (305) 754-4903 or Allied Black Contractors Association, Inc., 5535 N.W. 7 Avenue, telephone (305) 758-4554, if they require assistance in preparing their bid packages.

Proposal includes the time of performance, and specifications contain provisions for liquidated damages for failure to complete the work on time.

The City Commission reserves the right to waive any informality in any bid, and the City Manager may reject any or all bids and readvertise. (B-4503, Req. [illegible])

Sergio Pereira
City Manager

May 23, 1985
AD. NO. 356-707N

NOTICE OF SPECIAL ELECTION

Pursuant to Resolution No. R-490-85, adopted by the Board of County Commissioners of Dade County, Florida, on April 16, 1985, and in accordance with Section 18-3 (f), of the Code of Metropolitan Dade County, Florida, as amended, notice is hereby given of a special election in the proposed "NW 37 Court Water Improvement Special Taxing District" on June 25, 1985, for the purpose of submitting to the qualified electors residing in the district, for their approval or disapproval, Ordinance No. 85-28 creating and establishing said district pursuant to Section 18-3 (f), Code of Metropolitan Dade County, Florida.

The question shall appear on the ballot in substantially the following form:

A special taxing district known and designated as the "NW 37 Court Water Improvement Special Taxing District" shall be created and established as provided for in County Ordinance No. 85-28.

For Creation of Special Taxing District

Against Creation of Special Taxing District

Mailed ballots, in the same

A1-16 Legal notice

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

The Department of Environmental Regulation gives notice of its intent to issue a permit to Ivax Pharmaceuticals, Inc. to authorize construction of No. 2 and No. 3 fluidized bed coating units for a new product. The No. 2 and No. 3 Fluid Bed Coating Units are a new addition to the intermediate processing of tablets at the facility. The maximum input rate is 277.2 lb/hr per unit. The new product will utilize fluid bed coating units No. 1, No. 2, and No. 3. The unit has a dust collector system and a high efficiency absorber column for control of emissions. This addition will not have a significant increase of VOC or particulate matter. A determination of best available control technology (BACT) was not required.

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

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

The application, technical evaluation, and Department's intent for the proposed project are available for public inspection during normal business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays, at:

Dept. of Environmental Regulation, Southeast Florida District, 3301 Gun Club Road, P.O. Box 3858, West Palm Beach, Florida 33402

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

Dade County Department of Environmental Resources Management, 909 Southeast 1st Avenue, Brickell Plaza, Miami, Florida 33131

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

May 23, 1985

A1-16 Legal notice

LEGAL ADVERTISEMENT
BID NO. 84-85-60

Sealed bids will be received by the City Manager and City Clerk of the City of Miami, Florida not later than 2:30 P.M. June 5, 1985 for furnishing Computer Tapes to the Department of Computers.

Ordinance No. 9775 established a goal of Awarding 50% of the City's total dollar volume of all expenditures for All Goods and Services to Black and Hispanic Minority Business Enterprises on an equal basis.

Minority Vendors who are interested in submitting bids and who are not registered with the City as minority vendors are advised to contact the City Purchasing Office, 1145 N.W. 11th Street, Room 126, Telephone 579-6380.

Detailed specifications for the bid are available upon request at the City Purchasing Office.

The City Manager may reject all bids and readvertise.

(Ad No. 2282)

Sergio Pereira
City Manager

May 23, 1985
AD. NO. 356-706N

NOTICE OF SPECIAL ELECTION

Pursuant to Resolution No. R-646-85, adopted by the Board of County Commissioners of Dade County, Florida, on May 21, 1985, and in accordance with Section 18-3 (f), of the Code of Metropolitan Dade County, Florida, as amended, notice is hereby given of a special election in the proposed "Gem Homes Street Lighting Improvement Special Taxing District" on June 25, 1985, for the purpose of submitting to the qualified electors residing in the district, for their approval or disapproval, Ordinance No. 85-35 creating and establishing said district pursuant to Section 18-3 (f), Code of Metropolitan Dade County, Florida.

The question shall appear on the ballot in substantially the following form:

A special taxing district known and designated as the "Gem Homes Street Lighting Improvement Special Taxing District" shall be created and established as provided for in County Ordinance No. 85-35.

For Creation of Special Taxing District

Against Creation of Special Taxing District

Mailed ballots, in the same form as prescribed by the Florida Election Code, shall be used in this special election. All marked ballots must be received by 7:00 p.m. on the day of said election. All registered electors residing within the proposed district may vote for or against the creation of said special taxing district.

This special election shall be held and conducted in accordance with the applicable provisions of general law relating to special elections and the provisions of the Dade County Home Rule Charter.

David C. Leahy
Supervisor of Elections
Metropolitan Dade County, Florida

May 23, 1985
AD. NO. 356-717N

NOTICE OF SPECIAL ELECTION

Pursuant to Resolution No. R-489-84, adopted by the Board of County Commissioners of Dade County, Florida, on May 21, 1985, and in accordance with Section 18-3 (f), of the Code of Metropolitan Dade County, Florida, as amended, notice is hereby given of a special election in the proposed "NW 39 Court Water Improvement Special Taxing District" on June 25, 1985, for the purpose of submitting to the qualified electors residing in the district, for their approval or disapproval, Ordinance No. 85-27 creating and establishing said district pursuant to Section 18-3 (f), Code of Metropolitan Dade County, Florida.

The question shall appear on the ballot in substantial-

A1-16 Legal notice

MAY 7, 1985

To The Creditors of A & G DISCOUNT SHOE CORP., 1072 S.W. 8th Street, Miami, Florida. Please be advised that on May 7, 1985, A & G DISCOUNT SHOE CORP., executed to me, by way of an Assignment, all of its right, title and interest to its assets, for the benefits of its creditors. Additionally, all debt has been assigned for purpose of settlement. Creditors will be advised as to the method of perfecting their rights. Vincent Logino, Assignee, 1250 West Ave., 9C, Miami Beach, Florida 33139, 305-538-5792

May 23, 30, June 6, 1985
Ad No. 356-682N

ADVERTISEMENT FOR BIDS
DADE COUNTY, FLORIDA

Sealed bids for a Project known and identified as "Installation of 24-Inch Water Main in 49 Ave. and 45 Ave. From S.W. 8 St. To Comfort Canal, Contract No. 515-A", will be received by the Miami-Dade Water and Sewer Authority Department, Room 212 Main Office, 3575 South LeJeune Road, Miami, Florida, until 2:00 P.M. Local Time, June 20, 1985 at which time the bids will be transferred to Room 100 (Meeting Room, First Floor) where they will be publicly opened and read aloud. Any bid received after 2:00 P.M. will not be considered. The mailing address of the Miami-Dade Water and Sewer Authority Department is P.O. Box 330316, Miami, Florida 33233-0316.

The Project consists of installing approximately 7,900 feet of 24-inch ductile iron water main and appurtenances in the City of Miami, Dade County, Florida.

Sets of the Contract Documents are open to public inspection and may be obtained at the Specifications of the Miami-Dade Water and Sewer Authority Department at 3575 South LeJeune Road (2 blocks south of U.S. Highway 1), Miami, Florida. A deposit of Twenty-five Dollars ($25.00), in the form of check or money order made payable to the Miami-Dade Water and Sewer Authority Department, will be required for each set of Contract Documents. A refund of such deposit will be made to the successful bidder and to others upon the return of all documents in good condition, to the above address, within thirty (30) days after the bid opening date, after which time all remaining checks and money orders will be deposited in the General Fund of the Miami-Dade Water and Sewer Authority Department.

All bids must be submitted in sealed envelopes bearing on the outside the name of the Bidder, his address, the name and number of the project for which the bid is submitted, and the date of opening.

The Proposal shall be accompanied by bid security in an amount not less than five percent (5%) of the bid amount. Said security shall be in the form of a certified check or cashier's check on a solvent national or state bank, or a Bid Bond executed by the Bidder and a qualified Surety, satisfactory and payable to the Miami-Dade Water and Sewer Authority Department.

No Bidder may withdraw his bid within ninety (90) days after date set for the opening thereof.

The Board of County Commissioners, Dade County, Florida, reserves the right to reject any or all bids, to waive any informality in any bid or to readvertise for bids. Bids from any person, firm or Corporation in default on other contracts or agreements with the County may be rejected. Failure by the Bidder to satisfy claims on previous contracts with the County may be cause for rejection of his bid.

Garrett Sloan,
Director
Miami-Dade Water and Sewer Authority Department
Metropolitan Dade

A. ANNOUNCEMENT

A1 ANNOUNCEMENT

A1-19 Legal Services

SIMPLE DIVORCE $4[illegible] costs, Immigration 552-[illegible]

FREE CONSULTAT[illegible] Divorce-Immigration-[illegible] Atty. J. Mufson 858-[illegible]

When You need a law[illegible] Attorney 687-4180

Lawyers you CAN aff[illegible] 653-3030, Brwd 458-0[illegible]

DIVORCE CENTER
Personal Service Fee F[illegible] Atty B N Crown 687-39[illegible]

DIVORCE attorneys Miami, S. Miami 823-3[illegible]

DIVORCE, Wills, P[illegible] lem Solver, Ken 573-50[illegible]

SOCIAL SECURIT[illegible]
DISABILITY CLAIMS
Former Social Secur[illegible] Judge Is Available F[illegible] Representation In Yo[illegible] Disability Benefit Cla[illegible]
Free Consultation
LAW OFFICES
LYLE D. LIEBERMA[illegible]
Dade 358-0115
Brwd 524-5113
Palm Beach 655-859[illegible]

IMMIGRATION LAW
MIKE LEVINE ATT[illegible]
24 HRS 653-[illegible]

IMMIGRATION
For free consultation [illegible] G. Ramani 374-4340

A1-35 Fictitious Names

AIR Conditioning En[illegible] Services, Inc. Dba AC[illegible] 5353 nw 36 st Mia fl

PANAMA Jaks 2957 [illegible] 79 St Mia, FL E. M[illegible] Pres

HEALTH-CARE M[illegible] graphics Services Inc [illegible] HMS Corp. 7940 NW 66 [illegible]

Golfing Secu[illegible] Clearinghouse, 6161 Su[illegible] Dr. [illegible] C, South Mi[illegible] Fl 33143, Norman R. [illegible] tom

STAR Seafood Dist [illegible] SW 138 Ct Nelson Garci[illegible]

BASSETT Construc[illegible] Co. 2491 SW 27 Lane, [illegible] Fl 33133, George L. Bas[illegible]

Ultimate Connection[illegible] 10370 SW 200 St., Mi[illegible] M. Hitchcock, C. Mur[illegible]

A1-41 Lost and Found

LOST Pinecrest [illegible] Rottweiler 858-9680 [illegible] 667-4416 Reward

LOST- South Beach a[illegible] Black/White trim n[illegible] cat, white collar 538-323[illegible]

REWARD male gol[illegible] Lab lost near Falls [illegible] heartbroken 251-3060

LOST Pekingese pu[illegible] tan/black vicinity NE [illegible] Ave 108 St Rew[illegible] 893-3920, 891-1297

REWARD for large bl[illegible] male Labrador, has tea[illegible] ear vicinity NW 132 Av[illegible] 182 St. Work 887-0[illegible] home 821-4954

LOST May 10 NE 11[illegible] & 14 Av gray tiger fem[illegible] cat $50 reward 891-3530

LOST-Blonde Cock[illegible] spaniel "Sparkle" Bro[illegible] collar NE area 5 [illegible] Freshly groomed Rew[illegible] 949-5081

$300 REWARD
White female poodle "G[illegible] ger" lost vicinity 441[illegible] Pembroke Rd Hollyw[illegible] May 13 966-2734 collect

REWARD for contents [illegible] 1983 gray Olds Toron[illegible] taken from NE 134 [illegible] 895-4951

LOST-White Samoyed [illegible] the vic. of SW 72 Ave & [illegible] St Reward Karen 279-6[illegible] 358-2000

LOST Great Dane Bl[illegible] & white Male Area of N[illegible]

Key
Pharmaceuticals,
Inc.

DER

MAY 28 1985

BAQM

May 24, 1985

Mr. William Thomas
State of Florida Department
of Environmental Regulation
Twin Towers Building
2600 Blair Stone Road
Tallahassee, Florida 32301-8241

RE: Public Notice for Proposed Permit AC 13-100437

Dear Bill:

As prescribed by regulations, the Public Notice for the referenced proposed permit was published in the Legal Notice section of the Miami News. Attached is a copy of that section of the Thursday, May 23, 1985 paper. Therefore, the public comment period will extend from May 23 to June 22, 1985.

Note that the wording in the first two paragraphs of the Public Notice was changed to indicate that two new fluid bed processors (i.e. No. 2 and No. 3) were to be constructed and permitted. This change was discussed and agreed upon by by Willard Hanks and Lillian Jack of your offices. I still would like a formal revised Public Notice sent from your office.

I understand from Lillian that the final permit barring major comments should be available within two weeks after the end of the comment period. This would mean by July 6, 1985.

If there are any questions, please call me immediately.

Very truly yours,

KEY PHARMACEUTICALS, INC.

Stephen J. Goodstein, Manager
Environmental Engineering and
Waste Management

SJG/db

enclosure

5/29

We mailed them a 2nd revised public notice on 5/22 - the one they published

Patty

Cable Address: KEYPHARM 50 N.W. 176th St., P.O. Box 693670, Miami, Florida 33169-0670 Telephone (305) 652-2276 Telex: 808044

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

The Department of Environmental Regulation gives notice of its intent to issue a permit to Key Pharmaceuticals, Inc. to authorize construction of No. 2 and No. 3 fluidized bed coating units for a new product.

The No. 2 and No. 3 Fluid Bed Coating Units are a new addition to the intermediate processing of tablets at the facility. The maximum input rate is 277.2 lb/hr per unit. The new product will utilize fluid bed coating units No. 1, No. 2, and No. 3. The unit has a dust collector system and a high efficiency absorber column for control of emissions. This addition will not have a significant increase of VOC or particulate matter. A determination of best available control technology (BACT) was not required.

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

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

The application, technical evaluation, and Department's Intent for the proposed project are available for public inspection during normal business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays, at:

Dept. of Environmental Regulation, Southeast Florida District, 3301 Gun Club Road, P.O. Box 3858, West Palm Beach, Florida 33402

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

Dade County Department of Environmental Resources Management, 909 Southeast 1st Avenue, Brickell Plaza,, Miami, Florida 33131

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

May 23, 1985
AD. NO. 356-711N

NOTICE OF
ARREST AND SEIZURE
UNITED STATES
DISTRICT COURT

DER
MAY 28 1985
BAQM
4C

Clas

A1-65 Travel O

rtising

Thursday, May 23, 1985

09 Rent Apt Condos
39 Area Of Miami Shores
Biscayne Park El Portal

D2-11 Rent Apts-Condos

No. 0155561

RECEIPT FOR CERTIFIED MAIL

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

SENT TO
Mr. Allen F. Gant

STREET AND NO.

P.O., STATE AND ZIP CODE

POSTAGE			$
CONSULT POSTMASTER FOR FEES	CERTIFIED FEE		¢
	OPTIONAL SERVICES	SPECIAL DELIVERY	¢
		RESTRICTED DELIVERY	¢
		RETURN RECEIPT SERVICE — SHOW TO WHOM AND DATE DELIVERED	¢
		RETURN RECEIPT SERVICE — SHOW TO WHOM, DATE, AND ADDRESS OF DELIVERY	¢
		RETURN RECEIPT SERVICE — SHOW TO WHOM AND DATE DELIVERED WITH RESTRICTED DELIVERY	¢
		RETURN RECEIPT SERVICE — SHOW TO WHOM, DATE AND ADDRESS OF DELIVERY WITH RESTRICTED DELIVERY	¢
TOTAL POSTAGE AND FEES			$

POSTMARK OR DATE
5/22/85

PS Form 3800, Apr. 1976

PS Form 3811, July 1983

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

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

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

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

4. Type of Service:	Article Number
☐ Registered ☐ Insured XX Certified ☐ COD ☐ Express Mail	0155561

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature — Addressee
X

6. Signature — Agent
X

7. Date of Delivery
MAY

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

DOMESTIC RETURN RECEIPT

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

May 21, 1985

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

Dear Mr. Gant:

Please find enclosed the revised Notice of Proposed Agency Action. The revision concurs with Mr. Steve Goodstein's telephone conversation on May 21, 1985.

Please substitute this notice for the previous notice of proposed agency action.

Sincerely,

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

CHF/LJ/s

Attachments

cc: Art Bolivar
Roy Duke
Isidore Goldman
Marvin F. Nathan
Bill Voshell

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

The Department of Environmental Regulation gives notice of its intent to issue a permit to Key Pharmaceuticals, Inc. to authorize construction of No. 2 and No. 3 fluidized bed coating unit for a new product.

The No. 2 and No. 3 Fluid Bed Coating Units are new additions to the intermediate processing of tablets at the facility. The maximum input rate is 277.2 lb/hr per unit. The new product will utilize fluid bed coating units No. 1, No. 2, and No. 3. The unit has a dust collector system and a high efficiency absorber column for control of emissions. This addition will not have a significant increase of VOC or particulate matter. A determination of best available control technology (BACT) was not required.

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

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

The application, technical evaluation, and Department's Intent for the proposed project are available for public inspection during normal business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays, at:

Dept. of Environmental Regulation
Southeast Florida District
3301 Gun Club Road
P.O. Box 3858
West Palm Beach, Florida 33402

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

Dade County Department of
Environmental Resources Management
909 Southeast 1st Avenue
Brickell Plaza
Miami, Florida 33131

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

No. 0155559

RECEIPT FOR CERTIFIED MAIL

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

SENT TO
Mr. Allen F. Gant
STREET AND NO.
P.O., STATE AND ZIP CODE

POSTAGE		$
CONSULT POSTMASTER FOR FEES — OPTIONAL SERVICES: CERTIFIED FEE		¢
SPECIAL DELIVERY		¢
RESTRICTED DELIVERY		¢
RETURN RECEIPT SERVICE: SHOW TO WHOM AND DATE DELIVERED		¢
SHOW TO WHOM, DATE, AND ADDRESS OF DELIVERY		¢
SHOW TO WHOM AND DATE DELIVERED WITH RESTRICTED DELIVERY		¢
SHOW TO WHOM, DATE AND ADDRESS OF DELIVERY WITH RESTRICTED DELIVERY		¢
TOTAL POSTAGE AND FEES		$

POSTMARK OR DATE

5/17/85

PS Form 3800, Apr. 1976

PS Form 3811, July 1983

DOMESTIC RETURN RECEIPT

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

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

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

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

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

Article Number
0155559

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature — Addressee
X Kathy Frasi

6. Signature — Agent
X

7. Date of Delivery
5-20-85

FT. LAUDERDALE, FLA. MAY 20 1985

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

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

May ~~16~~ 21, 1985

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

Dear Mr. Gant:

Please find enclosed the revised Notice of Proposed Agency Action. The revision concurs with Mr. Steve Goldstein's telephone conversation on May ~~14~~ 21, 1985.

Please substitute this notice for the previous notice of proposed agency action.

Sincerely,

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

CHF/LJ/s

Attachments

cc: Art Bolivar
Roy Duke
Isidore Goldman
Marvin F. Nathan
Bill Voshell

Steve Hoolstein
Told to publish
as received.
Requested written
confirmation

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

The Department of Environmental Regulation gives notice of its intent to issue a permit to Key Pharmaceuticals, Inc. to authorize construction of No. 2 fluidized bed coating units for a new product.

The No. 2 Fluid Bed Coating Units are new additions to the intermediate processing of tablets at the facility. The maximum input rate is 277.2 lb/hr per unit. The new product will utilize fluid bed coating units No. 1, No. 2, and No. 3. The unit has a dust collector system and a high efficiency absorber column for control of emissions. This addition will not have a significant increase of VOC or particulate matter. A determination of best available control technology (BACT) was not required.

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

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

The application, technical evaluation, and Department's Intent for the proposed project are available for public inspection during normal business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays, at:

Dept. of Environmental Regulation
Southeast Florida District
3301 Gun Club Road
P.O. Box 3858
West Palm Beach, Florida 33402

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

Dade County Department of
Environmental Resources Management
909 Southeast 1st Avenue
Brickell Plaza
Miami, Florida 33131

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

Key
Pharmaceuticals,
Inc.

May 16, 1985

Mr. William Thomas
State of Florida
Department of Environmental Regulation
Twin Towers Building
2600 Blair Stone Road
Tallahassee, Florida 32301-8241

RE: PROPOSED PERMIT AC 13-100437

Dear Bill:

As we discussed, there are several discrepancies in the documents sent to Mr. Allen F. Gant of Key Pharmaceuticals, Inc. concerning Key Pharmaceutical's, Inc. permit to construct Glatt No. 2 and No. 3. The majority of which stem from the fact that Key intends to operate all three Glatts (i.e. No.'s 1, 2, and 3) at the same time. The permit present response is written as an "or" situation. Taking each item separately, the following are my comments:

1. Letter to be published:

   (A) Page 1, Paragraph 1

   Authorization for construction is for No. 2 and No. 3 Glatts. Glatt No. 3 is to be installed sometime in 1986 based on present marketing requirements.

   (B) Page 1, Paragraph 2

   Both Glatt No.'s 2 and 3 are additions to the intermediate processing of tablets at this facility. The maximum input rate of 277.2 lb/hr is for one Glatt. Therefore, the maximum for three Glatts (No.'s 1, 2, and 3) is three times 277.2 or 831.6 lb/hr.

2. Intent to Issue:

   (A) Page 1, Paragraph 2

   Construct No. 2 and No. 3 Fluidized Bed Coating Units as new additions. No. 3 (new - not existing).

   (B) Page 2, Paragraph 1

   Key requests operation of any or all of Glatt No.'s 1, 2, and 3 in any combination whatsoever.

Cable Address: KEYPHARM 50 N.W. 176th St., P.O. Box 693670, Miami, Florida 33169-0670 Telephone (305) 652-2276 Telex: 808044

3. Technical Evaluation and Preliminary Determination:

(A) Cover Page

for Glatt No.'s 2 and 3

(B) Page (i), Paragraph 1

Authorize construction of Glatt No.'s 2 and 3.

(C) Page (i), Paragraph 2

No.'s 2 and 3 Fluid Bed Coating Units are an addition to the intermediate processing of tablets at the facility. Maximum input rate is 277.2 lb/hr/Glatt, or 831.6 lb/hr for all three Glatts.

(D) Page (iv), Project Description

Section "B", Paragraph 2

Construction permit is for two Fluid Bed Coating Units designated No. 2 and No. 3. The addition of No. 2 and No. 3 Units will not have a significant net increase of VOC or particulate matter. The new product will be made in any combination whatsoever of No. 1, 2 and 3 Fluid Bed Processors.

