

Check Sheet

Company Name: Key Pharmaceuticals, Inc.
Permit Number: AC 13-091497
PSD Number: _____
Permit Engineer: _____

Application:

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

Cross References:

-
-
-

Intent:

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

Correspondence with:

- EPA
- Park Services
- Other

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

Final Determination:

- Final Determination
- Signed Permit
- BACT Determination
- Other

Post Permit Correspondence:

- Extensions/Amendments/Modifications
- Other

In the folder labeled as follows there are documents, listed below, which were not reproduced in this electronic file. That folder can be found in one of the file drawers labeled Supplementary Documents Drawer. Folders in that drawer are arranged alphabetically, then by permit number.

Folder Name: Key Pharmaceuticals

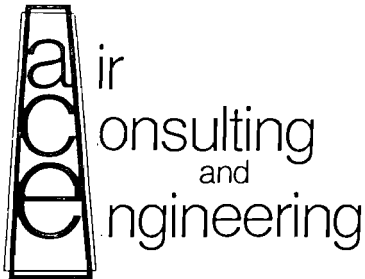
Permit(s) Numbered:

AC	16	-	091497
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Period during
which document
was received:

Detailed Description

Period during which document was received:	Detailed Description
1.	PHOTOS OF SITE



August 12, 1986
174 86 01

Mr. Willard Hanks
Florida Department of
Environmental Regulation
Northwest District Branch Office
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, FL 32301

DER

AUG 18 1986

BAQM

RE: Key Pharmaceuticals Methanol Reduction System Compliance Testing
(A013-114316).

In response to our recent phone conversation I wish to amend our proposed test methodology of July 7, 1986. We now plan to perform isokinetic sampling at the scrubber outlet. Only one sampling port is available, however, due to the unique construction materials of this source. The stack diameter is only 30" and the sampling location is downstream of a mist eliminator pad so a very even velocity profile is expected.

As you recall, we agreed that it would be a wise choice to select isokinetic sampling because we could not discount the possibility of methanol laden water aerosols at the scrubber outlet. In choosing this alternative, however, we can no longer utilize Method 18 or similiar Volatile Organic Sampling Train (VOST) technology, as these are all designed for single point, limited sample volume tests. I, therefore, am obligated to return to a slight modification to my original proposed collection media (HPLEC water) and analysis methodology. I shall use the modified Method 5 (MM5) train with a silica gel sorbent trap located after the third impinger (normal sorbent trap location is before first impinger). The sorbent trap has been moved to protect it from adverse effects of moisture and pollutant saturation. The particulate filter will also not be utilized and probe washings of water added to the first impinger catch. As suggested before, each of the three impinger mediums will be analyzed seperately along with the silica gel sorbent using GC/FID.

If you have additional comments, please contact me.