Section "C", Paragraph 2

The Fluid Bed Coating Units No.'s 1, 2, and 3 designed and fabricated by Glatt (Glatt Air Techniques, Inc. is the American marketing arm) are engineered to efficiently coat discrete particles.

Section "C", Paragraph 3

The vessel is for mixing only, not reacting.

Section "C", Paragraph 4

It is a Fluid Bed Coater/Granulator.

(E) Page (v)

Section "C", Paragraph 8

The activated sludge system reduces Methanol to 25 to 100 ppm in the water recycled to the Scrubber.

Section "C", Paragraph 9

The Scrubber will be manufactured by Munters in Ft. Meyers, Florida and be 7 ft in diameter and contain 11 ft of Plasdek 12060 (Polypropylene) packing manufactured by Munters.

Section 2, Paragraph 1

For construction of No. 2 and No. 3 Fluid Bed Coating Units.

(F) Page (v)

Section II, Paragraph 1

Construction of No. 2 and No. 3 Fluid Bed Coating Units to make a new product in any or all of the existing No. 1 or No. 2 and No. 3 Units.

(G) Page (vi)

Section III

Summary of emissions are based on output from all three Fluid Bed Coating Units not just one running 350 lots/year/unit or 1050 lots/year in total. The following addition of of emissions will result with the addition of No. 2 and No. 3 Fluid Bed Coating Units to the existing No. 1 Unit in the manufacture of the new product.

Section IV, Paragraph 1

Addition of No. 2 and No. 3 and use of all three Units can be approved without causing any violations of the air pollution regulations.

Section IV, Paragraph 2

Construction of No. 2 and No. 3 Units.

4. Draft Permit:

(A) Page 1, Paragraph 2

Installation is for No. 2 and No. 3 Fluid Bed Coating Units each with a maximum input rate of 277.2 lb/hr for a total maximum of 831.6 lb/hr.

(B) Page 1, Paragraph 4

Construction and operation is for No. 2 and No. 3 Glatts.

(C) Specific Conditions, Page 5, No. 1

Glatt No.'s 1 and No. 2 shall not be operated more than 90 days. Combined emissions from Glatt No.'s 1, 2, and 3 before and after installation of PCD's shall not exceed 40 tons/year of VOC.

No. 3. The input rate to Glatt No.'s 1, 2, and 3 shall not exceed 831.6 lb/hr in total.

Please note that in all correspondence including the permit application, the numbers generated were for three Glatts operating simultaneously or in any combination whatsoever. There will be times when none, one, two, or three Units will be operating at the same time.

Please amend the aforementioned documents. If there are any questions, please call.

Very truly yours,

KEY PHARMACEUTICALS, INC.

Stephen J. Goodstein, Manager
Environmental Engineering and
Waste Management

SJG/db

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

May 13, 1985

Mr. Isidore Goldman
3301 Gun Club Road
P. O. Box 3858
West Palm Beach, Florida 33402

Dear Mr. Goldman:

Thank you for your comments regarding Key Pharmaceutical's Construction permit AC 13-091497.

As agreed, Specific Condition No. 4 can be clarified by the following statement.

... the Glatt No. 2 shall not exceed 0.3 lb/hr; 1.3 25.9 ton/yr emission, if source operated without control; or 5% opacity.

We will keep a record of this clarification in our files.

Sincerely,

Lillian Jack

Lillian Jack
Engineer
Bureau of Air Quality
Management

LJ/ks

cc: B. Thomas

No. 0155558

RECEIPT FOR CERTIFIED MAIL

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

SENT TO: Mr. Allen F. Gant	
STREET AND NO.	
P.O., STATE AND ZIP CODE	
POSTAGE	$
CERTIFIED FEE	¢
SPECIAL DELIVERY	¢
RESTRICTED DELIVERY	¢
RETURN RECEIPT SERVICE: SHOW TO WHOM AND DATE DELIVERED	¢
RETURN RECEIPT SERVICE: SHOW TO WHOM, DATE, AND ADDRESS OF DELIVERY	¢
RETURN RECEIPT SERVICE: SHOW TO WHOM AND DATE DELIVERED WITH RESTRICTED DELIVERY	¢
RETURN RECEIPT SERVICE: SHOW TO WHOM, DATE AND ADDRESS OF DELIVERY WITH RESTRICTED DELIVERY	¢
TOTAL POSTAGE AND FEES	$
POSTMARK OR DATE: 5/10/85	

CONSULT POSTMASTER FOR FEES
OPTIONAL SERVICES

PS Form 3800, Apr. 1976

PS Form 3811, July 1983

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

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

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

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

4. Type of Service:	Article Number
☐ Registered ☐ Insured XX Certified ☐ COD ☐ Express Mail	0155558

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature – Addressee
X

6. Signature – Agent
X Robert Rose

7. Date of Delivery 5-13-85

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

DOMESTIC RETURN RECEIPT

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

May 10, 1985

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

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

Dear Mr. Gant:

Attached is one copy of the Technical Evaluation and Preliminary Determination, and proposed permit to construct the No. 2 Fluid Bed Coating Unit for a new product that is to be made in any of the Fluid Bed Units. The existing units are No. 1 and No. 3, and the new unit is designated No. 2. The proposed permit is for the Miami, Dade County, facility.

Before final action can be taken on your draft permit, you are required by Florida Administrative Code Rule 17-103.150 to publish the attached Notice of Proposed Agency Action in the legal advertising section of a newspaper of general circulation in Dade County no later than fourteen days after receipt of this letter. The department must be provided with proof of publication within seven days of the date the notice is published. Failure to publish the notice may be grounds for denial of the permit.

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/rw
Attachments
cc: Art Bolivar
Isidore Goldman
Marvin F. Nathan
Bill Voshell

BEFORE THE STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

In the Matter of an Application for Permit by	)	
Key Pharmaceuticals, Inc. 50 NW 176th Street Miami, Florida 33619	)	DER File No. AC 13-100437

INTENT TO ISSUE

The Department of Environmental Regulation hereby gives notice of its Intent to Issue, and proposed order of issuance for, a permit pursuant to Chapter 403, Florida Statutes, 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, applied on March 1, 1985, to the Department of Environmental Regulation for a permit to construct the No. 2 Fluidized Bed Coating Unit as a new addition to the intermediate processing of tablets at the facility. This application is for a new product that is to be made in any of the three Fluid Bed Units designated as No. 1 (existing), No. 2 (new), and No. 3 (existing).

The information supplied by meeting on February 27, 1985 with Key Pharmaceutical staff members and Mr. Marvin F. Nathan of Crawford & Russell, Inc. and additional information supplied by Mr. Marvin F. Nathan in his March 6, 1985 letter, received March 7th, and Mr. Stephen J. Goodstein's letter of April 3, 1985, received April 4th, completed the application so that it could be processed by the department.

Information submitted by the company for the new product requests the operation of the No. 2 Fluidized Bed Coating Unit and a choice of using any one but not all of the other Fluidized Bed Coating Unit No. 1 or No. 3. The operation will not exceed significant emission increases and will comply with all federal and state air pollution control regulations and consent order OGC Case No. 84-0644.

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 applicant was officially notified by the Department that an air construction permit was required for the proposed work.

This intent to issue shall be placed before the Secretary for final action unless an appropriate petition for a hearing pursuant to the provisions of Section 120.57, Florida Statutes, is filed within fourteen (14) days from receipt of this letter or publication of the public notice (copy attached) required pursuant to Rule 17-103.150, Florida Administrative Code, whichever occurs first. The petition must comply with the requirements of Section 17-103.155 and Rule 28-5.201, Florida Administrative Code (copy attached) and be filed pursuant to Rule 17-103.155(1) in the Office of General Counsel of the Department of Environmental Regulation at 2600 Blair Stone Road, Tallahassee, Florida 32301.

Petitions which are not filed in accordance with the above provisions are subject to dismissal by the Department. In the event a formal hearing is conducted pursuant to Section 120.57(1), all parties shall have opportunity to respond, to present evidence and argument on all issues involved, to conduct cross-examination of witness and submit rebuttal evidence, to submit proposed findings of facts and orders, to file exceptions to any order or hearing officer's recommended order, and to be represented by counsel. If an informal hearing is requested, the

agency, in accordance with its rules of procedure, will provide affected persons or parties or their counsel an opportunity, at a convenient time and place, to present to the agency or hearing officer, written or oral evidence in opposition to the agency's action or refusal to act, or a written statement challenging the grounds upon which the agency has chosen to justify its action or inaction, pursuant to Section 120.57(2), Florida Statutes.

If a petition is filed, the administrative hearing process is designed to formulate agency action. Accordingly, the Department's final action may be different from the proposed agency action. Therefore, persons who may not wish to file a petition, may wish to intervene in the proceeding. A petition for intervention must be filed pursuant to Model Rule 28-5.207 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, 2009 Apalachee Parkway, Tallahassee, Florida 32301. If no hearing officer has been assigned, the petition is to be filed with the Department's Office of General Counsel, 2600 Blair Stone Road, Tallahassee, Florida 32301. Failure to petition to intervene within the allowed time frame constitutes a waiver of any right such person has to request a hearing under Section 120.57, Florida Statutes.

Executed the 10 day of MAY, 1985, 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:
Allen F. Gant
Art Bolivar
Isadore Goldman
Marvin F. Nathan
Bill Voshell

CERTIFICATION

This is to certify that the foregoing Intent to Issue and all copies were mailed before the close of business on 10 MAY, 1985.

C. H. Fancy, P.E.
Deputy Chief
Bureau of Air Quality
Management
2600 Blair Stone Road
Tallahassee, Florida 32301

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

May 10, 1985 — Date

Technical Evaluation
and
Preliminary Determination

Key Pharmaceuticals, Inc.
No. 2 Fluidized Bed Coating Unit
New Product

Miami, Dade County, Florida

Proposed Permit Number: AC 13-100437

Florida Department of Environmental Regulation

Bureau of Air Quality Management

Central Air Permitting

May 10, 1985

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

The Department of Environmental Regulation gives notice of its intent to issue a permit to Key Pharmaceuticals, Inc. to authorize construction of No. 2 fluidized bed coating unit for a new product.

The No. 2 Fluid Bed Coating Unit is a new addition to the intermediate processing of tablets at the facility. The maximum input rate is 277.2 lb/hr. The unit has a dust collector system and a high efficiency absorber column for control of emissions. This addition will not have a significant increase of VOC or particulate matter. A determination of best available control technology (BACT) was not required.

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

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

The application, technical evaluation, and Department's Intent for the proposed project are available for public inspection during normal business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays, at:

Dept. of Environmental Regulation
Southeast Florida District
3301 Gun Club Road
P.O. Box 3858
West Palm Beach, Florida 33402

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

Dade County Department of
Environmental Resources Management
909 Southeast 1st Avenue
Brickell Plaza
Miami, Florida 33131

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

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.

I. PROJECT DESCRIPTION

A. Applicant

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

B. Project and Location

Key Pharmaceuticals, Inc., is operating a pharmaceuticals production facility located in Miami, Dade County, Florida. The facility is bounded on the west by S.R. 441, on the east and south by Interstate Highway 95, and on the north by NW 176th Street.

The company has applied for a construction permit to add a new fluid bed coating unit designated as fluid bed coating unit No. 2. This addition of the unit No. 2 will not have a significant net increase of VOC or particulate matter from the facility. The company's request is to produce a new product and it is to be made in No. 2 or in the existing units of No. 1 and No. 3.

C. Process and Controls

Raw material crystals are added to a fluid bed coating unit. They are fluidized by high volume air flow through the base of the unit. A slurry of excipients in a mixture of methylene chloride and methanol is sprayed onto the fluidized crystals.

The fluid bed coating unit #2 designed and fabricated by Glatt Air Techniques, Inc. is engineered to efficiently agglomerate blended products.

The fluid bed system consists of the reaction vessel, the fluid bed coating unit with air inlet, pocket prefilter, heater, solids loading, solids discharge, air outlet, and dust collection system.

The fluid bed granulator includes a controller and gauge for the inlet air temperature, a gauge for the outlet air temperature, and automatic filter shaking timer with pump controls for automatic operation during shake cycle, pneumatic outlet air flap controller and indicator, and atomization air regulator and indicator.

Each fluid bed processor has a process fan prior to the dust collector. The effluent from the fluid bed unit which is air plus solvents (methylene chloride and methanol) plus entrained dust goes to a dust collector. The air that exits the unit enters the exhaust air filter prior to the air outlet. The dust

collecting system for Glatt uses cartridge type filters manufactured by the Torit Donaldson Co., and it treats large volumes of dust-laden air on a continuing basis. The dust collector has a 99% efficiency, and is actually a second filtering within the fluid bed system.

The effluent from the dust collector goes to one variable flow fan, and then to a packed column water scrubber. The solvent laden air enters the bottom of the column and goes up. The water enters the top of the column going down and absorbs approximately 90% of the methanol and less than 0.5% of the methylene chloride. The air plus remaining solvents is vented to the atmosphere.

The solvent laden water exits the scrubber and goes to an aerobic digester where the remaining methylene chloride is flashed off. The methanol is biologically reduced; and in this process, the water after clarification is recycled to the scrubber.

There is make-up water for evaporation, and no discharge of water to the sewer system. Sludge is removed when solids reach to a high point. The activated sludge system which destroys most of the methanol absorbed is specified to meet 25 ppm methanol in the water recycled to the scrubber.

The scrubber or absorber column is manufactured by Koch Engineering Company. The column has an 8 ft. diameter and has Koch FLEXIPAC® packing. The scrubber will be packed with approximately 10 ft. of regularly structured Koch Flexipac for high efficiency, low pressure and high operating flexibility.

II. RULE APPLICABILITY

State Regulations

The proposed project to construct a No. 2 fluidized bed coating unit for the new product is subject to preconstruction review under the provisions of Chapter 403, FS, and Chapter 17-2, FAC.

The plant site is in an area designated as a non-attainment area for air pollutant ozone (17-2.410(1)(d)), and attainment for the air pollutants particulate matter (PM), sulfur dioxide, carbon monoxide, and nitrogen dioxide (17-2.420).

Presently, Key Pharmaceuticals has engaged in the construction, operation or modification of various pollution sources at its Miami facility without obtaining needed permits from the Department. Such sources that have operated without a permit are: coating pan room No. 1, coating pan room No. 2, coating pan room No. 3, granulation unit No. 1, granulation unit

No. 2, and fluid bed coating No. 1. Since Key Pharmaceuticals is operating under consent order (OGC Case No. 84-0644) and the additional emissions are below significant emission rates (Table 500-2), the department proposes to issue Key Pharmaceuticals, Inc. a permit for construction of the No. 2 Fluid Bed Coating Unit for the new product and to allow flexibility for the company to make the new product in either of the existing units of No. 1 or No. 3. The proposed project is subject to 17-2.520, Reasonably Available Control Technology (RACT) (17-2.650), and the consent order OGC case No. 84-0644.

III. SUMMARY OF EMISSIONS

Key Pharmaceuticals is designated as a major source for volatile organic compounds. The following addition of emissions will result with the addition of the No. 2 Fluid Bed Coating Unit, or the existing No. 1 or No. 3 unit in operation for the new product.

	Emission Max lb/hr	Emission Actual T/yr	Emission Without Control lb/hr	Emission Without Control T/yr
VOC	13.2	19.2		192
PM	.016	.068		6.8
Methylene Chloride	660	978		978

A screening model from Mr. Thomas Rogers, BAQM, indicates that the maximum 1-hour concentration is approximately 4 mg/m^3. The OSHA TLV for short term exposure is 870 mg/m^3. Therefore, it can be assumed that this source should not pose a threat to health.

IV. CONCLUSION

Based on a review of the data submitted by Key Pharmaceuticals, Inc., the department has concluded that the emissions for the addition of the No. 2 fluid bed coating unit and the flexible use of No. 1 or No. 3 can be approved without causing any violations of the air pollution control regulations.

Therefore, the department proposes to issue Key Pharmaceuticals, Inc. a permit for construction of the No. 2 Fluid Bed Coating Unit for the new product. The General and Specific Conditions listed in the proposed permit will assure compliance with all applicable air pollution regulations.

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

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

Permit Number:AC 13-100437
Expiration Date: February 28, 1986
County: Dade
Latitude/Longitude: 25° 56' 04"N/
80° 12' 11"W
Project: No. 2 Fluidized Bed
Coating Unit (New Product)

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 drawings, plans, and other documents attached hereto or on file with the department and made a part hereof and specifically described as follows:

Installation of the No. 2 Fluidized Bed Coating unit for intermediate processing prior to tableting at the facility. The maximum input rate to Glatt No. 2 is 277.2 lb/hr. The unit has a dust collector system and a high efficiency absorber column for control of emissions.

The facility location is bounded on the west by S.R. 441, on the east and south by Interstate Highway 95, and on the north by NW 176th Street in Miami, Dade County, Florida. The UTM coordinates of the site are 17-580.6 east and 2868.5 north.

The construction and operation of the No. 2 Glatt shall be in accordance with the application for permit to construct, submitted by Mr. Allen F. Gant on March 1, 1985, and the additional information provided in Mr. Marvin F. Nathan's March 6, 1985 letter and Mr. Stephen J. Goodstein's April 3, 1985 letter. Key Pharmaceuticals, Inc. must also comply with the terms and conditions of the consent order OGC No. 84-0644 issued.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number:AC 13-100437
Expiration Date: February 28, 1986

GENERAL CONDITIONS:

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

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

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

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

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

GENERAL CONDITIONS:

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

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

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

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

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

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

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

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

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

GENERAL CONDITIONS:

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

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

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

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

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

13. This permit also constitutes:

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

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

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

GENERAL CONDITIONS:

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

c. Records of monitoring information shall include:

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

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

SPECIFIC CONDITIONS:

1. The permittee must satisfy the requirements of consent order OGC case No. 84-0644 or the No. 2 Fluid Bed Coating Unit (Glatt No. 2) shall not be operated. Glatt No. 2 shall not be operated more than 90 days prior to installation of permanent pollution control equipment. Applicant shall provide documentation to the Department demonstrating that total VOC emissions during this 90 day period has not exceeded 10 tons. Combined emissions from Glatt No. 2 before and after the installation of permanent pollution control equipment shall not exceed 40 tons of VOC in any consecutive 12 month period. (consent order OGC case No. 84-0644 15(c) and 15 (d) and (e))

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-100437
Expiration Date: February 28, 1986

SPECIFIC CONDITIONS:

2. The operating hours shall not exceed 8,400 hours per year.

3. The input rate to the Glatt No. 2 or No. 1 or No. 3 shall not exceed 277.2 lb/hr.

4. The Glatt No. 2 or No. 1 or No. 3 opacity test shall meet all applicable requirements of 40 CFR 60, Appendix A, Reference Method 9. Particulate matter emissions from the Glatt No. 2 or No. 1 or No. 3 shall not exceed .016 lb/hr, .068 tons/yr, or 5% opacity.

5. The applicant will demonstrate compliance with the conditions of this construction permit and consent order and submit a complete application for an operating permit to the Southeast District prior to 90 days before the expiration date of this permit. The applicant may continue to operate in compliance with all terms of the consent order and construction permit until its expiration or until issuance of an operating permit.

6. Upon obtaining an operating permit, the applicant will be required to submit annual reports on the actual operation of the facility. These reports will include, as a minimum: the amount of solvents used by inventory control, total hours of operation of the Glatt No. 2 or No. 1 or No. 3, and emission test reports for particulate matter and visible emissions. The initial compliance test should use Method 25 as the acceptance test to verify emission factors for VOC. Inventory control can be used, thereafter, to verify emissions of VOC; however, in case of doubt with the emission factors, the department may request a Reference Method 25, 40 CFR 60, Appendix A.

7. This construction permit, AC 13-100437, will supercede construction permit AC 13-091497. Key Pharmaceuticals has the option of either AC 13-100437 or AC 13-091497, but not both.

Issued this____day of _____, 1985

STATE OF FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATION

_____
VICTORIA J. TSCHINKEL, Secretary

Key
Pharmaceuticals,
Inc.

May 2, 1985

Mr. Thomas A. Tittle
State of Florida
Department of Environmental Regulations
3301 Gun Club Road
Post Office Box 3858
West Palm Beach, Florida 33402

Dear Tom:

This is in response to our phone conversation earlier today relating to our Application to Construct (AC13-100437). As you mentioned, you did not receive a copy of our submitted Dispersion Calculations relating to maximum ground level concentrations of Methylene Chloride. I have attached a copy of the calculations for your review.

As you suggested, responses to your other questions and concerns relating to our Application will be addressed through Bill Thomas' office in Tallahassee.

Again, should you have additional questions or if you would like us to visit your office for a review meeting, please advise.

Sincerely,

KEY PHARMACEUTICALS, INC.

Robert A. Franke, Director
Production Engineering

RAF/db

attachment

DEPARTMENT OF ENVIRONMENTAL REGULATION

ROUTING AND TRANSMITTAL SLIP

ACTION NO

ACTION DUE DATE

1. TO: (NAME, OFFICE, LOCATION) Bill Thomas DER	Initial	
	Date	
2. BAQM MAY 10 1985	Initial	
	Date	
3. Tallahassee BAQM	Initial	
	Date	
4.	Initial	
	Date	

REMARKS:

Key Pharmaceuticals

letter for files

INFORMATION	
	Review & Return
	Review & File
	Initial & Forward

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

FROM: DG

DATE 5/8/85

PHONE

```
C)cd\fortram n

C)7


PTPLU--IMPROVED MODEL FOR SCREENING MAXIMUM CONCENTRATIONS -- VERSION 81035

)))INPUT PARAMETERS(((

***TITLE***
KEY PHARMACEUTICALS, INC.

***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.)

***METEOROLOGY***
AMBIENT AIR TEMPERATURE =   293.00 (K)
MIXING HEIGHT           =  2000.00 (M)
ANEMOMETER HEIGHT       =     7.00 (M)
WIND PROFILE EXPONENTS  = A: .10, B: .15, C: .20
                          D: .25, E: .30, F: .30

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

***SOURCE***
EMISSION RATE =    83.16 (G/SEC)
STACK HEIGHT  =    15.24 (M)
EXIT TEMP.    =   305.00 (K)
EXIT VELOCITY =    19.34 (M/SEC)
STACK DIAM.   =      .76 (M)

)))CALCULATED PARAMETERS(((
```

Max. 1-hr concentration = 4.3 mg/m³
This compares to the OSHA TLV-STEL of 870. mg/m³

DEPARTMENT OF ENVIRONMENTAL REGULATION

ROUTING AND TRANSMITTAL SLIP

ACTION NO

ACTION DUE DATE

	Initial	Date
1. TO: (NAME, OFFICE, LOCATION) Lillian		
2.		
3.		
4.		

REMARKS:

I ran a screening model on the Key Pharmaceutical facility to determine the max. 1-hr ambient concentration. (This model is one step further than the hand calculation performed by the applicant.) The result indicates that the max. 1-hr concentration is approx. 4 mg/m^3. The OSHA TLV for short-term exposure is 870 mg/m^3. Therefore, it can be assumed that this source should not pose a threat to health.

P.S. I have attached the model output.

INFORMATION

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

DISPOSITION

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

FROM: Tom

DATE 5/2/85

PHONE

JOHN BROWN

Crawford & Russell Incorporated

Maximum methylene chloride ground level concentration based on maximum emission of 660 lbs/hr = 2.4 ppm

Average emission of methylene chloride = 978 tons/yr
= 233 lb/hr

Methylene chloride ground level concentration based on average emission

$$\frac{233}{660} \times 2.4 = 0.85 \text{ ppm}$$

Calculation of maximum ground level concentration corresponds to 3 minute sample. Table 5-1, Page 38 of Turner shows relation of 24 hour sample to 3 minute sample resulting from "Increased Meander of Wind Direction"

Sample Time	Ratio of Calculated Concentration to 3 minute concentration
3 minutes	1
24 hours	0.36

24 hr concentration based on average emission of

233 lb/hr = 0.36 x 0.85 = 0.31 ppm (vol)

COMPARISON OF CONCENTRATIONS FOR METHYLENE CHLORIDE

	ppm (vol)
OSHA Standard (29 CFR 1910.1000)	500
TLV of Amer. Conf. Gov. Ind. Hyg. (1981)	100
Odor threshold	150-200
New York State Guideline AAL(1)	0.33
Key 24 hr concentration calculated from average emission of 233.0 lbs/hr	0.31(2)
Key maximum concentration (3 minute) calculated from maximum emission of 660 lbs/hr	2.4

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

(2) In conversation with Bruce Turner of the EPA, he expressed the opinion that annual average ambient concentration at any off-site receptor will be no more than 1/10 of 24 hour concentration of 0.31 ppm, i.e. 0.031 ppm and probably will be considerably less than 0.031 ppm.

KEY PHARMACEUTICALS

METHYLENE CHLORIDE MAXIMUM GROUND LEVEL CONCENTRATION

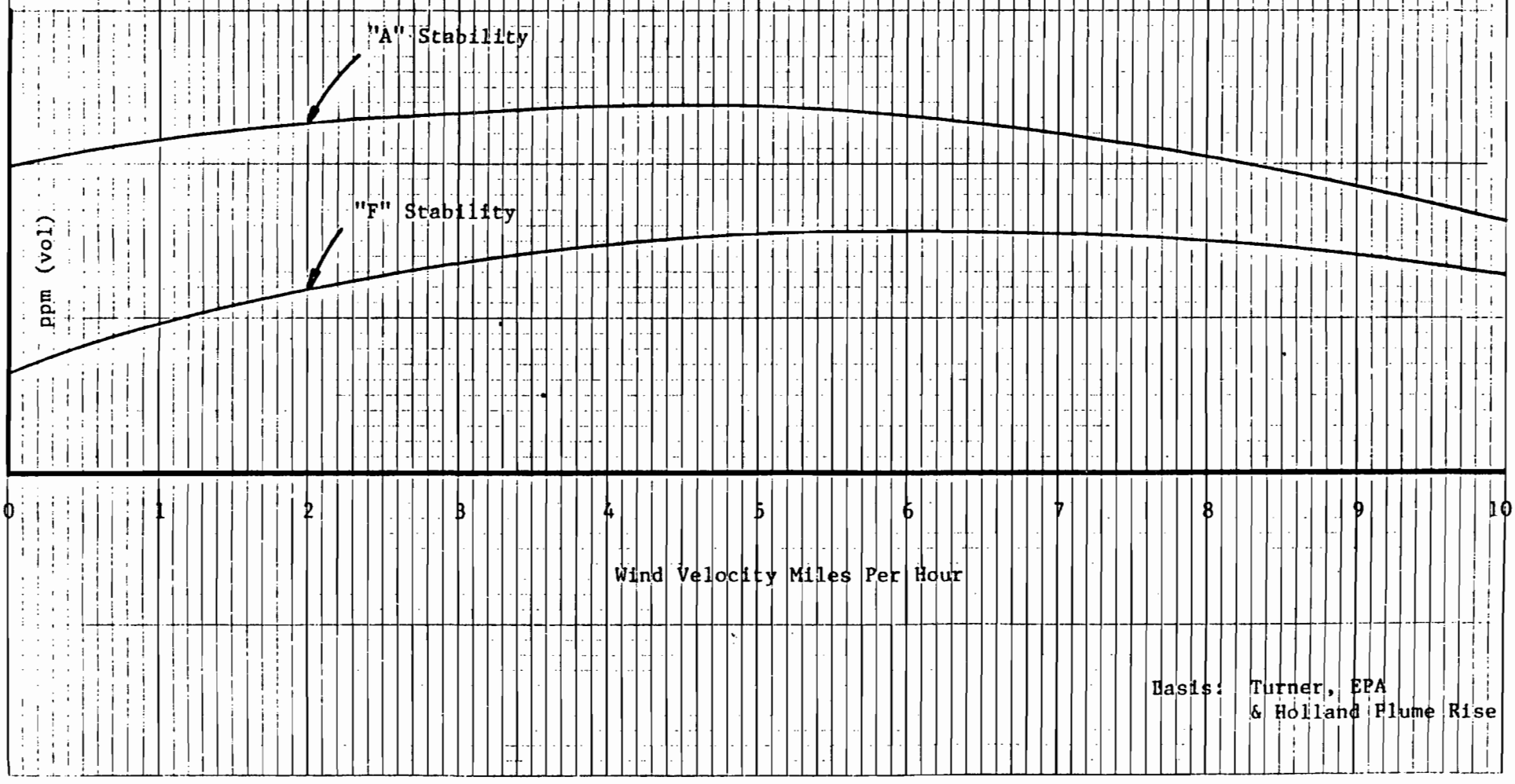
AS FUNCTION OF WIND VELOCITY

Stack Height 50 feet above grade

Stack Exit Velocity 19.34 M/Sec = 63.5 FPS

Stack Exit Temperature 90°F

Maximum Emission Rate of 660 lbs/hr



Basis: Turner, EPA
& Holland Plume Rise

JOHN BROWN

Crawford & Russell Incorporated

Plume Rise - Summer Condition (cont'd)

p = 1013.5 mb
Ts = 90°F = 305.2°K
Ta = 95°F = 308°K

Wind Vel. mph	ΔH M
1	49.15
5	9.83
10	4.92

Maximum Concentration - Distance of Maximum Concentration

$$Q = \frac{660 \text{ lbs/hr} \times 454 \text{ gms/lb}}{3600 \text{ Sec/Hr}} = 83.23 \text{ gms/sec},$$

Xmax = distance of max concentration, kilometers x 0.6214 $\frac{\text{miles}}{\text{kilometer}}$ = miles

u = 1 mph = o.446 M/Sec
5 mph = 2.234 M/Sec
10 mph = 4.47 M/Sec

H = effective height = plume rise plus stack elevation

X = max ground level conc. gms/M^3 x 1000 mg/gm x 0.278 = ppm (vol)

Wind vel. MPH	Stability Class	Effect Height	(Xu) $(Q)_{max}$	X gms/M^3	X ppm(v)	x max Miles
1	F	64.4	1.2×10^{-5}	0.00223	0.622	3.54
1	E	64.4	1.7×10^{-5}	0.00315	0.880	1.80
1	D	64.4	2.0×10^{-5}	0.00372	1.04	1.06
1	C	64.4	3.2×10^{-5}	0.00596	1.65	0.46
1	B	64.4	3.4×10^{-5}	0.00633	1.76	0.36
1	A	64.4	3.7×10^{-5}	0.00713	1.98	0.19
5	F	25.1	1.5×10^{-4}	0.00559	1.55	0.78
5	G	25.1	1.7×10^{-4}	0.00633	1.76	0.44
5	D	25.1	1.85×10^{-4}	0.00689	1.91	0.29
5	C	25.1	2.1×10^{-4}	0.00782	1.17	0.17
5	B	25.1	2.2×10^{-4}	0.00819	2.20	0.11
5	A	25.1	2.3×10^{-4}	0.00856	2.38	0.07
10	F	20.2	2.5×10^{-4}	0.00465	1.29	0.56
10	E	20.2	2.8×10^{-4}	0.00521	1.45	0.33
10	D	20.2	3.1×10^{-4}	0.00576	1.60	0.22
10	C	20.2	3.3×10^{-4}	0.00614	1.71	0.12
10	B	20.2	3.2×10^{-4}	0.00595	1.66	0.09
10	A	20.2	3.15×10^{-4}	0.00586	1.63	0.065

JOHN BROWN
Crawford & Russell Incorporated

Dispersion Calculations: Maximum Ground Level Concentrations of Methylene Chloride

Basis of Calculations: Workbook of Atmospheric Dispersion Estimates, D. Bruce Turner, U.S. Environmental Protection Agency, 1970

Figure 3-9; Maximum Concentrations and Distance of Maximum Concentrations

Page 31; Holland's Equation for Plume Rise (correspondence with Dr. Turner indicates Holland's equation generally is conservative.)

Methylene Chloride Emissions:

Average per Glatt: Tons per year	326
Average for 3 Glatts; Tons per year	978
Maximum for 3 Glatts; lbs per hour	660

Air Flow

Maximum	SCFM @ 70°F	18000

Stack exit elevation above grade; feet	50
Stack diameter; inches	30
Stack exit temperature; °F	90
Air temperature; °F	95
Atmospheric pressure; bar	1.0135
Wind speeds considered; MPH	1, 5, 10

Plume Rise - Summer Condition

Holland's Equation

$$\Delta H = \frac{V_s d}{u}\left(1.5 + 2.68 \times 10^{-3} p \frac{(Ts-Ta)}{Ts} d\right)$$

$$Vs = \frac{18000 \text{ SCFM}}{60 \text{ Sec/Min}} \cdot \frac{550°R}{530°R} \cdot \frac{}{0.785 \times 2.5 \text{ Ft}^2} \times \frac{1}{3.281 \text{ Ft/M}}$$

$$= 19.34 \text{ M/Sec}$$

$$d = \frac{2.5 \text{ Ft}}{3.281 \text{ Ft/M}} = 0.762 \text{ M}$$

u = 1 mph = 0.447 M/Sec

5 mph = 2.234 M/Sec

10 mph = 4.47 M/Sec

VOLUMETRIC FLOW = 8.82 (M**3/SEC)
BUOYANCY FLUX PARAMETER = 1.08 (M**4/SEC**3)

KEY PHARMACEUTICALS, INC.

****WINDS CONSTANT WITH HEIGHT****

STABILITY	WIND SPEED (M/SEC)	MAX CONC (G/CU M)	DIST OF MAX (KM)	PLUME HT (M)
1	1.00	3.5556E-03	.290	59.5
1	1.50	3.8899E-03	.225	44.7
1	2.00	4.0346E-03	.190	37.3
1	2.50	4.0587E-03	.169	32.9
1	3.00	4.0113E-03	.155	30.0

****STACK TOP WINDS (EXTRAPOLATED FROM 7.0 METERS)****

STABILITY	WIND SPEED (M/SEC)	MAX CONC (G/CU M)	DIST OF MAX (KM)	PLUME HT (M)
1	1.08	3.6269E-03	.278	56.1
1	1.62	3.9406E-03	.215	42.5
1	2.16	4.0531E-03	.182	35.7
1	2.70	4.0459E-03	.163	31.6
1	3.24	3.9735E-03	.149	28.9

****WINDS CONSTANT WITH HEIGHT****

STABILITY	WIND SPEED (M/SEC)	MAX CONC (G/CU M)	DIST OF MAX (KM)	PLUME HT (M)
2	1.00	3.8990E-03	.437	59.5
2	1.50	3.7677E-03	.322	44.7
2	2.00	3.9924E-03	.268	37.3
2	2.50	4.0682E-03	.235	32.9
2	3.00	4.0595E-03	.214	30.0
2	4.00	3.9315E-03	.184	26.3
2	5.00	3.7404E-03	.167	24.1

****STACK TOP WINDS (EXTRAPOLATED FROM 7.0 METERS)****

STABILITY	WIND SPEED (M/SEC)	MAX CONC (G/CU M)	DIST OF MAX (KM)	PLUME HT (M)
2	1.12	3.4308E-03	.394	54.6
2	1.69	3.8745E-03	.298	41.5
2	2.25	4.0437E-03	.250	34.9
2	2.81	4.0701E-03	.221	31.0
2	3.37	4.0193E-03	.199	28.4
2	4.50	3.8416E-03	.175	25.1
2	5.62	3.6110E-03	.160	23.1

****WINDS CONSTANT WITH HEIGHT****

STABILITY	WIND SPEED (M/SEC)	MAX CONC (G/CU M)	DIST OF MAX (KM)	PLUME HT (M)
3	1.00	3.2635E-03	.664	59.5
3	1.50	3.8456E-03	.486	44.7
3	2.00	4.1357E-03	.399	37.3
3	2.50	4.2581E-03	.348	32.9
3	3.00	4.2818E-03	.314	30.0
3	4.00	4.1766E-03	.272	26.3
3	5.00	3.9846E-03	.247	24.1
3	7.00	3.5545E-03	.219	21.6
3	10.00	2.9926E-03	.198	19.7
3	12.00	2.6925E-03	.190	18.9
3	15.00	2.3327E-03	.182	18.2

****STACK TOP WINDS (EXTRAPOLATED FROM 7.0 METERS)****

STABILITY	WIND SPEED (M/SEC)	MAX CONC (G/CU M)	DIST OF MAX (KM)	PLUME HT (M)
3	1.17	3.5035E-03	.587	53.1
3	1.75	4.0191E-03	.436	40.5

3	2.34	4.2316E-03	.362	34.2
3	2.92	4.2828E-03	.318	30.4
3	3.51	4.2461E-03	.289	27.9
3	4.67	4.0519E-03	.254	24.7
3	5.84	3.8032E-03	.233	22.8
3	8.18	3.3173E-03	.209	20.6
3	11.68	2.7364E-03	.191	19.0
3	14.02	2.4399E-03	.184	18.4
3	17.53	2.0935E-03	.177	17.8

****WINDS CONSTANT WITH HEIGHT****

STABILITY	WIND SPEED (M/SEC)	MAX CONC (G/CU M)	DIST OF MAX (KM)	PLUME HT (M)
4	1.00	2.3682E-03	1.315	59.5
4	1.50	3.0707E-03	.946	44.7
4	2.00	3.3775E-03	.757	37.3
4	2.50	3.5329E-03	.648	32.9
4	3.00	3.5948E-03	.577	30.0
4	4.00	3.5651E-03	.490	26.3
4	5.00	3.4392E-03	.440	24.1
4	7.00	3.1114E-03	.384	21.6
4	10.00	2.6504E-03	.342	19.7
4	12.00	2.3962E-03	.327	18.9
4	15.00	2.0866E-03	.311	18.2
4	20.00	1.7088E-03	.300	17.5

****STACK TOP WINDS (EXTRAPOLATED FROM 7.0 METERS)****

STABILITY	WIND SPEED (M/SEC)	MAX CONC (G/CU M)	DIST OF MAX (KM)	PLUME HT (M)
4	1.21	2.7396E-03	1.055	51.6
4	1.82	3.2897E-03	.811	39.5
4	2.43	3.5177E-03	.660	33.4
4	3.04	3.5967E-03	.572	29.8
4	3.64	3.5917E-03	.515	27.4
4	4.86	3.4599E-03	.446	24.3
4	6.07	3.2668E-03	.405	22.5
4	8.50	2.8692E-03	.359	20.4
4	12.15	2.3792E-03	.326	18.9
4	14.58	2.1258E-03	.313	18.3
4	18.22	1.8277E-03	.300	17.7
4	24.29	1.4740E-03	.294	17.1

****WINDS CONSTANT WITH HEIGHT****

STABILITY	WIND SPEED (M/SEC)	MAX CONC (G/CU M)	DIST OF MAX (KM)	PLUME HT (M)
5	1.00	3.3788E-03	1.618	45.8
5	1.50	2.7931E-03	1.406	41.9
5	2.00	2.4252E-03	1.278	39.5
5	2.50	2.1657E-03	1.190	37.7
5	3.00	1.9697E-03	1.124	36.4
5	4.00	1.6884E-03	1.030	34.5
5	5.00	1.4908E-03	1.000	33.1

****STACK TOP WINDS (EXTRAPOLATED FROM 7.0 METERS)****

STABILITY	WIND SPEED (M/SEC)	MAX CONC (G/CU M)	DIST OF MAX (KM)	PLUME HT (M)
5	1.26	3.0318E-03	1.491	43.5
5	1.89	2.4917E-03	1.301	39.9
5	2.53	2.1543E-03	1.186	37.7
5	3.16	1.9173E-03	1.106	36.0
5	3.79	1.7390E-03	1.047	34.8
5	5.05	1.4820E-03	1.000	33.0
5	6.31	1.2954E-03	.985	31.8

Max 1 hr. 4283. $\mu g/m^3$ @ 318 m

4.283 mg/m^3

OSHA STEL = 870 mg/m^3

****WINDS CONSTANT WITH HEIGHT****

STABILITY	WIND SPEED (M/SEC)	MAX CONC (G/CU M)	DIST OF MAX (KM)	PLUME HT (M)
6	1.00	3.5028E-03	2.586	40.6
6	1.50	2.9065E-03	2.221	37.4
6	2.00	2.5283E-03	2.005	35.3
6	2.50	2.2503E-03	2.000	33.9
6	3.00	2.0322E-03	1.912	32.8
6	4.00	1.7224E-03	1.765	31.2
6	5.00	1.5093E-03	1.664	30.1

****STACK TOP WINDS (EXTRAPOLATED FROM 7.0 METERS)****

STABILITY	WIND SPEED (M/SEC)	MAX CONC (G/CU M)	DIST OF MAX (KM)	PLUME HT (M)
6	1.26	3.1504E-03	2.366	38.7
6	1.89	2.5969E-03	2.043	35.7
6	2.53	2.2377E-03	2.000	33.8
6	3.16	1.9742E-03	1.884	32.5
6	3.79	1.7778E-03	1.791	31.5
6	5.05	1.5000E-03	1.659	30.0
6	6.31	1.3098E-03	1.567	28.9

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

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

(3) NO COMPUTATION WAS ATTEMPTED FOR THIS HEIGHT AS THE POINT OF MAXIMUM CONCENTRATION IS GREATER THAN 100 KILOMETERS FROM THE SOURCE.

SPTPLU 1)OPT 2)MET 3)REC 4)SOR 5)TTL 6)DISP 7)RUN 8)END

State of Florida
DEPARTMENT OF ENVIRONMENTAL REGULATION

INTEROFFICE MEMORANDUM

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

TO: Clair Fancy/Lillian Jack, BAQM

FROM: Tom Tittle/I.Goldman, SEFD

DATE: April 10, 1095

Re: Key Pharmaceuticals, Inc. Construction Application File No. AC13 - 100437 - No. 2 Fluidized Bed Coating Unit; Comments on:

---

1) How will sludge be handled so as to comply with hazardous waste regulations until it has been determined that the sludge is not hazardous?

2) Suggest the following:

a) A permit condition be included stating that sludge draw-off be treated as hazardous waste until Key Pharmaceuticals demonstrates to EPA that the waste is not hazardous

b) That Key Pharmaceuticals recover methylene chloride by refrigeration or some other viable method.

c) That methylene chloride emissions be modelled to determine if their toxic impact warrants controls.

IG:sw:I

01

DEPARTMENT OF ENVIRONMENTAL REGULATION

ROUTING AND TRANSMITTAL SLIP

ACTION NO.

ACTION DUE DATE

1. TO: (NAME, OFFICE, LOCATION)	INITIAL / DATE
Clair Fancy/Lillian Jack	
2. BAQM	INITIAL / DATE
3.	INITIAL / DATE
4.	INITIAL / DATE

REMARKS:

It appears that Key Pharmaceuticals response of April 3, 1985 indicates a new product/process in addition to that under construction per AC13-091497. If so, a separate permit should be issued and not supercede AC13-09147

DER
APR 12 1985
BAQM

INFORMATION
- REVIEW & RETURN
- REVIEW & FILE
- INITIAL & FORWARD

DISPOSITION
- REVIEW & RESPOND
- PREPARE RESPONSE
- FOR MY SIGNATURE
- FOR YOUR SIGNATURE
- LET'S DISCUSS
- SET UP MEETING
- INVESTIGATE & REPT
- INITIAL & FORWARD
- DISTRIBUTE
- CONCURRENCE
- FOR PROCESSING
- INITIAL & RETURN

FROM: AC13-091497 I. Goldman/T. Tittle

DATE 4/10/85

PHONE

Key
Pharmaceuticals,
Inc.

April 3, 1985

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

RE: No. 2 Fluidized Bed Coating Unit, Application to Construct AC13-100437, Request for Additional Information

Dear Mr. Fancy:

The following is the reply to your request for additional information:

(1) The application is for a new product or process termed Product 0410. It is to be made in any of three fluid bed processing units termed Glatts or Fluid Bed Coating Units 1, 2 and 3. It is understood that any other new processes will be permitted separately.

(2) Please refer to flowsheet CR-85021 which is attached and was included in the permit application.

(a) Into the mix tank are placed Methylene Chloride, Methanol and solid materials (i.e., excipients) and mixed to form a suspension. Two of the solid materials go into solution. The third suspends.

(b) Into the fluid bed processor (i.e., manufactured by Glatt) is placed the active ingredient which is a granular material.

(c) Dehumidified heated air is blown into the processor to fluidize the active and cause it to flow in a set pattern.

(d) The contents of the mix tank are pumped into the processor to seven dual feed nozzles. Atomization of the liquid is provided by compressed air at 70 to 100psig. The spraying continues until all material is used up.

(e) Each fluid bed processor has a process fan prior to the dust collector which is not shown. The effluent from any processor (i.e., Glatts 1, 2 and/or 3) which is air plus solvents (Methylene Chloride and Methanol) plus some entrained dust (overspray) goes to a dust collector. The unit is a cartridge type unit (manufactured by the Torit Donaldson Co.) having a 99+% efficiency.

(f) The effluent from the dust collector goes to one variable flow fan (flow varies based on number of Glatts on-line) and then to a packed column water scrubber. The solvent laden air enters the bottom of the column and goes up. The water enters the top of the column going down absorbing at least 90% of the Methanol and less than 0.5% of the Methylene Chloride (i.e., based on activity coefficients of the respective solvents). The air plus remaining solvents (i.e., Stream "A" which is less than 10% of the Methanol plus greater than 99.5% of the Methylene Chloride) is vented to the atmosphere.

(g) The water, laden with solvents, exits the scrubber and goes to an aerobic digester where the remaining Methylene Chloride is flashed off. The Methanol biologically reduces. The water after clarification (i.e., part of the biological process) is recycled to the scrubber. There is water make-up for evaporation. There is no discharge of water to the sewer system. Sludge is removed when solids reach too a high point.

(3) (a) The maximum flow rate in any one Glatt is

2.1 kg/min = 277.2 lb/hr (This is based on 300 g/min per nozzle. Each Glatt has 7 spray nozzles.)

The breakdown of this stream is

Methanol - 15.9% = 44.1 lb/hr
Methylene Chloride - 79.5% = 220 lb/hr
The remainder is solids.

Therefore, the maximum rate before treatment for three Glatts is

Methanol = 3 x 44.1 lb/hr = 132.3 lb/hr total
Methylene Chloride = 3 x 220 lb/hr = 660 lb/hr

The Methanol is to be treated to eliminate 90% of it. Therefore, emission maximum rates as described in Section IIIC are:

Methanol = 0.1 x 132.3 lb/hr = 13.2 lb/hr
Methylene Chloride remains unchanged at 660 lb/hr

The 141.7 lb/hr as stated in Marv Nathan's letter was a design number for the digester which gave some slack. The correct number is 132.3 lb/hr maximum of Methanol uncontrolled and 13.2 lb/hr maximum of Methanol controlled.

It is only coincidence that the maximum rate of 132.3 lb/hr is close to three times the average rate of 45.7 lb/hr.

(b) Each Glatt lot = 300 kg = 660 lb

Based on 1050 lots/year the total weight processed is:

$$\frac{660 \text{ lb}}{\text{lot}} \times \frac{1050 \text{ lots}}{\text{year}} = 693{,}000 \text{ lb/year}$$

Note that the 82.5 lb/hr total process input rate is 693,000 lb/yr divided by 8400 operating hours/year (Section IIIB).

Based on a 98% yield (i.e., 2% loss to dust collector) the Material to Collector is 0.02 x 693,000 lb/yr = 13,860 lb/yr (5 microns or larger).

Efficiency of Collector = 99%. Therefore,

Material to Scrubber = 0.01 x 13,860 lb/yr = 138.6 lb/yr

Based on 8400 operating hours per year

$$\text{Effluent to Scrubber} = \frac{138.6 \text{ lb/yr}}{8400 \text{ hr/yr}} = 0.0165 \text{ lb/hr}$$

which corresponds to number of Section IIIC.

Please note in your letter (last line), you say 0.0016 lb/hr. In the permit it is 0.016 lb/hr. Also, the previous process was less efficient and, therefore, more material (i.e., up to 10%) could have gone to the dust collector.

These descriptions and calculations should be sufficient for your needs to continue your work on the referenced permit. Your

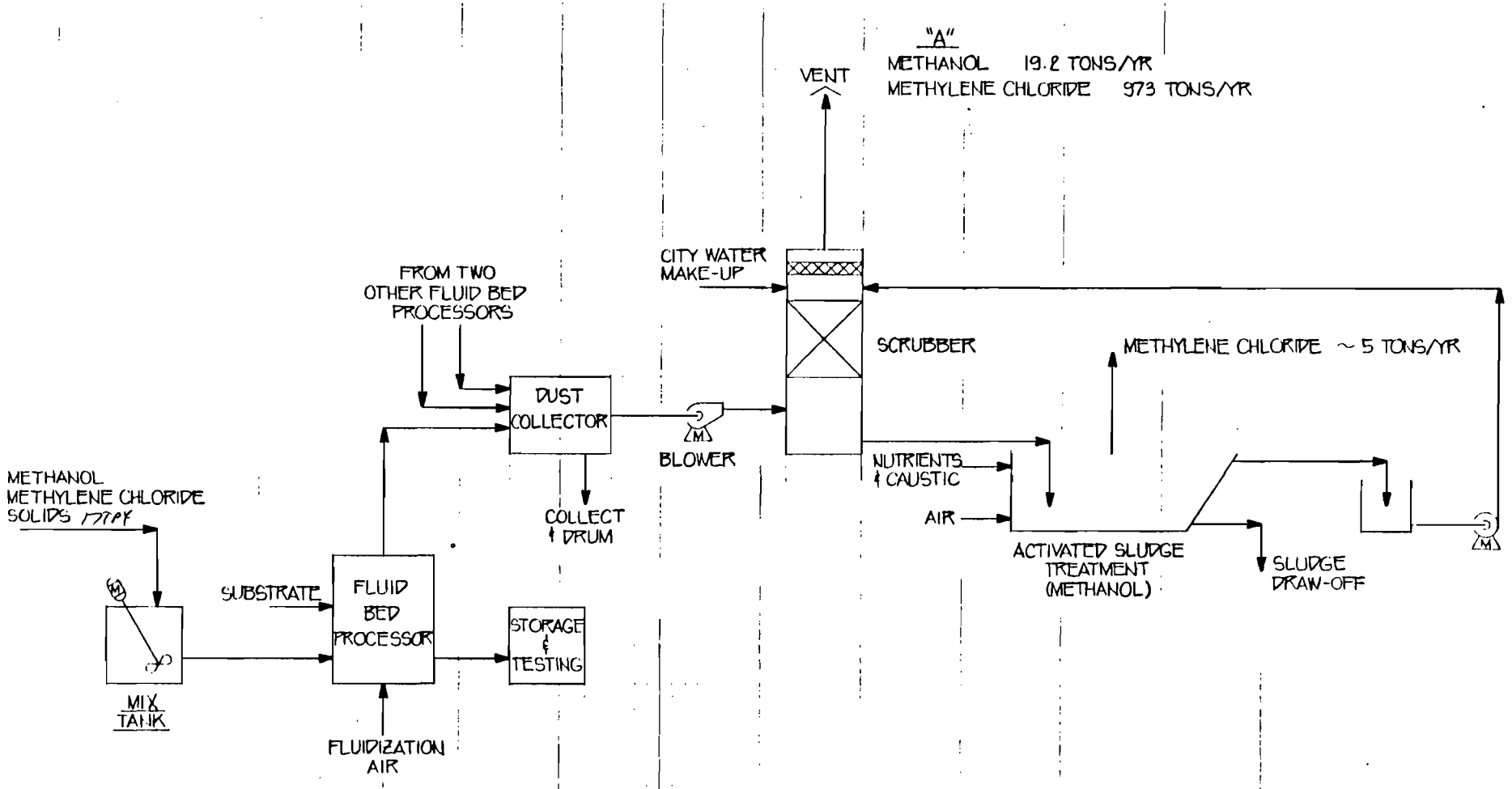
prompt review is required to keep this project going. If there are any additional questions, please contact me.

Very truly yours,

Stephen J. Goodstein
Manager Environmental Engineering
and Waste Management

SJG:lj

cc: A. F. Gant
R. Quinlan
W. Smyth
R. A. Franke
C. Newcomb
M. Nathan - Crawford & Russell
P. Salazzo - Crawford & Russell
P. Rothchild



REVISIONS	DATE	APPR BY	MADE BY	DESCRIPTION	NO.

	BY	DATE
DRAWN	SRG	2/22/95
CHK'D		
APPR.		
APPR.		

SCALE: NONE

JOHN BROWN
Crawford & Russell Incorporated
Process Plants Stamford, CT

FLUID BED COATING PROCESS

FOR KEY PHARMACEUTICALS, INC. MIAMI BEACH, FLA

CR-85021

No. 0155531

RECEIPT FOR CERTIFIED MAIL

**NO INSURANCE COVERAGE PROVIDED—
NOT FOR INTERNATIONAL MAIL**

(See Reverse)

SENT TO	Mr. Allen F. Gant		
STREET AND NO.			
P.O., STATE AND ZIP CODE			
POSTAGE			$
CONSULT POSTMASTER FOR FEES — OPTIONAL SERVICES	CERTIFIED FEE		¢
	SPECIAL DELIVERY		¢
	RESTRICTED DELIVERY		¢
	RETURN RECEIPT SERVICE	SHOW TO WHOM AND DATE DELIVERED	¢
		SHOW TO WHOM, DATE, AND ADDRESS OF DELIVERY	¢
		SHOW TO WHOM AND DATE DELIVERED WITH RESTRICTED DELIVERY	¢
		SHOW TO WHOM, DATE AND ADDRESS OF DELIVERY WITH RESTRICTED DELIVERY	¢
TOTAL POSTAGE AND FEES			$
POSTMARK OR DATE	3/29/85		

PS Form 3800, Apr. 1976

PS Form 3811, July 1983

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

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

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

3. Article Addressed to:

Mr. Allen F. Gant
Key Pharmaceuticals, Inc.
50 Northwest 176th Street
Miami, Florida 33169

4. Type of Service:	Article Number
☐ Registered ☐ Insured ☒ Certified ☐ COD ☐ Express Mail	0155531

Always obtain signature of addressee or agent and DATE DELIVERED.

5. Signature – Addressee
X

6. Signature – Agent
X

7. Date of Delivery

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

DOMESTIC RETURN RECEIPT

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

March 29, 1985

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

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

Dear Mr. Gant:

Re: No. 2 Fluidized Bed Coating Unit, Application to Construct AC 13-100437; Request for Additional Information

The department has reviewed your application to construct and has determined that additional information is needed to complete this review.

Please forward the following information for clarification.

1. It was the department's understanding that the permit to construct is for a new product with the No. 2 Fluid Bed Coating Unit only; however, the application states three (3) Fluid Bed Processors with scrubbers. Please specify the fluid bed(s) designated for permitting.

2. Provide a general written process description of the fluid bed operation for product #0410.

3. Provide background calculations (Section III.C) for the maximum lbs/hr of emissions for VOC and particulates. In M. F. Nathan's letter of March 6, 1985, to Ms. Jack, it was stated that 141.7 lbs/hr methanol is the maximum flow with approximately one third of this value as the average flow. Calculations from Crawford & Russell Incorporated, Section C addendum, appear to indicate an additional one-third value of the above one-third value mentioned for each unit. Please clarify. For particulates, the previous application utilized historical experience of less than 10% of particulate input leaving the fluid bed and a 99% efficient dust collector. Please provide basis for the "solid" calculations of .0016 #/hr.

When we have received the above information, we will continue to process your application as soon as possible. If you have any questions, please call Bill Thomas, Chief Engineer, at (904)488-1344 or write to me at the above address.

Sincerely,

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

CHF/LJ/s

c: Marvin F. Nathan
Roy Duke

JOHN BROWN

Crawford & Russell Incorporated
17 Amelia Place
P.O. Box 1432
Stamford, Connecticut 06904
Telephone (203) 327-1450
TWX 710-474-0738
Telex 96-5900

CR-85021

March 6, 1985

DER
MAR 7 1985
BAQM

Ms. Lillian Jack
Bureau of Air Quality Management
State of Florida Department of
Environmental Regulation
2562 Executive Center Circle East
Montgomery Building, Suite 100
Tallahassee, Florida 32301

Re: Key Pharmaceuticals Methanol Absorber

Dear Ms. Jack:

In accordance with the request made at our meeting on Wednesday, February 27, at which the permit application for Key Pharmaceuticals was discussed, please find a letter from Koch Engineering guaranteeing 90% removal of methanol from approximately 18,000 SCFM of air. The absorber has been designed on the basis of using only three theoretical stages, which we feel is conservative. It should also be noted that Koch, in their letter, has made use of the safety factors Crawford & Russell added to the design calculations, i.e., our calculations to achieve 90% removal of 141.7 lbs/hr of methanol were based on 100 ppm of methanol in 50 gpm of inlet water; Koch then recommended 8 feet of their packing. The activated sludge system which destroys most of the methanol absorbed has been specified to meet 25 ppm methanol in the water recycled to the absorber and the water flow to the absorber was arbitrarily raised to 100 gpm, while the packing height was increased to 10 ft.

Note too that 141.7 lbs/hr of methanol is the maximum flow; average flow will be approximately one-third that value. The system, however, would be operated with constant flow of 100 gpm of water to the scrubber inlet.

Please let me know if you have any questions.

Very truly yours,

CRAWFORD & RUSSELL INCORPORATED

M. F. Nathan

M. F. Nathan
Corporate Manager of
Environmental Engineering

MFN/amg
CC: W. A. Thomas - Florida Dept. of Envr. Reg.
S. Goodstein - Key Pharmaceuticals

RECEIVED
MAR - 6 1985
M. F. NATHAN

KOCH
ENGINEERING COMPANY INC

Reply to:
161 EAST 42nd STREET
NEW YORK, N.Y. 10017
PHONE: 212 - 682-5755

March 4, 1985

Crawford and Russell
17 Amelia Place
Stamford, CT. 06904

Attention: Dr. Marvin Nathan, Corp. Mgr.
Environmental Engineering

Reference: C & R Project 85021

Gentlemen:

For the Key Pharmaceutical, Inc. facility in Miami, Florida, an 8 ft. diameter Koch high efficiency absorber column with Koch FLEXIPAC® packing and internals will provide 90% or higher removal of methanol from 80,214 lb/hr. of inlet air at 140°F with 141.7 lb./hr. of methanol. Design rate is 100 gpm of inlet water with maximum of 100 ppm methanol with inlet and outlet temperature of 100°F maximum.

The Koch high efficiency absorber will be packed with approximately 10 ft. of regularly structured Koch Flexipac packing which provides high efficiency, low pressure and high operating flexibility. The packing provides high surface area for efficiency and is also very open to allow high capacity with low pressure drop. The packing geometry insures good mixing and radial distribution of the liquid and gas streams. The Koch absorber will also provide high operating flexibility to maintain high efficiency performance even with varying loading conditions.

Literature is enclosed on Koch Flexipac packing.

Sincerely,

KOCH ENGINEERING COMPANY, INC.

Joseph H. Hill

Joseph H. Hill
JHH:tb
Enc. - KFP-3 (2)

KEY PHARMACEUTICALS, INC.
18425 N.W. 2nd AVENUE
MIAMI, FLORIDA 33169-0670

SOUTHEAST FIRST NATIONAL BANK OF MIAMI
MIAMI, FLORIDA

[redacted]

[redacted]

REFERENCE

CHECK NO.

CHECK DATE
02 26 85

PAY THIS AMOUNT
***100.00

VOID AFTER 60 DAYS

PAY THE SUM OF *****100. DOLLARS AND 00 CENTS

TO THE ORDER OF FLORIDA STATE DEPT. OF ENVIRONMENTAL REGULATIONS

BY Michael Jibbens Jr

BY David L. Windley

[redacted]

INVOICE NUMBER	INVOICE DATE	VOUCHER NO.	GROSS AMOUNT	DISCOUNT AMOUNT	NET AMOUNT PAID
	02 26 85		PERMIT FEE		$100.00

CHECK NO.	CHECK DATE	VENDOR NUMBER	VENDOR NAME	TOTAL AMOUNT OF CHECK

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

No 76065

RECEIPT FOR APPLICATION FEES AND MISCELLANEOUS REVENUE

Received from Key Pharmaceuticals Date March 4, 1985

Address 18425 N.W. 2nd Ave., Miami FL 33169-0670 Dollars $ 100.00

Applicant Name & Address Same as above

Source of Revenue

Revenue Code 001031 Application Number AC 13-099446

By Patricia G. Adams

JOHN BROWN

Crawford & Russell Incorporated
17 Amelia Place
P.O. Box 1432
Stamford, Connecticut 06904
Telephone (203) 327-1450
TWX 710-474-0738
Telex 96-5900

February 28, 1985

CR-85021

Mr. William A. Thomas
Bureau of Air Quality Management
State of Florida Department of
Environmental Regulation
2562 Executive Center Circle East
Montgomery Building, Suite 100
Tallahassee, Florida 32301

Dear Mr. Thomas:

In accordance with our discussion yesterday, Key Pharmaceuticals' Air Permit Application is enclosed, together with their check for $100; Carl Ruspini has added his seal to his signature.

Please let me know if you have any questions.

Very truly yours,

CRAWFORD & RUSSELL
Incorporated

M. F. Nathan

M. F. Nathan
Corporate Manager of
Environmental Engineering

MFN/amg
Enclosures
CC: S. Goodstein w/o enclosure

STATE OF FLORIDA AC 13-100437

DEPARTMENT OF ENVIRONMENTAL REGULATION

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

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

APPLICATION TO OPERATE/CONSTRUCT AIR POLLUTION SOURCES

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

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

COMPANY NAME: Key Pharmaceuticals, Inc. COUNTY: Dade

Identify the specific emission point source(s) addressed in this application (i.e. Lime Kiln No. 4 with Venturi Scrubber; Peaking Unit No. 2, Gas Fired) 3 fluid bed processors with scrubber

SOURCE LOCATION: Street 50 NW 176th Street City Miami

UTM: East 57987 North 2868445

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

APPLICANT NAME AND TITLE: Allen F. Gant, Vice President, Production & Engineering

APPLICANT ADDRESS: 50 NW 176th Street, Miami, Florida 33169

SECTION I: STATEMENTS BY APPLICANT AND ENGINEER

A. APPLICANT

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

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

*Attach letter of authorization

Signed: Allen F. Gant

Allen F. Gant
Vice President, Production & Engineering
Name and Title (Please Type)

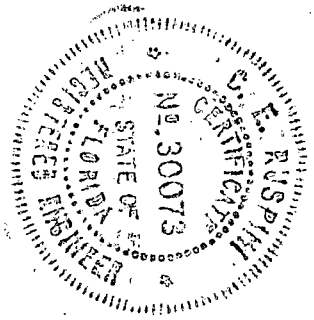
Date: 27 Feb 85 Telephone No. 305/652-2276

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)

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 Carl E. Ruspini

Carl Ruspini
Name (Please Type)

Crawford & Russell Inc.
Company Name (Please Type)

P. O. Box 1432 Stamford, CT 06904
Mailing Address (Please Type)

Florida Registration No. 30073 Date: 27 Feb 85 Telephone No. 203-327-1450

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.

Raw material crystals are added to a fluid bed coating unit. They are fluidized by high volume air flow through the base of the unit. A slurry of excipients in a mixture of methylene chloride and methanol is sprayed onto the fluidized crystals. The final material is inspected and compressed into tablets, packaged, inspected, released and shipped.

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

Start of Construction June 1, 1985 Completion of Construction November 1, 1985

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

$500,000

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

i. Consent order for halting or permitting Theo-Dur operations in Miami by Nov. 1986.

i.i. Permit to construct catalytic incinerator for reduction of solvent emissions from fluid bed unit (Glatt 2) on Theo-Dur operation.

E. Requested permitted equipment operating time: hrs/day 24 ; days/wk 7 ; wks/yr 50 ;
if power plant, hrs/yr N/A ; if seasonal, describe: N/A

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

1. Is this source in a non-attainment area for a particular pollutant? Yes

   a. If yes, has "offset" been applied? No

   b. If yes, has "Lowest Achievable Emission Rate" been applied? No

   c. If yes, list non-attainment pollutants. Ozone

2. Does best available control technology (BACT) apply to this source? If yes, see Section VI. No

3. Does the State "Prevention of Significant Deterioriation" (PSD) requirement apply to this source? If yes, see Sections VI and VII. No

4. Do "Standards of Performance for New Stationary Sources" (NSPS) apply to this source? No

5. Do "National Emission Standards for Hazardous Air Pollutants" (NESHAP) apply to this source? No

H. Do "Reasonsbly 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:

1 Glatt only

Description	Contaminants		Utilization Rate - lbs/hr	Relate to Flow Diagram
	Type	% Wt		
Methanol	VOC	17	45.7 (132.3 3 units)	"A"
Methylene Chloride	Exempt under 17-2.510	83	233 (660 for 3 units)	"A"
		100	979	

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

1. Total Process Input Rate (lbs/hr): 82.5

2. Product Weight (lbs/hr): 80.9

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

Name of Contaminant	Emission[1]		Allowed[2] Emission Rate per Rule 17-2	Allowable[3] Emission lbs/hr	Potential[4] Emission		Relate to Flow Diagram
	Maximum lbs/hr	Actual T/yr			lbs/yr	T/yr	
VOC	13.2 3 units	19.2	N.A.	N.A.		192	"A"
Particulates	0.016 3 units	0.068	N.A.	N.A.		6.8	"A"
Methylene Chloride	660	978	N.A.	N.A.		978	"A"

[1]See Section V, Item 2.

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

[3]Calculated from operating rate and applicable standard.

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

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

Name and Type (Model & Serial No.)	Contaminant	Efficiency	Range of Particles Size Collected (in microns) (If applicable)	Basis for Efficiency (Section V Item 5)
Scrubber	VOC	90%	N/A	Suppliers
				Design
Dust Collector	Particulates	99.0%	2 micron or larger	Suppliers
Torit 3DF60				Design

E. Fuels N/A

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

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

Fuel Analysis:

Percent Sulfur: _____ Percent Ash: _____

Density: _____ lbs/gal Typical Percent Nitrogen: _____

Heat Capacity: _____ BTU/lb _____ BTU/gal

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

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

Annual Average _____ Maximum _____

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

13,500#/yr particulates from filter equivalent to about 34 drums/year to off-site disposal. 355 tons/year aerobic activated sludge methanol digestion to disposal. Both are Non Hazardous.

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

Stack Height: 50 ft. Stack Diameter: 2' 6" ft.

Gas Flow Rate: 18,000 ACFM _____ DSCFM Gas Exit Temperature: 90° °F.

Water Vapor Content: 2.75 Vol % Velocity: 60 FPS @ 90° F FPS

SECTION IV: INCINERATOR INFORMATION

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

Description of Waste _____

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

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

Manufacturer _____

Date Constructed _____ Model No. _____

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

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

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

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

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

[ ] Other (specify) _____

Brief description of operating characteristics of control devices: _____

_____

_____

_____

_____

Ultimate disposal of any effluent other than that emitted from the stack (acrubber 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 aupplements where required for this application.

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

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

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

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

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

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

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

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

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

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

SECTION VI: BEST AVAILABLE CONTROL TECHNOLOGY

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

[ ] Yes [ ] No

Contaminant	Rate or Concentration

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

[ ] Yes [ ] No

Contaminant	Rate or Concentration

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

Contaminant	Rate or Concentration

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

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

*Explain method of determining

5. Useful Life:

6. Operating Costs:

7. Energy:

8. Maintenance Cost:

9. Emissions:

Contaminant	Rate or Concentration

10. Stack Parameters

a. Height: ft.

b. Diameter: ft.

c. Flow Rate: ACFM

d. Temperature: °F.

e. Velocity: FPS

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

1.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

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

2.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

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

j. Applicability to manufacturing processes:

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

3.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Cost:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

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

4.

a. Control Device:

b. Operating Principles:

c. Efficiency:[1]

d. Capital Costs:

e. Useful Life:

f. Operating Cost:

g. Energy:[2]

h. Maintenance Cost:

i. Availability of construction materials and process chemicals:

j. Applicability to manufacturing processes:

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

F. Describe the control technology selected:

1. Control Device:

2. Efficiency:[1]

3. Capital Cost:

4. Useful Life:

5. Operating Cost:

6. Energy:[2]

7. Maintenance Cost:

8. Manufacturer:

9. Other locations where employed on similar processes:

a. (1) Company:

(2) Mailing Address:

(3) City:

(4) State:

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

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

b. (1) Company:

(2) Mailing Address:

(3) City: (4) State:

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:[1]

Contaminant	Rate or Concentration

(8) Process Rate:[1]

10. Reason for selection and description of systems:

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

SECTION VII - PREVENTION OF SIGNIFICANT DETERIORATION

A. Company Monitored Data

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

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

Other data recorded _____

Attach all data or statistical summaries to this application.

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

2. Instrumentation, Field and Laboratory

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

b. Was instrumentation calibrated in accordance with Department procedures?

[ ] Yes [ ] No [ ] Unknown

B. Meteorological Data Used for Air Quality Modeling

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

2. Surface data obtained from (location)_____

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

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

C. Computer Models Used

1. _____ Modified? If yes, attach description.

2. _____ Modified? If yes, attach description.

3. _____ Modified? If yes, attach description.

4. _____ Modified? If yes, attach description.

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

D. Applicants Maximum Allowable Emission Data

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

E. Emission Data Used in Modeling

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

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

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

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

Key
Pharmaceuticals,
Inc.

August 10, 1984

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

TO WHOM IT MAY CONCERN:

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

Yours truly,

D. M. Bell
Senior Vice President
Operations

KEY PHARMACEUTICALS, INC. CORPORATE SEAL FLORIDA 1944

Cable Address: KEYPHARM 50 N.W. 176th St., P.O. Box 693670, Miami, Florida 33169-0670 Telephone (305) 652-2276 Telex: 808044

SUBJECT ____

C. AIRBORNE CONTAMINANTS EMITTED

PROCESS QUANTITIES

PER UNIT

MEOH 64 TONS/HR
128000 #/HR.
15.2 #/HR

STRIPPER REMOVES 90% MEOH

1.52 #/HR VENTED × 3 = 4.6 #/HR FOR 3 UNITS

4.6 #/HR = 38400 #/HR = 19.2 TONS/HR.

ALL? asked 13.2 #/hr in applic

METHYLENE CHLORIDE 326 TONS/HR × 3 = 978 TON/HR
652000 #/HR
77.6 #/HR × 3 = 233 #/HR AVG.

PEAK FLOW FOR 3 UNITS
660 #/HR MAX

SOLIDS

224540 #/HR × 3 UNITS = 675000 #/HR 3 UNITS

98% removal in Glass =
2% GOES TO FILTER = 13500 #/HR = 6.8 TONS/HR
5 micron + Larger 1.6 #/HR

99 % removal in Filter
1 % TO SCRUBBER 13.5 #/HR
2 micron & Larger 0.016 #/HR

SUBJECT ____

H. EMISSION STACK GEOMETRY

FOR ONE COATER

		MW	mol/HR
26734 #/HR	AIR	29	921.862
476	H_2O	18	26.444
220	H_2CCl_2	85	2.586
27430			950.895

$950.895 \times 379 = 360389\ FT^3/HR$

$6006\ FT^3/MIN$

$18019\ FT^3/MIN$ 3 UNITS

$26.444 / 950.895 = 2.75$ VOL % H_2O

$18019 / 60 = 300.32\ FT^3/SEC \div 4.9087\ FT^2 = 61\ FT/SEC$ VEL IN 30" STACK AT STD COND.

$61 \times \frac{460+90}{460+60} = 64.5\ FT/SEC$ AT 90° F

JOHN BROWN
Crawford & Russell Incorporated
Stamford, Connecticut

SHEET NO. ____ OF ____
FILE ____
PROJECT NO. 25021
CUSTOMER KEY
DATE 21 FEB 85
BY SWE

SUBJECT ____

C. AIRBORNE CONTAMINANTS EMITTED

PROCESS QUANTITIES

PER UNIT

MEOH — 64 TONS/HR
128000 #/HR
15.2 #/HR

maximum (lbs/hr) Section III, C (VOC)
141.7 lb/hr.

STRIPPER REMOVES 90% MeOH

1.52 #/HR VENTED × 3 = 4.6 #/HR FOR 3 UNITS

4.6 #/HR = 38400 #/YR = 19.2 TONS/YR.

METHYLENE CHLORIDE — 326 TONS/YR × 3 = 978 TON/YR
652000 #/YR
77.6 #/HR × 3 = 233 #/HR AVG.

PEAK FLOW FOR 3 UNITS
660 #/HR MAX

SOLIDS (8 hrs.)

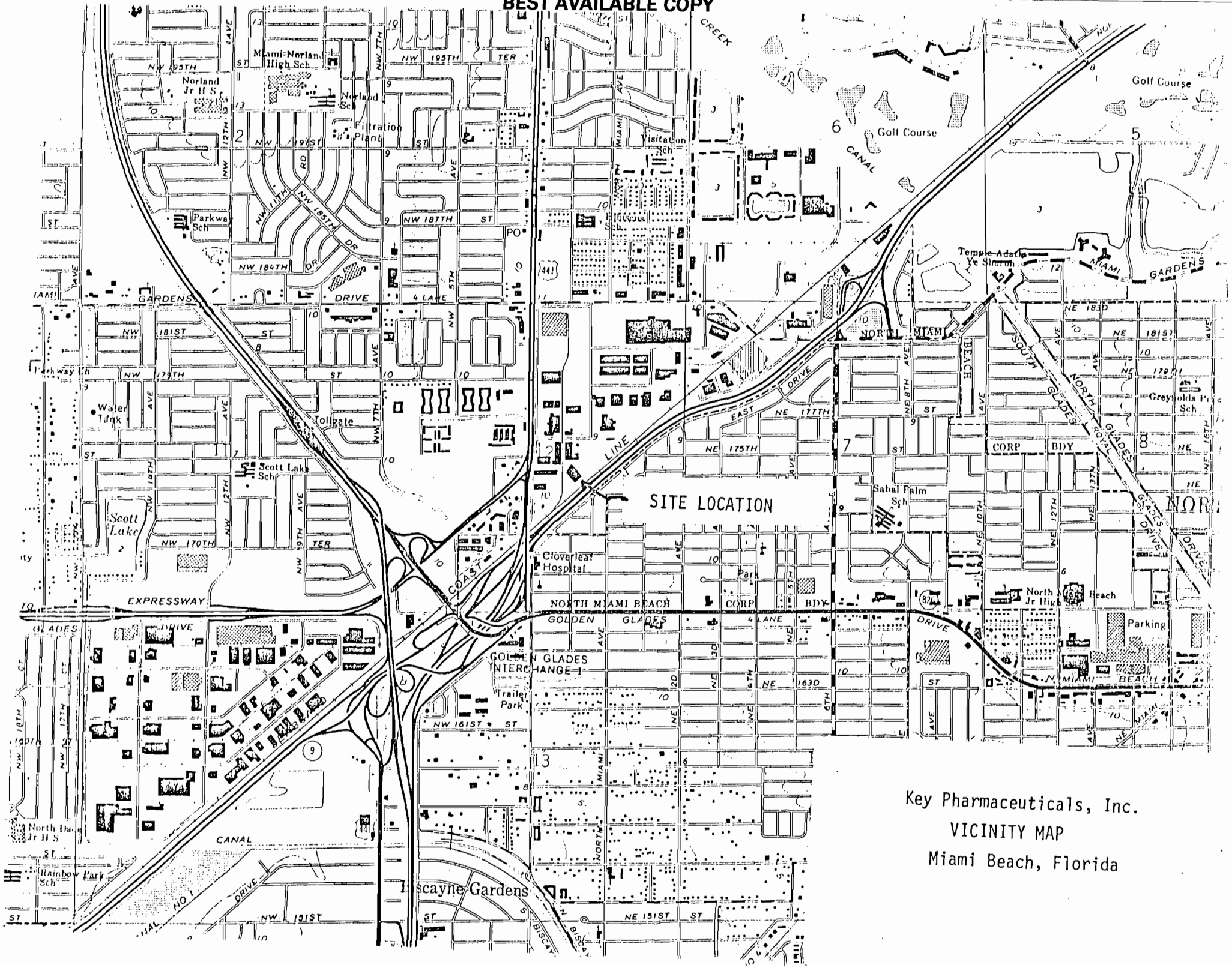
Product weight
86.9 #/hr ⇒ 679560 #/yr

226,520
224540 #/YR × 3 UNITS = 675000 #/YR 3 UNITS

Δ 82.5 − 80.9 = 13,440

98% removal in Glass =
2% Goes to Filter : 13500 #/YR = 6.8 TONS/YR
5 micron + Larger 1.6 #/HR

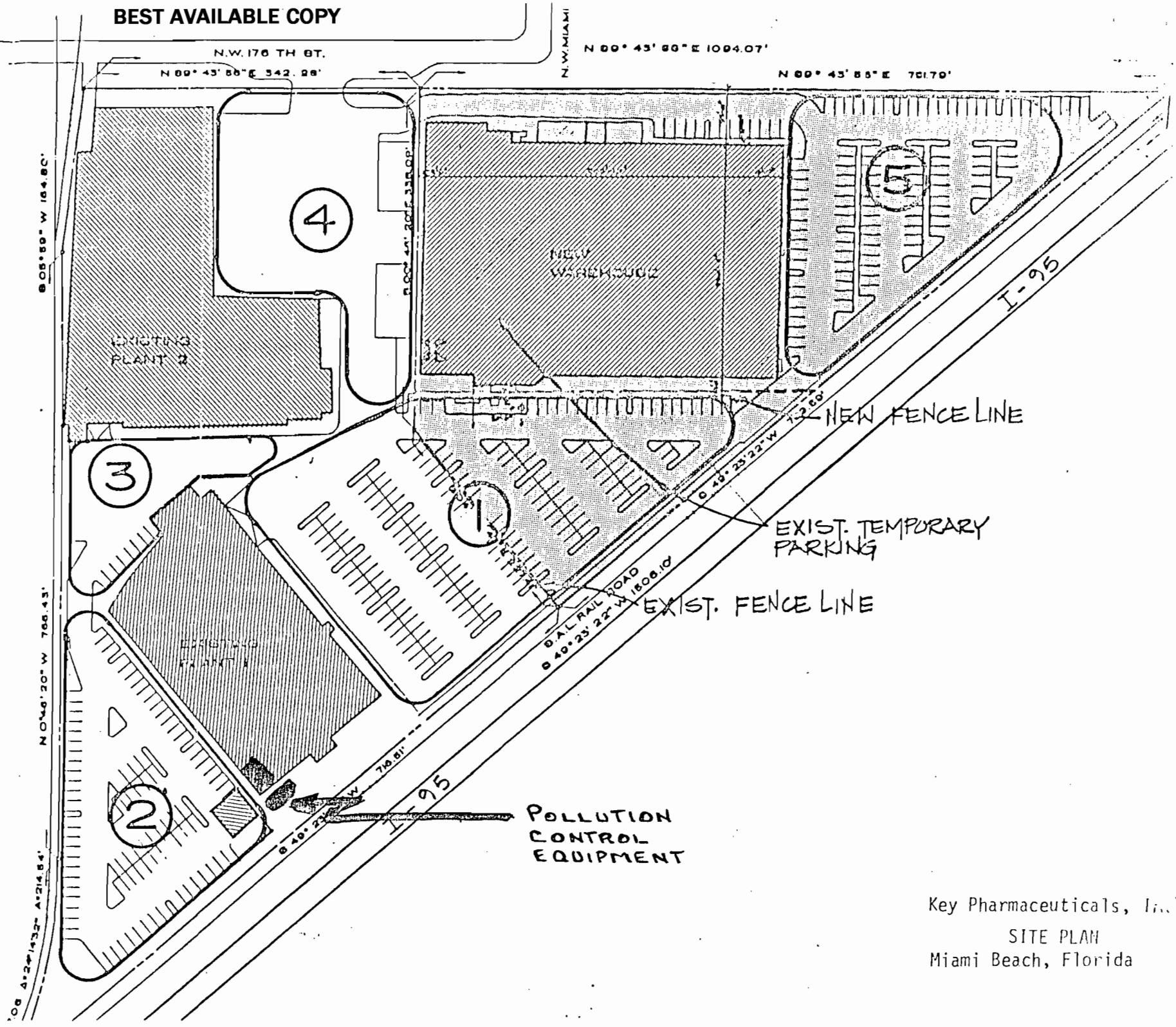
99.9% removal in Filter
0.1% to scrubber 13.5 #/YR 8400
2 micron & ~~Larger~~ smaller 0.0016 #/YR



Key Pharmaceuticals, Inc.

VICINITY MAP

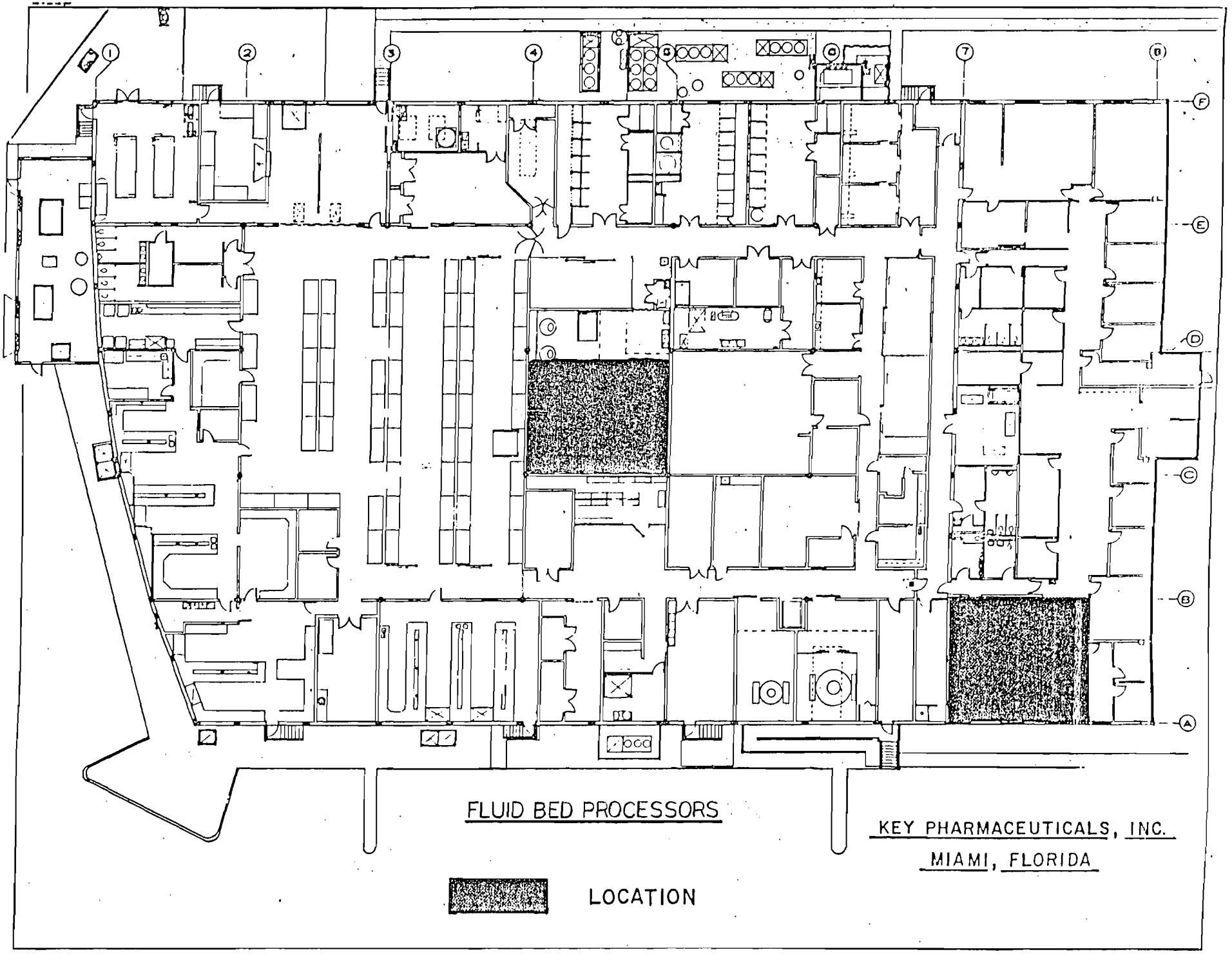
Miami Beach, Florida

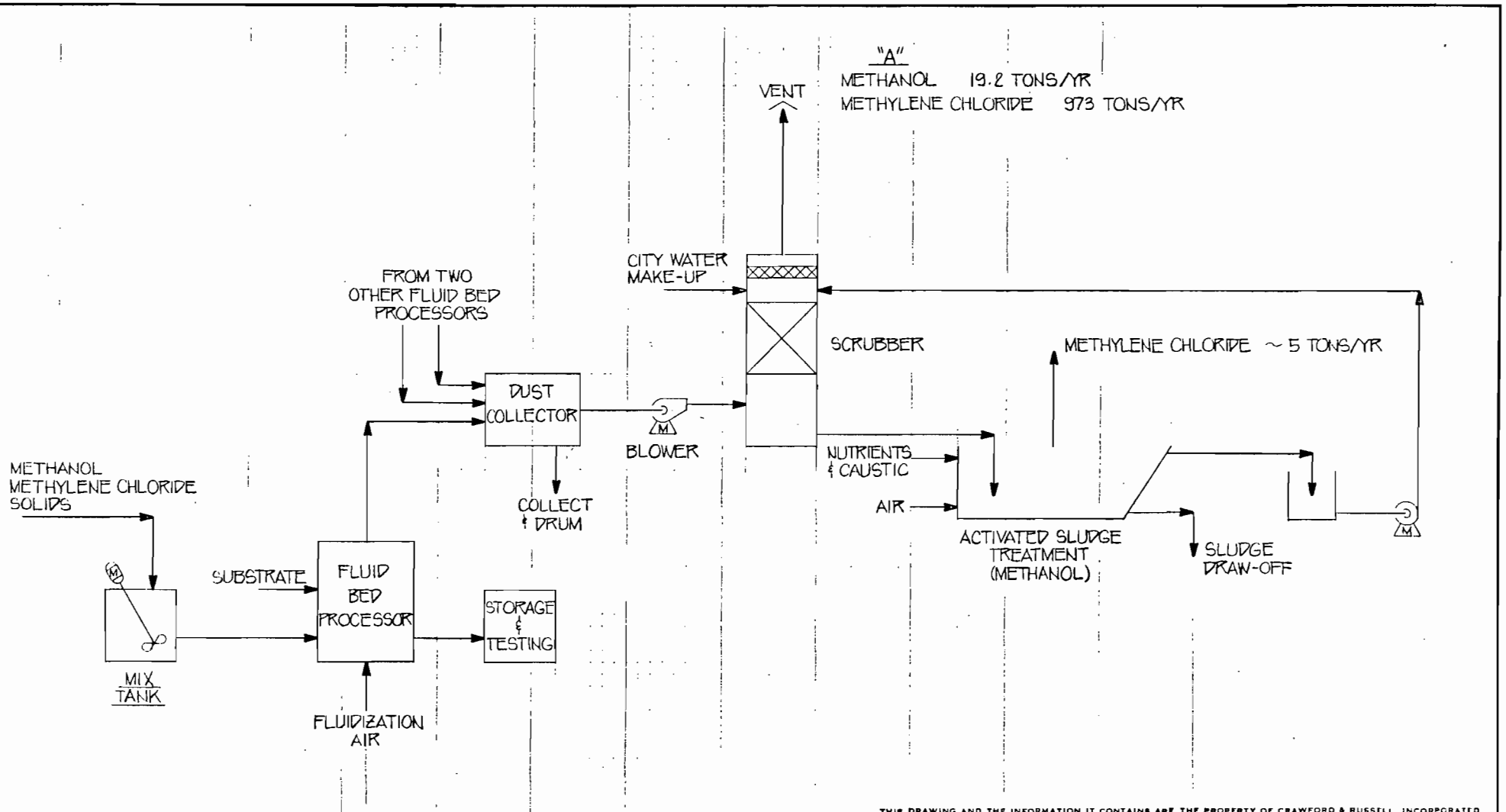


Key Pharmaceuticals, I...

SITE PLAN

Miami Beach, Florida


FLUID BED PROCESSORS
KEY PHARMACEUTICALS, INC.
MIAMI, FLORIDA
LOCATION



NO.	DESCRIPTION	DATE	APPR. BY	MADE BY

REVISIONS

	BY	DATE
DRAWN	SRG	2/4/85
CHK'D.		
APPR.		
APPR.		

SCALE: NONE

JOHN BROWN
Crawford & Russell Incorporated
Process Plants Stamford, CT

FLUID BED COATING PROCESS

FOR KEY PHARMACEUTICALS, INC. MIAMI BEACH, FLA

CR-85021

BEST AVAILABLE COPY

JOHN BROWN

PROCESS VESSEL SPECIFICATION

REVISION			NOZZLE SCHEDULE				
NO.	DATE	BY	MK	SIZE	NO.	SERVICE	RATING
			A	36"	1	GAS INLET	150# DRILL
			B	30"	1	GAS outLet +	↓
			C	6"	1	Liquor outlet	150#
			D	3"	1	Liquor Inlet	150#
			M 1, 2	20	2	MANholes/cover AND DAVITS	STD
			P 1, 2, 3	1 1/2	3	Pressure taps	150#

PROJECT NO. 85021

ITEM NO. ______

FOR KEY PHARM

TITLE SCRUBBER

CAPACITY, GAL. ______

I.D.-O.D. 8'-0" T. TO T. 26'-0"

CODE NONE

	SHELL	JACK OR COIL
MATL. CONST.	FRP *	
CORR. ALL.,"		
OPER. PSI G	-0.2	
@ °F	100	
DESIGN PSIG	±2	
@ °F	200	
CONTENTS	AIR/water	
SP. GR. CONT.	0.069/1.0	

FINISH Mfg STD

INTERNALS As NOTED

HEADS Dished top/Bottom

STRESS RELIEVE ______ X-RAY ______

PAINTING CS only

INSULATION NONE

METHOD OF SUPPORT LUGS

MIXER NONE

Notes Cont. (Location Page 2)

1) Packing - Koch type 2 Flexipac 8'-0" ϕ x 10'-0" TEFLON

2) Packing Support Plate Koch Figure 104 style - Grid type plate - Hetron 800 FRP - no exposed metal permitted. Provide Support Ring (Hetron 800 FRP) at least 2 1/2". Gas loading 1637 pph/ft²

3) Liquid Distributor Koch model 201 weir type (Liquid loading [illegible] gpm/ft²) (50 gpm). HETRON 800 FRP or teflon. Provide At Least 2 1/2" Support Ring Hetron 800 FRP

4) Demister PAD Koch Style 911 Flexi mesh Separator 8" thickness teflon.

Notes:

A) + Design nozzle for 30 in ϕ x 10' tall stack FRP, weight ≈ 200 Lbs

B) Design wind loading 125 mph at 50 ft High (to be confirmed by Bldg. Code)

C) * HETRON 800 FRP

JOHN BROWN
Crawford & Russell Incorporated

MATERIAL REQUISITION

REQUISITION NO.	DATE
85021	Feb. 1985
PURCHASE ORDER NO.	

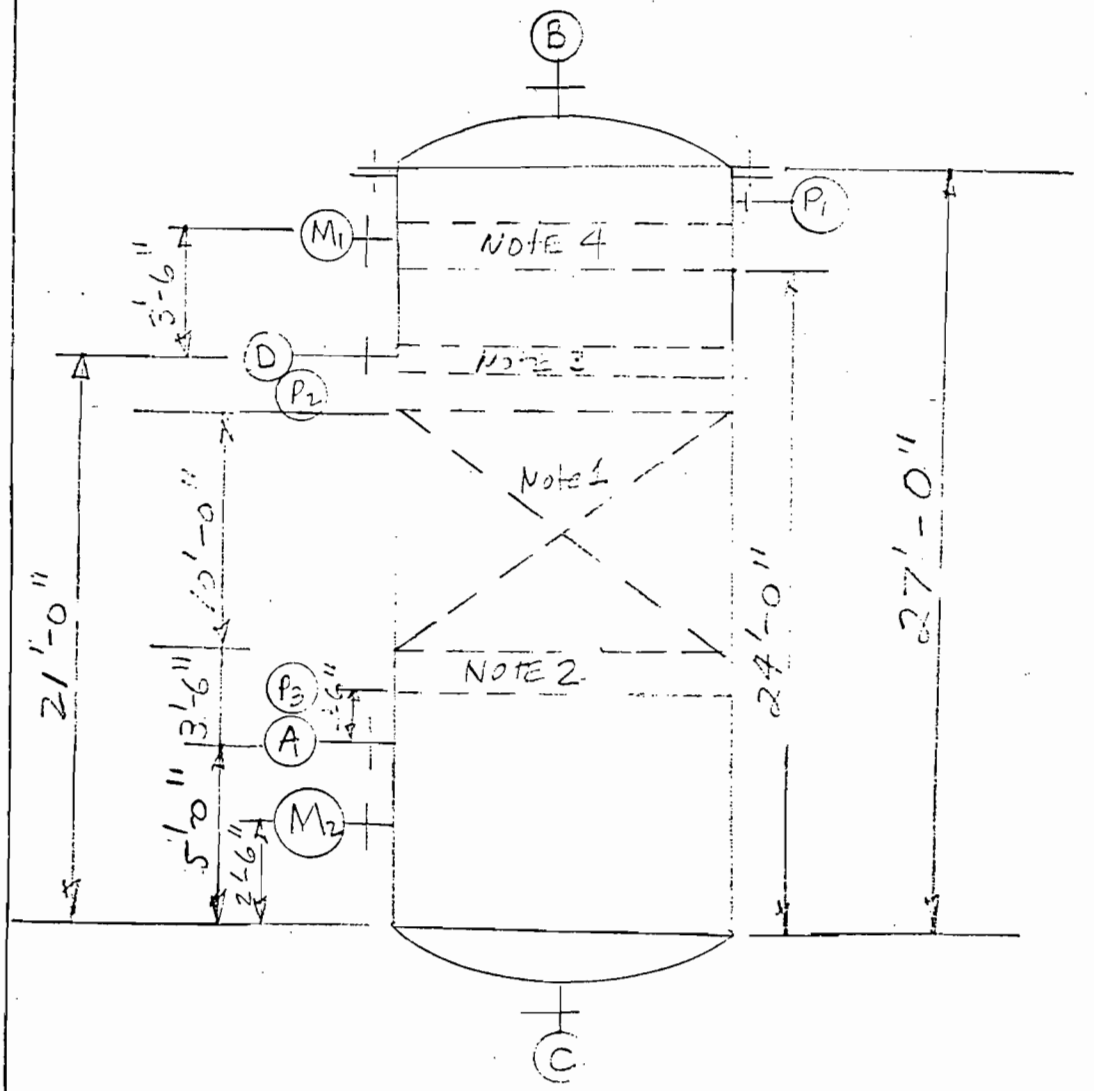
CUSTOMER KEY PHARMACEUTICALS

VENDOR

LOCATION MIAMI BEACH FLORIDA

REV. NO.	DATE	APPV'D	REV. NO.	DATE	APPV'D

ITEM NO.	MATERIAL
	SCRUBBER



MADE BY DL

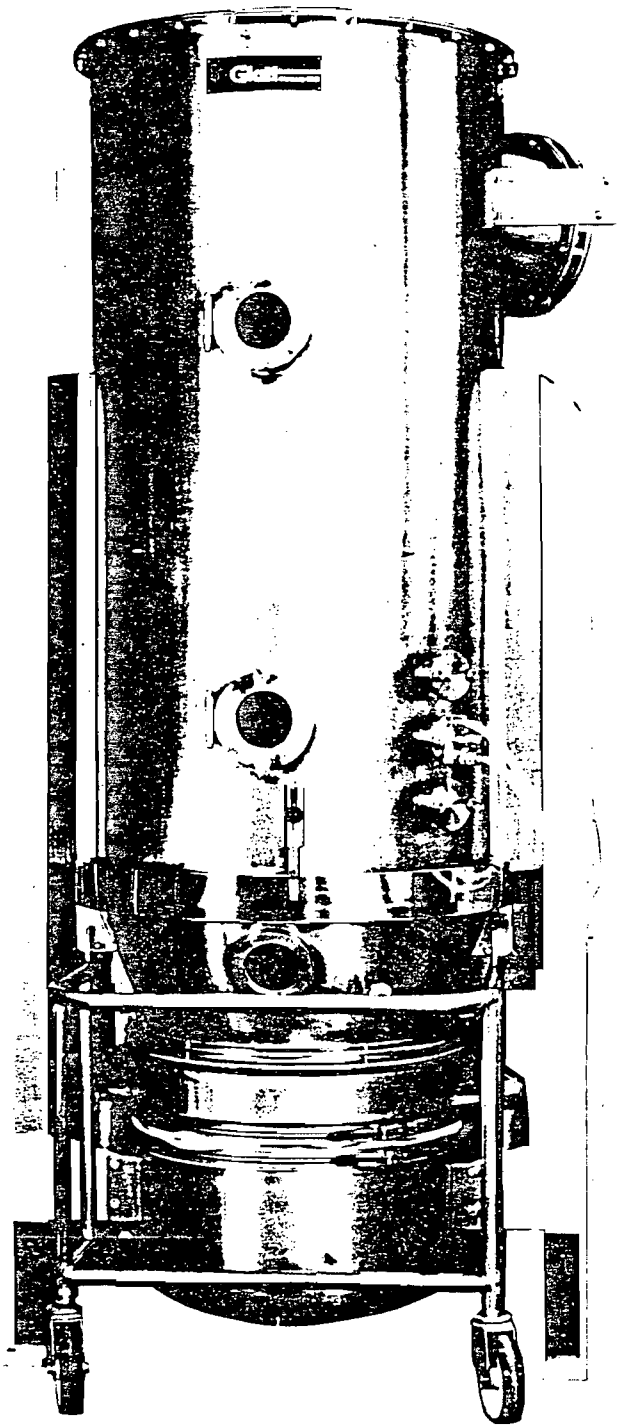
C & R APPROVED

CUSTOMER APPROVED

Glatt Fluid Bed Granulator/Dryers

WSG

Batch or batch-continuous granulating and drying. Agglomeration and instantizing of blended products. Coating of small and intermediate size particles. Dedusting, by agglomeration, of materials with large quantities of fines.



WSG Fluid Bed Granulator/Dryer

Air Handling

- remote fan for quieter, safer, and cleaner operation
- 80 micron pocket prefilter
- efficient, high capacity galvanized steel heating coils

Product Handling

- exclusive product bowl design for effective circulation of material providing maximum transfer of heat and uniform, rapid drying
- windows for observing product in bowl and expansion area
- multiple nozzle positions for nozzle height adjustment
- quick disconnect coaxial air atomized spray nozzle
- peristaltic pump
- window in filter area to observe filter shaking operation
- rapid change filter bag system
- pneumatic outlet air flap for control of fluidization height

Good Manufacturing Practices (GMP)

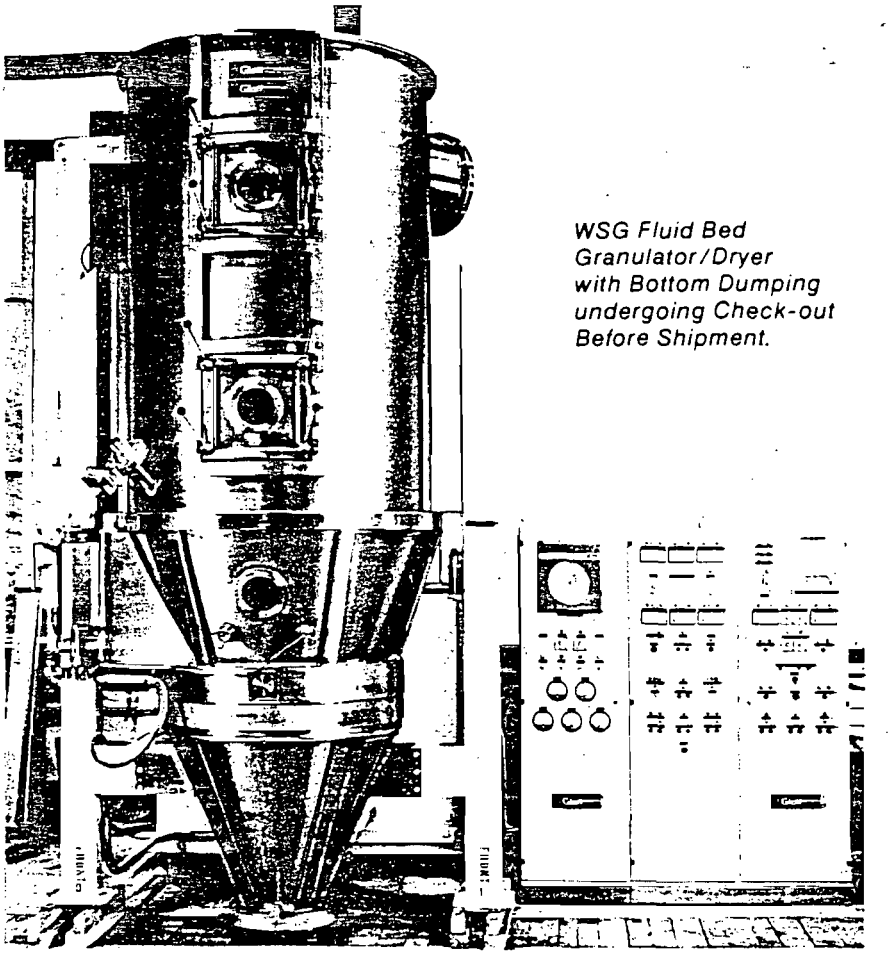
- continuous welds
- all product contact parts mirror polished
- all filters and gaskets easily removable for inspection and cleaning
- drains provided in lower plenum
- sufficient doors provided for access to all parts of machine

Safety

- remote reinforced fan
- external hydraulic pressing system which seals the machine closed and capable of withstanding a 2 bar pressure differential
- exclusive reinforced lower plenum
- totally pneumatic control system, no electrics in process area
- approved explosion relief vents
- side, rear or top explosion relief venting

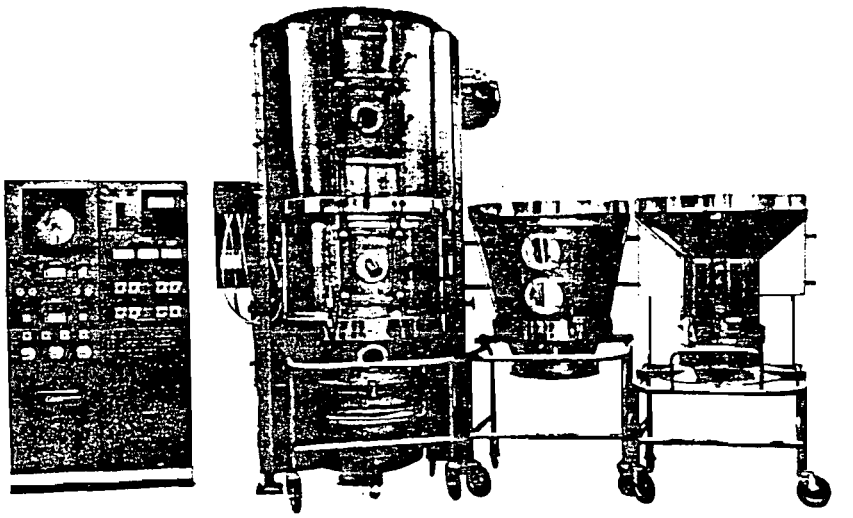
Process Control

- all pneumatic free-standing panel includes:
  - inlet air temperature controller
  - inlet air temperature gauge
  - outlet air temperature gauge
  - automatic filter shaking timers
  - pneumatic outlet air flap controller and indicator
  - pump controls for automatic operation during shake cycle
  - atomization air regulator and indicator



WSG Fluid Bed Granulator/Dryer with Bottom Dumping undergoing Check-out Before Shipment.

- sealing flap
- cooling flap
- magnehelic gauges
- H.E.P.A. filters (inlet or outlet)
- gear-type or piston-type positive displacement liquid pumps
- product bed temperature sensing
- side loading charge port
- automatic process control
- process protection interlock system
- batch-continuous operation
- bottom discharge
- exterior mirror polish finish
- surge hoppers on supply and discharge
- high speed chopper system for delumping of raw materials and/or product densification
- CIP system
- noise attenuation package for remote fan
- fan vibration detector
- less expensive, non-reinforced construction where applications do not present explosion hazard
- solvent recovery systems
- controllable inlet air flap
- doors with windows installed in expansion chamber and filter housing
- face and bypass heat control
- future plans for micro-processor control
- others



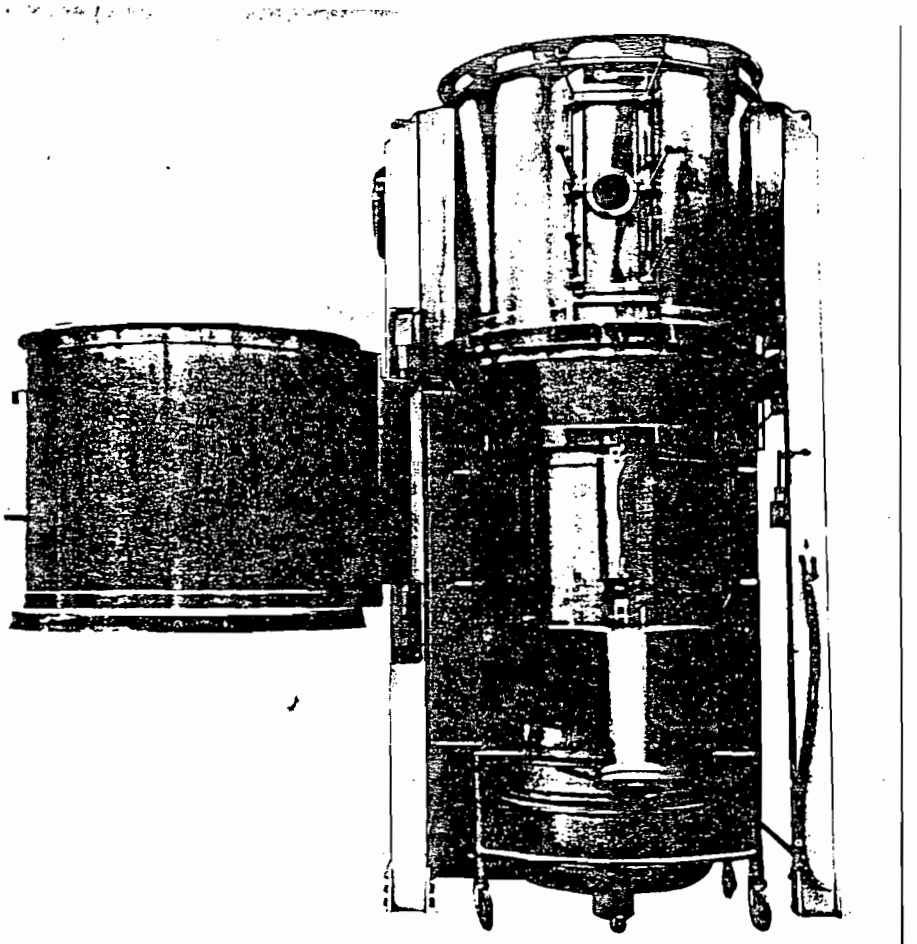
Pilot Plant WSG 60-100 Shown in Reinforced Construction with 30 kg Granulator Change Part and 18" Wurster Change Part

Construction for
Glatt WSG Machines

- for use in installations where there is a requirement for conversion parts to reduce the batch size by approximately one-half (i.e., a 30-50 kilogram granulator/dryer can be supplied with change part for batches of 15-25 kilograms).
- to allow conversion of a fluid bed granulator to a fluid bed Wurster tablet and intermediate size particle coater while retaining the use of the original machine's air handling, control and pumping systems.
- to allow greater access to the machine for maintenance and cleaning.

Safety and CGMP Feature Highlights

- The Glatt exclusive hydraulic pressing system for sealing and locking the machine closed insures its 2-bar explosion shock resistant protection without the use of external clamping devices. This method of closing the machine also allows for the selection of the three piece option for WSG granulator/dryers without any further modifications or the addition of external manual or pneumatic clamps. Conversion of the WSG unit to a smaller batch size machine or a Wurster coater is simple, safe and takes only minutes.
- The lower plenum is dome-shaped, completely open and accessible for cleaning, holds a 2-bar pressure shock-resistant rating, and is equipped with a cleanout drain. When installed, it is positioned several inches above the floor to prevent the accumulation of bacteria and contaminants and to provide for easy cleaning of the exterior of the machine and the surrounding process area.
- The exhaust air filter is suspended on a stainless steel ring with metal to metal contact between filter socks and ring for proper grounding. The entire filter system is quickly and easily removeable for cleaning.



WSG 300-500 Granulator/Dryer in Reinforced Construction Shown with Expansion Chamber Swung Away and 46" Wurster Tablet or Nonpareil Coater in Place (Average Capacity 400 kg.)

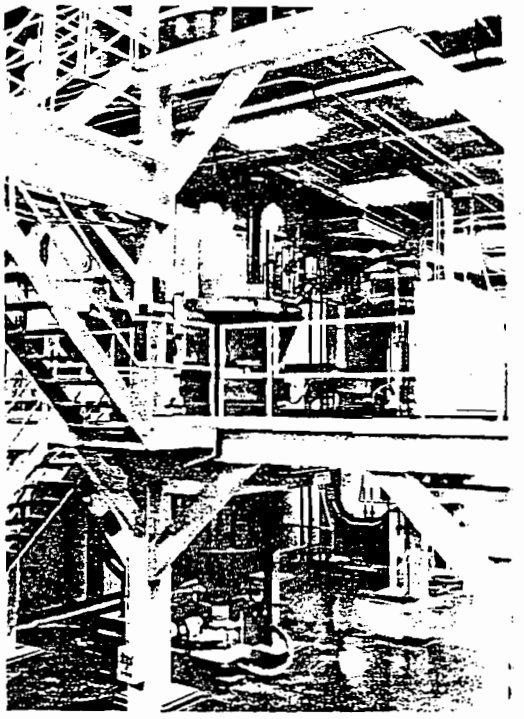
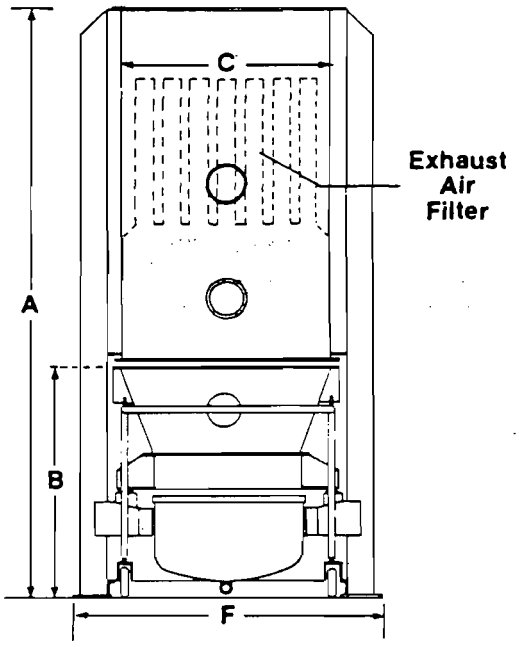
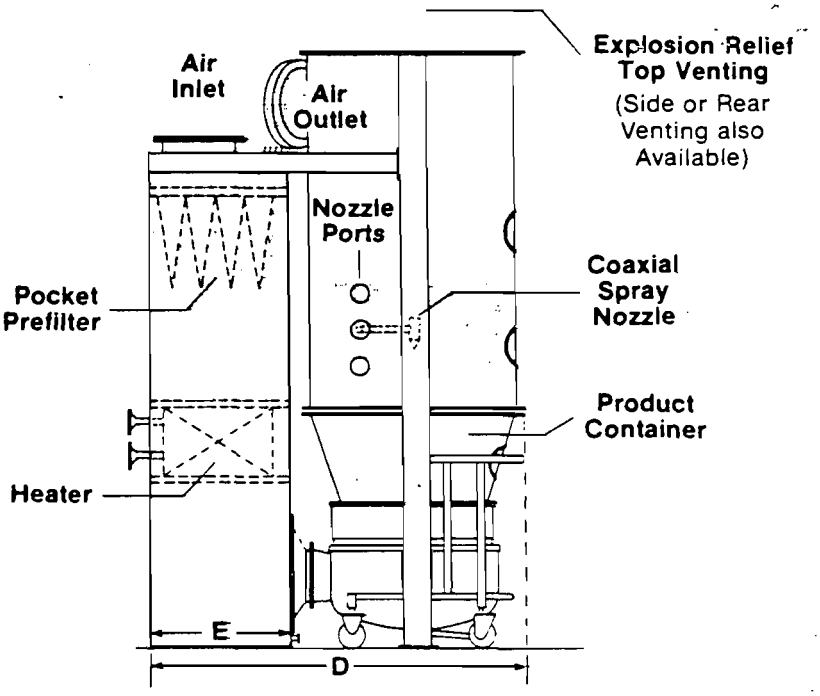


Photo shows a full view of two WSG 1000-1500 granulators showing the three service levels of the machine. The upper level accesses the exhaust air filter housing and bulk material loading facility. The middle section is the process floor where the expansion housing, 3000 liter product container and automatic control panels are located. The lower level contains the discharge surge hopper which receives the finished batch for quick recycle times between batches.





Model Number WSG		5-9	15-25	30-50	60-100	120-180	200-280	300-500	500-800	1000-1500
capacity in liters		22	45	100	220	420	670	1100	1560	3000
F	motor size in KW	5.5	11	18.5	22	30	37	45	55	
A	air capacity in cfm	440	880	1760	2640	3520	4700	5880	7040	
N	static pressure inches of water	40	40	40	40	40	40	40	40	Details
heating capacity in BTU's per hour		64.000	120.000	240.000	360.000	440.000	720.000	840.000	1.008.000	Available
DIMENSIONS in MM	A	2400	2700	3000	3200	3500	4000	4200	5000	On
	B	870	915	985	1175	1375	1590	1760	1980	Request
	C	400	550	720	1000	1200	1400	1590	1800	
	D	1550	1625	1810	2150	2350	2550	2750	3100	
	E	750	750	750	800	800	800	800	900	
	F	800	1020	1160	1500	1700	2060	2360	2600	

All dimensions are approximate and subject to change due to selected options.

*Model number denotes average capacity range in kilograms

Glatt **The leader in fluid bed technology**

Glatt Air Techniques, Inc.
20 Spear Road
Ramsey, New Jersey 07446
Tel: (201) 825-8700
Telex: 642378

Glatt GmbH
7851 Binzen/Lörrach, West Germany
Tel: (7621) 6049, Telex 773573 glatt d
Cable: Glatt Binzen

KEY PHARMACEUTICALS, INC.
NEW PROCESS REVIEW

I. Product

A. Termed product 0410 (Prescription Drug)

B. Solvents involved:

Methylene Chloride
Methanol

C. Process description (see attached Flow Sheet I)

D. Process Quantities

Basis - 350 lots of product per fluid bed processor (i.e. Glatt)

Methanol - 64 tons/year

Methylene Chloride - 326 tons/year

Solids - 17 tons/yr in spray; 98 tons/yr as substrate

E. Overall plant loadings for product

Stage 1 - Two fluid bed processors by about Dec'85

Stage 2 - Add 1 fluid bed processor about Mar'86

NOT this permit → Stage 3 - Add 3 fluid bed processors in latter half of '86.

F. THEO-DUR Production moving to Puerto Rico in 1986 and with it most of the plant's solvent use (i.e. Acetone, IPA, Chloroform, etc.).

II. Solvent Treatment - Scrubber followed by Water Treatment

Description (see attached Flow Sheet II).

(16,500 for 3)

Process air (about 5500 scfm per fluid bed processor) is passed up through a packed column (9 to 10 ft in dia) designed to give about 350 ft/min air velocity based on three units (i.e. fluid bed processors) operating. The column is filled with packing. Water flows down the column at a rate of about 21.5 gal.min per fluid bed processor or 31,000 gal/day/processor (Stage 1: 62,000 gal/day; Stage 2: 93,000 gal/day). Note this system only treats the fluid bed processing units containing Methanol and Methylene Chloride. The water absorbs 80% to 90% of the Methanol and less than 0.5% of the Methylene Chloride. Water containing the Methanol and Methylene Chloride is directed to a water treatment plant (about 1200 ppm to 1400 ppm Methanol and 35 ppm to 40 ppm Methylene Chloride). The Methylene Chloride will flash off and the Methanol is treated biologically. The water is returned to the Scrubber. Evaporation losses are made up by city water. There is no effluent to the sewer system from this plant.

KEY PHARMACEUTICALS, INC.
NEW PROCESS REVIEW

The total Methylene Chloride effluent (about 978 tons/year for 3 units - Stage 2) has been modeled (as per EPA workbook) for discharge from a 50 ft high stack. The maximum flow rate of solvent (Methylene Chloride) is about 220 lb/hour per processor or 660 lb/hour for three processors. The maximum ground level concentration calculates based on a 5 mph wind to less than 2.4 ppmv of Methylene Chloride. The OSHA and ACGIH TLV's are 500 ppmv and 100 ppmv, respectively. The average emission rate is about 1/3 of the maximum which equals 0.85 ppmv. This number is based (as per attached) on a 3 minute sample. The ratio from 3 minutes to 24 hours is to multiply by 0.36 which gives 0.31 ppmv. Based upon conversations with EPA's Bruce Turner, the ratio of 24 hour data to 1 year data is no more than 1/10. Therefore, average daily Methylene Chloride concentrations downwind of the stack are less than 0.031 ppmv. Based upon the stringent New York State AAL Standard, the average value should be less than 1/300 of the TLV. Even using the ACGIH TLV, this is 0.33 ppmv. We are at less than 1/10 of that.

At 80% absorption, total Methanol effluent is 38.4 tons/year and at 90%, 19.2 tons/year. This is less than the 40 ton/year increase limit to a major facility which would normally involve LAER consideration. Methylene Chloride as per 17-2.510 is ignored with respect to New Source Review.

S T A G E 2 P R O D U C T I O N:

Total in (tons/year)		Total out (tons/year)
Methanol	192	~~19.2~~ to 38.4
Methylene Chloride	978	978

SUMMARY

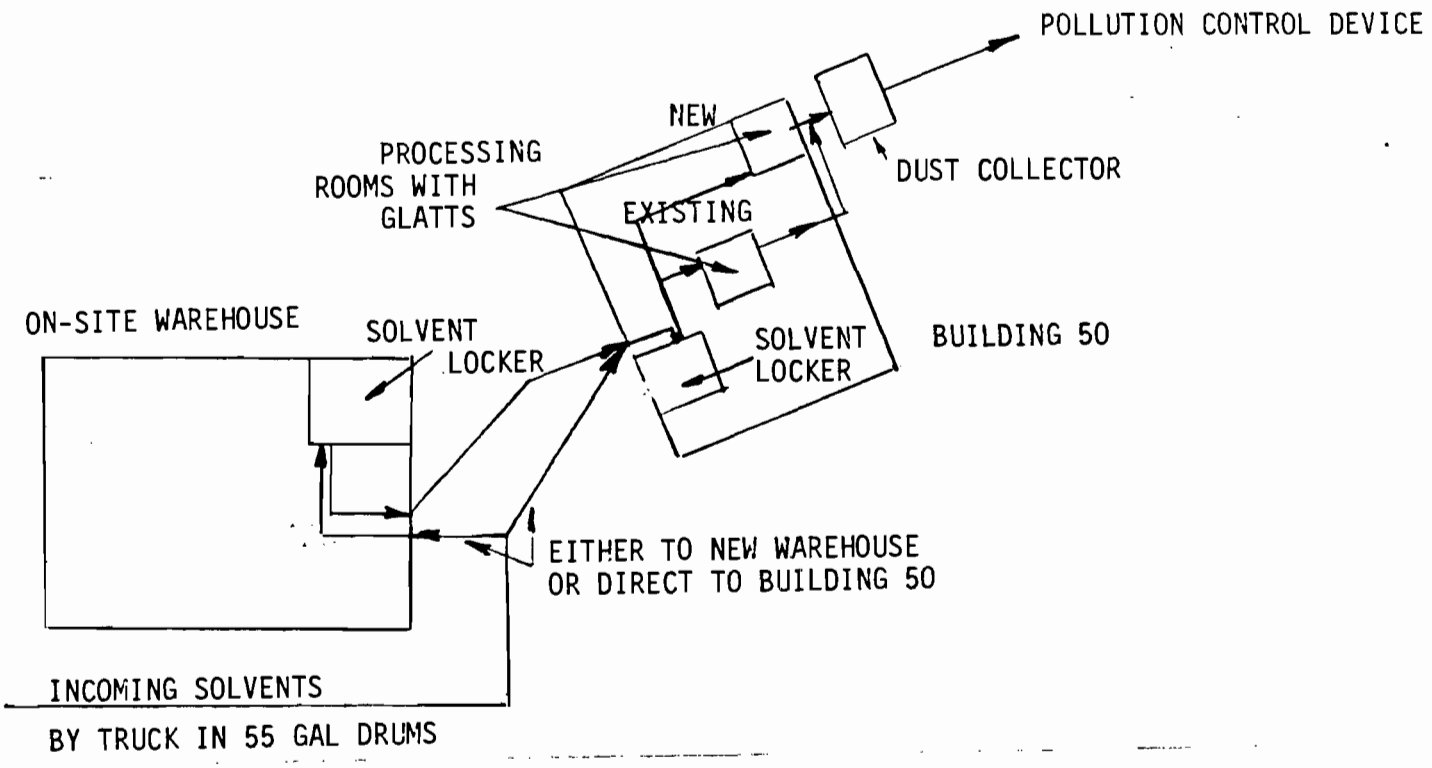
Based on the information presented:

1. Key Pharmaceuticals, Inc. should be allowed to produce a new product (#0410) involving a substantial amount of both Methanol and Methylene Chloride at 50 N.W. 176th Street in Miami, which is in the East Drive Well Field.

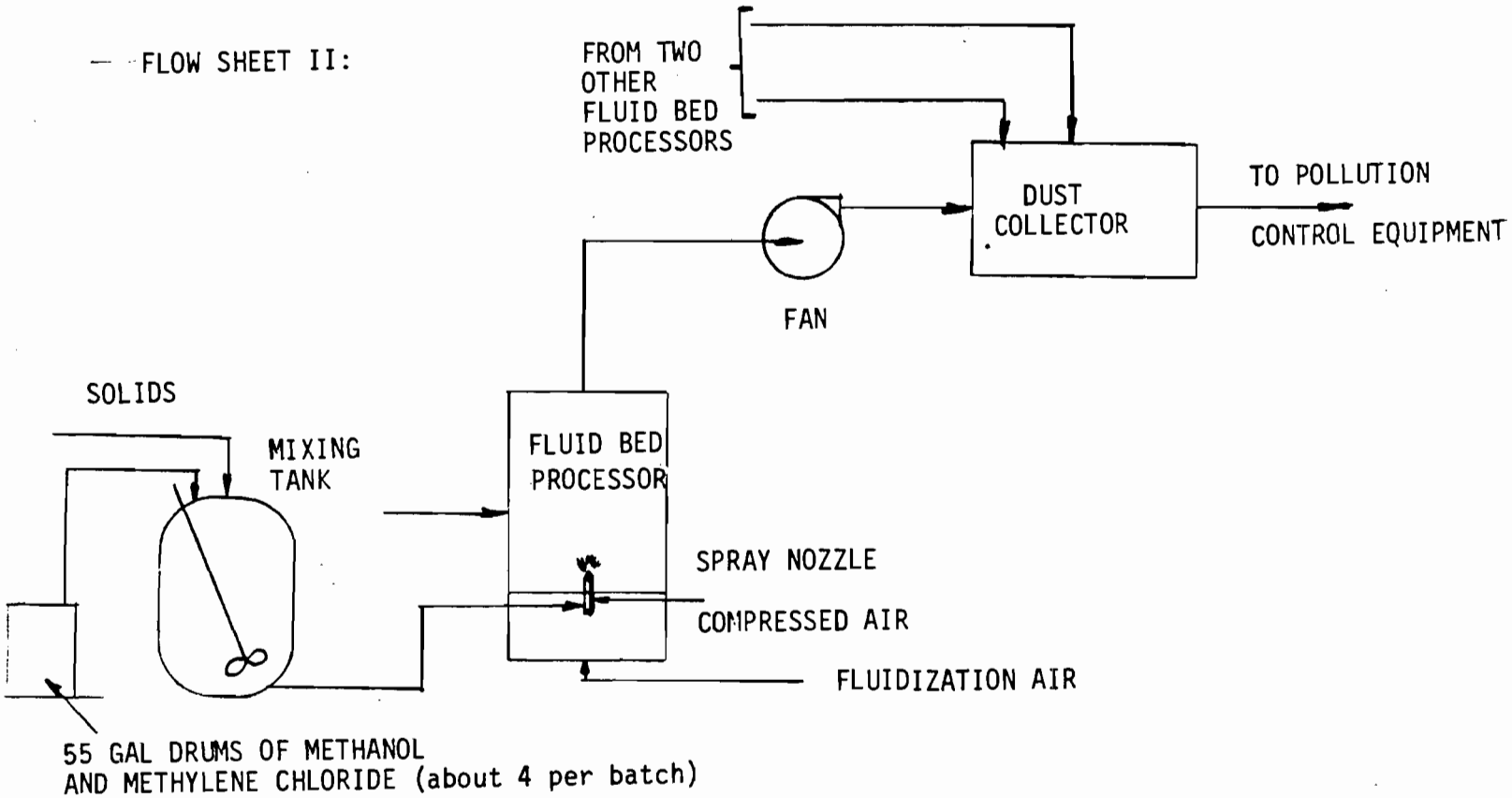
2. The Pollution Control Device for the processes through Stage 2 be Scrubbing with water followed by Waste Water Treatment (biological). There will be no effluent to the sewer system.

FLOW SHEET I

SOLVENT HANDLING



FLOW SHEET II:



JOHN BROWN

Crawford & Russell Incorporated

Dispersion Calculations: Maximum Ground Level Concentrations of Methylene Chloride

Basis of Calculations: Workbook of Atmospheric Dispersion Estimates, D. Bruce Turner, U.S. Environmental Protection Agency, 1970

Figure 3-9; Maximum Concentrations and Distance of Maximum Concentrations

Page 31; Holland's Equation for Plume Rise (correspondence with Dr. Turner indicates Holland's equation generally is conservative.)

Methylene Chloride Emissions:

Average per Glatt: Tons per year	326
Average for 3 Glatts; Tons per year	978
Maximum for 3 Glatts; lbs per hour	660

Air Flow

Maximum	SCFM @ 70°F	18000

Stack exit elevation above grade; feet	50
Stack diameter; inches	30
Stack exit temperature; °F	90
Air temperature; °F	95
Atmospheric pressure; bar	1.0135
Wind speeds considered; MPH	1, 5, 10

Plume Rise - Summer Condition

Holland's Equation

$$\Delta H = \frac{V_s d}{u} \left(1.5 + 2.68 \times 10^{-3} p \frac{(Ts-Ta)}{Ts} d\right)$$

$$Vs = \frac{18000 \text{ SCFM}}{60 \text{ Sec/Min}} \frac{550°R}{530°R} \frac{}{0.785 \times 2.5 \text{ Ft}^2} \times \frac{1}{3.281 \text{ Ft/M}}$$

$$= 19.34 \text{ M/Sec}$$

$$d = \frac{2.5 \text{ Ft}}{3.281 \text{ Ft/M}} = 0.762 \text{ M}$$

u = 1 mph = 0.447 M/Sec

5 mph = 2.234 M/Sec

10 mph = 4.47 M/Sec

Plume Rise - Summer Condition (cont'd)

p = 1013.5 mb
Ts = 90°F = 305.2°K
Ta = 95°F = 308°K

Wind Vel. mph	ΔH M
1	49.15
5	9.83
10	4.92

Maximum Concentration - Distance of Maximum Concentration

$Q = \frac{660 \text{ lbs/hr} \times 454 \text{ gms/lb}}{3600 \text{ Sec/Hr}} = 83.23 \text{ gms/sec},$

Xmax = distance of max concentration, kilometers x 0.6214 $\frac{\text{miles}}{\text{kilometer}}$ = miles

u = 1 mph = o.446 M/Sec
5 mph = 2.234 M/Sec
10 mph = 4.47 M/Sec

H = effective height = plume rise plus stack elevation

X = max ground level conc. gms/M^3 x 1000 mg/gm x 0.278 = ppm (vol)

Wind vel. MPH	Stability Class	Effect Height	$(Xu)/(Q)_{max}$	X gms/M^3	X ppm(v)	x max Miles
1	F	64.4	1.2×10^{-5}	0.00223	0.622	3.54
1	E	64.4	1.7×10^{-5}	0.00315	0.880	1.80
1	D	64.4	2.0×10^{-5}	0.00372	1.04	1.06
1	C	64.4	3.2×10^{-5}	0.00596	1.65	0.46
1	B	64.4	3.4×10^{-5}	0.00633	1.76	0.36
1	A	64.4	3.7×10^{-5}	0.00713	1.98	0.19
5	F	25.1	1.5×10^{-4}	0.00559	1.55	0.78
5	G	25.1	1.7×10^{-4}	0.00633	1.76	0.44
5	D	25.1	1.85×10^{-4}	0.00689	1.91	0.29
5	C	25.1	2.1×10^{-4}	0.00782	1.17	0.17
5	B	25.1	2.2×10^{-4}	0.00819	2.20	0.11
5	A	25.1	2.3×10^{-4}	0.00856	2.38	0.07
10	F	20.2	2.5×10^{-4}	0.00465	1.29	0.56
10	E	20.2	2.8×10^{-4}	0.00521	1.45	0.33
10	D	20.2	3.1×10^{-4}	0.00576	1.60	0.22
10	C	20.2	3.3×10^{-4}	0.00614	1.71	0.12
10	B	20.2	3.2×10^{-4}	0.00595	1.66	0.09
10	A	20.2	3.15×10^{-4}	0.00586	1.63	0.065

KEY PHARMACEUTICALS

METHYLENE CHLORIDE MAXIMUM GROUND LEVEL CONCENTRATION

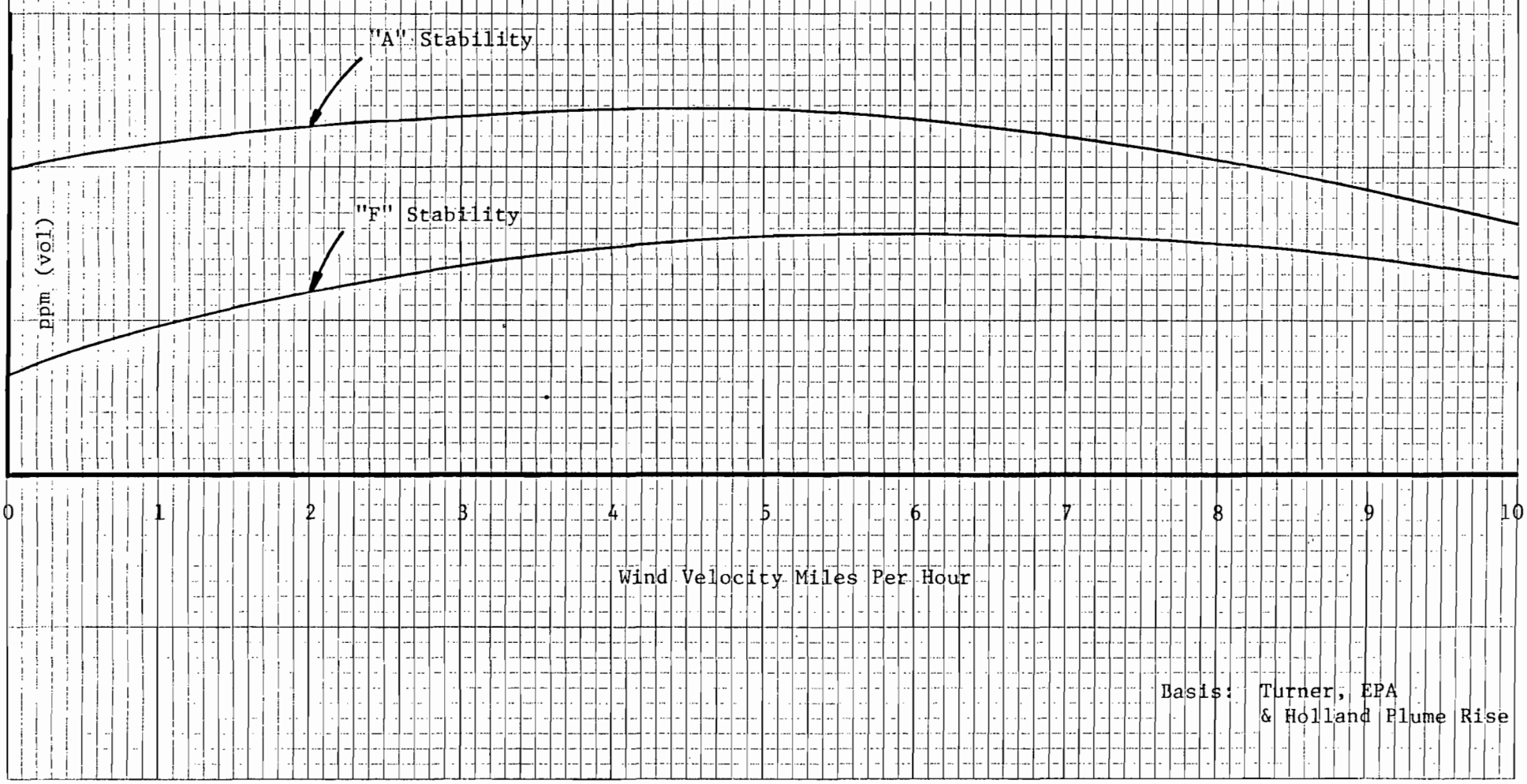
AS FUNCTION OF WIND VELOCITY

Stack Height 50 feet above grade

Stack Exit Velocity 19.34 M/Sec = 63.5 FPS

Stack Exit Temperature 90°F

Maximum Emission Rate of 660 lbs/hr



Basis: Turner, EPA
& Holland Plume Rise

JOHN BROWN

Crawford & Russell Incorporated

Maximum methylene chloride ground level concentration based on maximum emission of 660 lbs/hr = 2.4 ppm

Average emission of methylene chloride = 978 tons/yr
= 233 lb/hr

Methylene chloride ground level concentration based on average emission

$$\frac{233}{660} \times 2.4 = 0.85 \text{ ppm}$$

Calculation of maximum ground level concentration corresponds to 3 minute sample. Table 5-1, Page 38 of Turner shows relation of 24 hour sample to 3 minute sample resulting from "Increased Meander of Wind Direction"

Sample Time	Ratio of Calculated Concentration to 3 minute concentration
3 minutes	1
24 hours	0.36

24 hr concentration based on average emission of

233 lb/hr = 0.36 x 0.85 = 0.31 ppm (vol)

COMPARISON OF CONCENTRATIONS FOR METHYLENE CHLORIDE

	ppm (vol)
OSHA Standard (29 CFR 1910.1000)	500
TLV of Amer. Conf. Gov. Ind. Hyg. (1981)	100
Odor threshold	150-200
New York State Guideline AAL(1)	0.33
Key 24 hr concentration calculated from average emission of 233.0 lbs/hr	0.31(2)
Key maximum concentration (3 minute) calculated from maximum emission of 660 lbs/hr	2.4

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

(2) In conversation with Bruce Turner of the EPA, he expressed the opinion that annual average ambient concentration at any off-site receptor will be no more than 1/10 of 24 hour concentration of 0.31 ppm, i.e. 0.031 ppm and probably will be considerably less than 0.031 ppm.

5.23 PHARMACEUTICALS PRODUCTION

5.23.1 Process Description

Thousands of individual products are categorized as pharmaceuticals. These products usually are produced in modest quantities in relatively small plants using batch processes. A typical pharmaceutical plant will use the same equipment to make several different products at different times. Rarely is equipment dedicated to the manufacture of a single product.

Organic chemicals are used as raw materials and as solvents, and some chemicals such as ethanol, acetone, isopropanol and acetic anhydride are used in both ways. Solvents are almost always recovered and used many times.

In a typical batch process, solid reactants and solvent are charged to a reactor where they are held (and usually heated) until the desired product is formed. The solvent is distilled off, and the crude residue may be treated several times with additional solvents to purify it. The purified material is separated from the remaining solvent by centrifuge and finally is dried to remove the last traces of solvent. As a rule, solvent recovery is practiced for each step in the process where it is convenient and cost effective to do so. Some operations involve very small solvent losses, and the vapors are vented to the atmosphere through a fume hood. Generally, all operations are carried out inside buildings, so some vapors may be exhausted through the building ventilation system.

Certain pharmaceuticals - especially antibiotics - are produced by fermentation processes. In these instances, the reactor contains an aqueous nutrient mixture with living organisms such as fungi or bacteria. The crude antibiotic is recovered by solvent extraction and is purified by essentially the same methods described above for chemically synthesized pharmaceuticals. Similarly, other pharmaceuticals are produced by extraction from natural plant or animal sources. The production of insulin from hog or beef pancreas is an example. The processes are not greatly different from those used to isolate antibiotics from fermentation broths.

5.23.2 Emissions and Controls

Emissions consist almost entirely of organic solvents that escape from dryers, reactors, distillation systems, storage tanks and other operations. These emissions are exclusively nonmethane organic compounds. Emissions of other pollutants are negligible (except for particulates in unusual circumstances) and are not treated here. It is not practical to attempt to evaluate emissions from individual steps in the production process or to associate emissions with individual pieces of equipment, because of the great variety of batch operations that may be carried out

at a single production plant. It is more reasonable to obtain data on total solvent purchases by a plant and to assume that these represent replacements for solvents lost by evaporation. Estimates can be refined by subtracting the materials that do not enter the air because of being incinerated or incorporated into the pharmaceutical product by chemical reaction.

If plant-specific information is not available, industrywide data may be used instead. Table 5.23-1 lists annual purchases of solvents by U.S. pharmaceutical manufacturers and shows the ultimate disposition of each solvent. Disposal methods vary so widely with the type of solvent that it is not possible to recommend average factors for air emissions from generalized solvents. Specific information for individual solvents must be used. Emissions can be estimated by obtaining plant-specific data on purchases of individual solvents and computing the quantity of each solvent that evaporates into the air, either from information in Table 5.23-1 or from information obtained for the specific plant under consideration. If solvent volumes are given, rather than weights, liquid densities in Table 5.23-1 can be used to compute weights.

Table 5.23-1 gives for each plant the percentage of each solvent that is evaporated into the air and the percentage that is flushed into the sewer. Ultimately, much of the volatile material from the sewer will evaporate and will reach the air somewhere other than the pharmaceutical plant. Thus, for certain applications it may be appropriate to include both the air emissions and the sewer disposal, in an emissions inventory that covers a broad geographic area.

Since solvents are expensive and must be recovered and reused for economic reasons, solvent emissions are controlled as part of the normal operating procedures in a pharmaceutical industry. In addition, most manufacturing is carried out inside buildings, where solvent losses must be minimized to protect the health of the workers. Water or brine cooled condensers are the most common control devices, with carbon adsorbers in occasional use. With each of these methods, solvent can be recovered. Where the main objective is not solvent reuse but is the control of an odorous or toxic vapor, scrubbers or incinerators are used. These control systems are usually designed to remove a specific chemical vapor and will be used only when a batch of the corresponding drug is being produced. Usually, solvents are not recovered from scrubbers and reused, and of course, no solvent recovery is possible from an incinerator.

It is difficult to make a quantitative estimate of the efficiency of each control method, because it depends on the process being controlled, and pharmaceutical manufacture involves hundreds of different processes. Incinerators, carbon adsorbers and scrubbers have been reported to remove greater than 90 percent of the organics in the control equipment inlet stream. Condensers are limited, in that they can only reduce the concentration in the gas stream to saturation at the

condenser temperature, but not below that level. Lowering the temperature will, of course, lower the concentration at saturation, but it is not possible to operate at a temperature below the freezing point of one of the components of the gas stream.

TABLE 5.23-1. SOLVENT PURCHASES AND ULTIMATE DISPOSITION BY PHARMACEUTICAL MANUFACTURERS[a]

Solvent	Annual Purchase (metric tons)	Ultimate Disposition (percent)					Liquid Density lb/gal @ 68°F
		Air Emissions	Sewer	Incineration	Solid Waste or Contract Haul	Product	
Acetic Acid	930	1	82	-	-	17	8.7
Acetic Anhydride	1,265	1	57	-	-	42	9.0
Acetone	12,040	14	22	38	7	19	6.6
Acetonitrile	35	83	17	-	-	-	6.6
Amyl Acetate	285	42	58	-	-	-	7.3
Amyl Alcohol	1,430	99	-	-	-	1	6.8
Benzene	1,010	29	37	16	8	10	7.3
Blendan (AMOCO)	530	-	-	-	-	100	NA
Butanol	320	24	8	1	36	31	6.8
Carbon Tetrachloride	1,850	11	7	82	-	-	13.3
Chloroform	500	57	5	-	38	-	12.5
Cyclohexylamine	3,930	-	-	-	-	100	7.2
o-Dichlorobenzene	60	2	98	-	-	-	10.9
Diethylamine	50	94	6	-	-	-	5.9
Diethyl Carbonate	30	4	71	-	-	25	8.1
Dimethyl Acetamide	95	7	-	-	93	-	7.9
Dimethyl Formamide	1,630	71	3	20	6	-	7.9
Dimethylsulfoxide	750	1	28	71	-	-	11.1
1,4-Dioxane	43	5	-	-	95	-	8.6
Ethanol	13,230	10	6	7	1	76	6.6
Ethyl Acetate	2,380	30	47	20	3	-	7.5
Ethyl Bromide	45	-	100	-	-	-	12.1
Ethylene Glycol	60	-	100	-	-	-	9.3
Ethyl Ether	280	85	4	-	11	-	6.0
Formaldehyde	30	19	77	-	-	4	b
Formamide	440	-	67	-	26	7	9.5
Freons	7,150	0.1	-	-	-	99.9	c
Hexane	530	17	-	15	68	-	5.5
Isobutyraldehyde	85	50	50	-	-	-	6.6
Isopropanol	3,850	14	17	17	7	45	6.6
Isopropyl Acetate	480	28	11	61	-	-	7.3
Isopropyl Ether	25	50	50	-	-	-	6.0
Methanol	7,960	31	45	14	6	4	6.6
Methyl Cellosolve	195	47	53	-	-	-	8.7
Methylene Chloride	10,000	53	5	20	22	-	11.1
Methyl Ethyl Ketone	260	65	12	23	-	-	6.7
Methyl Formate	415	-	74	-	12	14	8.2
Methyl Isobutyl Ketone	260	80	-	-	-	20	6.7
Polyethylene Glycol 600	3	-	-	-	-	100	9.5
Pyridine	3	-	100	-	-	-	8.2
Skelly Solvent B (hexanes)	1,410	29	2	69	-	-	5.6
Tetrahydrofuran	4	-	-	100	-	-	7.4
Toluene	6,010	31	14	26	29	-	7.2
Trichloroethane	135	100	-	-	-	-	11.3
Xylene	3,090	6	19	70	5	-	7.2

[a] These data were reported by 26 member companies of the Pharmaceutical Manufacturers Association, accounting for 53 percent of pharmaceutical sales in 1975.

[b] Sold as aqueous solutions containing 37% to 50% formaldehyde by weight.

[c] Some Freons are gases, and others are liquids weighing 12 - 14 lb/gal.

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

SOUTHEAST FLORIDA
DISTRICT

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

December 17, 1984

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert A. Franke
Director Production Engineering
50 N.W. 176th Street
P.O. Box 693670
Miami, Florida 33169-0670

Dear Mr. Franke:

Enclosed for your implementation is the fully executed and filed Consent Order in the above-styled case. Please familiarize yourself with the compliance dates and terms of the Order so that the complete and timely performance of those obligations is accomplished.

Sincerely,

Richard R. Reis

Richard R. Reis
Enforcement Section Head

RRR:rr/23

Enclosure

cc: Legal Assistant, Office of General Counsel, DER, Tallahassee
Office of Public Information, DER, Tallahassee
Bureau of Air Quality Management, DER, Tallahassee
U.S. Environmental Protection Agency, Air Program, Atlanta
Metro-Dade County Environmental Resources Management, Air Program
West Palm Beach DER Files

FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATION

GUARANTY OF KEY PHARMACEUTICALS, INC.
FOR CESSATION OF OPERATION OF UNPERMITTED SOURCES OF
VOLATILE ORGANIC COMPOUND EMISSIONS
AS REQUIRED BY CONSENT ORDER ENTERED IN
OGC CASE NO. ~~83-0373~~ PURSUANT TO
CHAPTER 403, FLORIDA STATUTES

84-0644

Know All Men By These Presents, that Key Pharmaceuticals, Inc. is held hereby and firmly bound unto the Florida Department of Environmental Regulation to maintain corporate assets sufficient to discharge any obligations during the term of this Guaranty up to a total of $150,000. This Guaranty is issued in connection with the Department of Environmental Regulation Consent order Case No. ~~83-0373~~ 84-0644 and the agreements of the parties stated therein. The Guaranty shall remain in full force and effect until the expiration of the Consent Order pursuant to its terms.

NOW, THEREFORE, if Key Pharmaceuticals, Inc. shall shut down and remove and/or dismantle any unpermitted sources of volatile organic compound emissions covered by the Consent Order on or before November 30, 1986, then this obligation shall become void.

In Testimony Whereof, Witness our hands, this 7th day of December, 1984.

ATTEST:

Assistant Secretary

KEY PHARMACEUTICALS, INC.

By: Allen Z. Gant
Vice President

Issued December 10, 1984
Received December 17, 1984

BEFORE THE STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

STATE OF FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATION, Complainant, vs. KEY PHARMACEUTICALS, INC., Respondent.	)	IN THE OFFICE OF THE SOUTHEAST FLORIDA DISTRICT OGC CASE NO. ~~83-0373~~ 84-0644

CONSENT ORDER

This Consent Order is made and entered into between the STATE OF FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATION ("Department"),and KEY PHARMACEUTICALS, INCORPORATED ("Respondent"). It is agreed between the parties that this Consent Order is not intended to constitute an admission or denial by Respondent of any wrong doing or violation of the laws of the State of Florida, rather it is a means of expeditiously resolving a dispute existing between the parties. To that end, the parties agree as follows:

1. Respondent is now and has been at all times pertinent hereto owner and operator of a pharmaceuticals production facility located in Miami, Dade County, Florida. The facility is bounded on the west by S.R. 441, on the east and south by Interstate highway 95, and on the north by northwest 176th Street.

2. Respondent's facility is a source of uncontrolled volatile organic compound (VOC) emissions associated with the production of sustained release theophylline (Theo-dur and Theo-nar) tablets and sprinkle capsules. Theo-dur and Theo-nar are pharmaceutical preparations used to prevent or control attacks in chronic asthmatics. Organic solvents (VOC's) utilized in both preparations include isopropyl alcohol, acetone, ethyl acetate, chloroform, and methanol.

Theo-nar preparations comprise five percent or less of the current product mix and are expected to decrease in coming months.

3. VOC's in general, and specifically those emitted by Respondent's facility, are chemical precursors in the formation of the air pollutant, ozone. Dade County has been designated as a non-attainment area for ozone by the Department and the U.S. Environmental Protection Agency. Department rules require a permit prior to the construction, operation or modification of major sources of VOC emissions in non-attainment areas.

4. From 1976 to the present, Respondent has unintentionally engaged in the construction, operation or modification of various pollution sources at its Miami facility without first obtaining needed permits from the Department. The Department alleges that such failure to obtain required Department permits constitutes a violation of Sections 403.087(1) and 403.161(1)(b), Florida Statutes, and Florida Administrative Code Rules 17-2.210, 17-4.03 and 17-4.23. Each of the following separate sources has been constructed, operated or modified without Department permits: coating pan room #1, coating pan room #2, coating pan room #3, granulation unit #1, granulation unit #2, and fluid bed coating #1.

5. From 1980 to the present, Respondent has unintentionally engaged in the modification or construction of the sources listed in paragraph 4 above without seeking from the Department a determination of lowest achievable emission rates (LAER) as required by Rule 17-2.640(1), Florida Administrative Code, or without utilization of VOC controls sufficient in the Department's view to exempt such sources from the LAER determination requirement. The Department alleges that such failure to use appropriate controls for VOC emissions constitutes a violation of Section

403.161(1)(a), Florida Statutes, and Florida Administrative Code Rule 17-2.510(4)(a).

6. Respondent voluntarily, through its representatives, brought the above referenced matters to the Department's attention in early 1984 and has since that time worked diligently to provide the Department with additional information requested so that this matter might be resolved.

7. Respondent and the Department have met and cooperated with each other in an attempt to resolve any disputes between them and eliminate any potential violations of Department rules or Chapter 403, Florida Statutes. Respondent has expressed its intent to achieve compliance by shutting down each of its unpermitted sources of VOC's in its Miami facility on or before November 30, 1986. At that time, Respondent will have relocated its current Theo-dur product line which constitutes ninety-five percent of its product mix and the associated VOC emitting processes to a new facility being constructed in Puerto Rico. Although Respondent may elect to utilize its Florida facility with regard to the future production of other product lines, possibly including the currently produced Theo-nar preparations, it would not begin such operations except under the conditions of any necessary air construction and/or operating permit(s) from the Department.

8. The Department and the Respondent have conducted an analysis of the historical development of Respondent's facility, including but not limited to equipment changes and emissions increases. The Department has reviewed and accepted information submitted by Respondent regarding capital expenditures and maintenance costs foregone as a result of not having installed VOC control equipment at its various sources located within its Miami facility.

9. Respondent has applied with the Department for a permit to construct "Glatt #2", a new source of VOC emissions at the Miami facility. The new source is expected

to commence operations in early 1985 and to continue operation past the November 30, 1986 shutdown date of the existing sources at the facility. At the present time it is estimated that in order to meet current demands for Theophylline product, the source will need to be operated from 60 to 90 days prior to the time that pollution control equipment can be installed.

10. The Department has incurred costs in the investigation of this case and preparation of this Consent Order estimated at $1,500. Projected costs to be incurred in the monitoring of this Consent Order are estimated at $500.

THEREFORE, having reached a resolution of these matters, pursuant to Florida Administrative Code Rule 17-103.110(3), Respondent and the Department mutually agree, and it is

ORDERED:

11. Respondent shall comply with the following interim "milestone" requirements for the Puerto Rico facility:

Milestone	Compliance Date
(a) Environmental Assessment Approval	January 1984
(b) Site Preparation Contracts	February 1984
(c) Filed Application for Water Quality Certification	April 1984
(d) Filed NPDES Permit Application	July 1984
(e) Issuance of Certificate of Occupancy (or equivalent) by Local Zoning Authority	February 1986
(f) Validation of Constructed Facility by FDA Inspectors	July 1986
(g) FDA Final Process Approval	September 1986
(h) Commence Commercial Scale Production	November 1986

12. Failure to comply with the interim deadlines set forth in paragraph 11 shall result in a stipulated fine of $250 per day for each day of noncompliance past the applicable deadline; provided however that Respondent's liability for and obligation to make such payments shall cease during

such time as the failure to meet any milestone noted above for the completion of the facility in Puerto Rico is excused by the Department due to the occurrence of delay as a result of any of the following:

(a) An act of war.

(b) An act of government, either state, federal, or municipal.

(c) An act of God, which means an unforeseeable act exclusively occasioned by the violence of nature without the interference of any human agency.

(d) An act or omission of a third party without regard to whether any such act or omission was or was not negligent.

(e) Other good cause as determined by the Department.

13. Respondent shall submit progress reports within ten (10) working days after each interim deadline has occurred certifying completion of the interim requirement and providing a progress report on construction of the Puerto Rico facility. Such reports shall be submitted to the Southeast District Office of the Department referred to in paragraph 17, below.

14. Respondent, on or before November 30, 1986, shall submit a certificate of completion of construction or equivalent for the Puerto Rico facility. The certificate shall be attested to by an engineer registered in the Commonwealth of Puerto Rico.

15. During the term of this Consent Order Glatt #2 may be operated if all of the following conditions are met:

(a) Respondent must be in compliance with all the terms of this Consent Order; and

(b) Respondent must have received any appropriate permit from the Department for Glatt #2; and

(c) Glatt #2 shall not be operated more than 90 days prior to the installation of permanent pollution control equipment. Respondent shall provide documentation to the Department demonstrating that total VOC emissions from Glatt #2 during this interim 90 day period has not exceeded ten

tons. Combined emissions from Glatt #2 before and after the installation of permanent pollution control equipment shall not exceed 40 tons in any consecutive 12 month period; and

(d) In the event that the emission limitations in the preceeding sentence are exceeded, Respondent shall pay $500 for each day of operation of Glatt #2 in excess of such limitation.

(e) Respondent shall cease operations of Glatt #2 if the above conditions are not met, unless such noncompliance is excused by the Department.

16. Respondent shall not operate new VOC emitting processes at the Miami facility prior to obtaining all necessary Department permits. Any such new process to be located within the facility that emits VOC's shall be reviewed as a minor source only if it would not result in a significant net increase (40 tons per year or more) in the "allowable" level of VOC emissions from the facility. For the purposes of this provision the "allowable" level of VOC emissions from the facility shall be the average level of emissions that would be associated with normal operations at maximum capacity of the sources listed in paragraphs 4 and 15 above; provided, however, that after November 30, 1986, this "allowable" level of VOC emissions shall be decreased by the amount of emissions reductions that would hypothetically occur if 90% of the non-chlorinated hydrocarbon emissions from the sources listed in paragraph 4 were removed by incineration.

17. Respondent, within sixty (60) days of the effective date of this Consent Order shall submit to the Department a Cashier's check in the amount of $97,000 as full settlement of all the matters set forth in this Consent Order and for past and projected costs and expenses incurred in the investigation of this case and in the preparation and monitoring of this Consent Order. The cashier's check shall be made payable to the Pollution Recovery Fund of the State of

Florida Department of Environmental Regulation and addressed to the Department of Environmental Regulation, 3301 Gun Club Road, West Palm Beach, Florida 33402.

18. Respondent has executed a corporate guaranty with the Department in the amount of $150,000, a copy of which is attached hereto as Exhibit "A". This guaranty shall be forfeited if the Respondent fails to shut down non-permitted VOC sources at its Miami facility on or before November 30, 1986. The $150,000 corporate guaranty shall be returned in whole to the Respondent if Respondent provides satisfactory documentation that it has, by November 30, 1986, successfully completed the shutdown and removal and/or dismantling of any VOC sources at the Miami facility which have not obtained necessary permits from the Department.

19. Respondent shall pay $750 per day for each day after January 1, 1987 that any unpermitted VOC source at Respondent's facility that is identified in this Consent Order operates. These monies shall be remitted thereafter on a monthly basis to the Department's Pollution Recovery Fund at the address specified in paragraph 17 until Respondent complies with the Consent Order by VOC source shutdown.

20. The Department, for and in consideration of the complete and timely performance by the Respondent of the obligations agreed to in this Consent Order, hereby waives its right to seek administrative or judicial imposition of damages, or civil or criminal penalties for the alleged violations outlined in this Consent Order. This waiver shall apply to such violations that have occurred prior to the effective date of this order and to any future activities authorized under this Consent Order. Respondent waives its right to a hearing or judicial review of the terms of this Order. However, nothing herein shall be deemed to constitute an admission of liability by Respondent.

21. Respondent shall allow authorized representatives of the Department access to the property at reasonable times for purposes of determining compliance with this Consent Order and the rules and regulations of the Department.

22. The Department hereby expressly reserves the right to initiate appropriate legal action to prevent or prohibit the future violation of applicable statutes, or the rules promulgated thereunder, other than those allowed by this Consent Order.

23. Entry of this Consent Order does not relieve Respondent of the need to comply with applicable federal, state, or local laws, regulations, or ordinances not addressed herein, nor does it abrogate the rights of substantially affected persons who are not parties to this Consent Order, pursuant to Chapter 120, Florida Statutes.

24. The terms and conditions set forth in the Consent Order may be enforced in a court of competent jurisdiction pursuant to Sections 120.69 and 403.121, Florida Statutes. Failure to comply with the terms of this Consent Order may constitute a violation of Section 403.161(1)(b), Florida Statutes.

25. Respondent is fully aware that a violation of the terms of this Consent Order, other than as is specifically covered in the penalty provisions thereof, may subject Respondent to judicial imposition of damages, civil penalties of up to $10,000 per offense, and criminal penalties.

26. This Consent Order shall take effect upon the date of filing and acknowledgment by the Clerk of the Department and shall constitute final agency action by the Department pursuant to Section 120.69, Florida Statutes and Florida Administrative Code Rule 17-103.110(3).

27. In the event of a legal challenge to this Consent Order by a party not subject to this Consent Order, the parties shall comply with the terms and conditions herein

unless and until such time as the resolution of the challenge results in agency action inconsistent with this Consent Order.

28. The terms of this Consent Order shall be in effect until Respondent provides the documentation of shutdown specified in paragraph 18 or November 30, 1987, whichever is sooner, except that paragraph 16 shall have continuing effect.

29. This Consent Order may only be modified by the written agreement of both parties.

FOR THE RESPONDENT

DATE: Dec 10, 1984 — Allen F. Grant

DONE AND ORDERED this 10 day of December, 1984, in West Palm Beach, Florida.

Roy M Duke

ROY M. DUKE
District Manager
Southeast Florida District
Department of
Environmental Regulation
3301 Gun Club Road
Post Office Box 3858
West Palm Beach, FL 33402
(304) 689-5800

FILING AND ACKNOWLEDGEMENT
FILED, on this date, pursuant to S120.52 (9), Florida Statutes, with the designated Department Clerk, receipt of which is hereby acknowledged.

Joan A. Hubbard — Clerk
12-17-84 — Date

Copies furnished to:

Wali Kharif, Office of General Counsel, DER, Tallahassee
Office of Public Information, DER, Tallahassee
Bureau of Air Quality Management, DER, Tallahassee
U.S. Environmental Protection Agency, Air Program, Atlanta
Metro-Dade County Environmental Resources Management, Air Program
West Palm Beach DER files