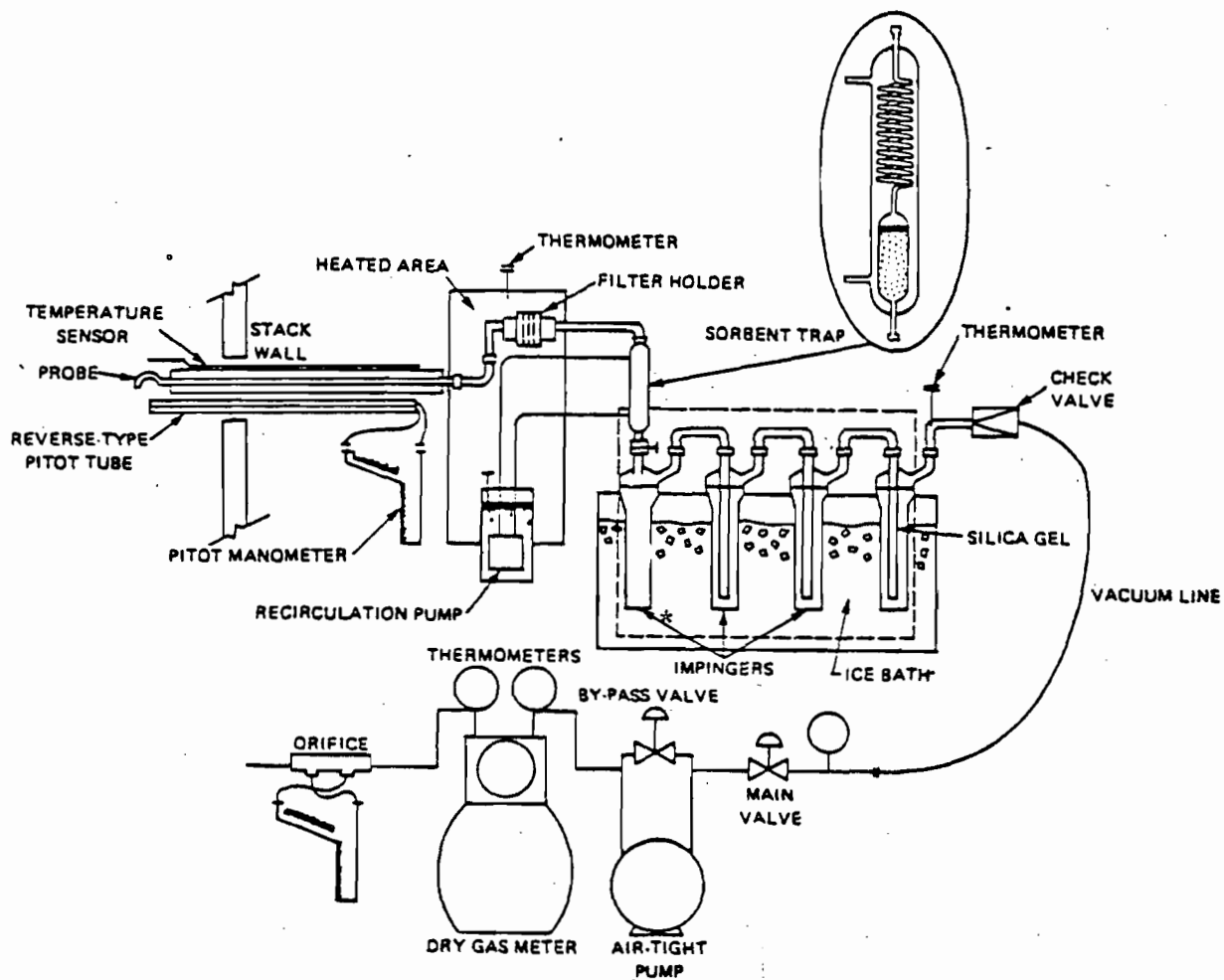
Respectfully,

AIR CONSULTING AND ENGINEERING

Stephen L. Neck, P.E.

SLN:klp

cc: Ms. Stephanie Brooks (FDER-Southeast District)
Mr. Stephen J Goodstein (Key Pharmaceuticals)



*First impinger which serves as condensate trap has a very short stem that does not extend into the condensate; it may be oversized.

FIGURE 3: Modified Method 5 Train

United States
Environmental Protection
Agency

Office of Water and
Waste Management
Washington, DC 20460

Betty Willis

February 1982



Sampling and Analysis Methods for Hazardous Waste Incineration

(First Edition)

RETURN TO:

*Betty C. Willis - 404-881-3423
Waste Engineering Section
U.S. Environmental Protection Agency
345 Courtland Street NE
Atlanta, GA 30365*

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

8-21-85
This permit was
replaced by
AC 13-100437
LJ/k

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

Dear Mr. Goldman:

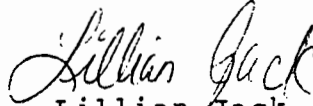
Thank you for your comments regarding Key Pharmaceutical's
Construction permit AC 13-091497.

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

... the Glatt No. 2 shall not exceed 0.3 lb/hr; 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
Engineer
Bureau of Air Quality
Management

LJ/ks

cc: B. Thomas

Patty,
this is a
copy to keep
in the 1st permit
file for Key
Pharmaceutical.
Goldman's comments
were minor and
done late
2-

No. 0158668

RECEIPT FOR CERTIFIED MAIL

NO INSURANCE COVERAGE PROVIDED—
NOT FOR INTERNATIONAL MAIL

(See Reverse)

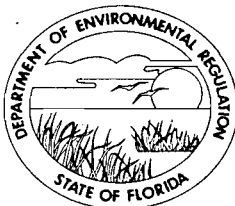
SENT TO			
Mr. Allen F. Gant			
STREET AND NO.			
P.O., STATE AND ZIP CODE			
POSTAGE	\$		
CONSULT POSTMASTER FOR FEES	CERTIFIED FEE	¢	
	SPECIAL DELIVERY	¢	
	RESTRICTED DELIVERY	¢	
	OPTIONAL SERVICES	RETURN RECEIPT SERVICE	¢
		SHOW TO WHOM, DATE, AND ADDRESS OF DELIVERY	¢
		SHOW TO WHOM AND DATE DELIVERED	¢
		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			
2/27/85			

PS Form 3800, Apr. 1976

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

February 25, 1985

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

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

Dear Mr. Gant:

Enclosed is Permit Number AC 13-091497 dated February 25, 1985, to Key Pharmaceuticals, Inc. issued pursuant to Section 403, Florida Statutes.

Acceptance of this permit constitutes notice and agreement that the department will periodically review this permit for compliance, including site inspections where applicable, and may initiate enforcement actions for violation of the conditions and requirements thereof.

Sincerely,

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

CHF/pa

Enclosure

cc: Art Bolivar
Roy Duke
Lloyd H. Stebbins
Bill Voshell

Final Determination

Key Pharmaceuticals, Inc.
Miami, Dade County, Florida

No. 2 Fluidized Bed Coating Unit
Permit Number AC 13-091497

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

February 25, 1985

Final Determination
Key Pharmaceuticals, Inc.
AC 13-091497

Key Pharmaceutical's permit application for construction of the No. 2 Fluidized Bed Coating Unit has been reviewed by the department. Public notice of the department's intent to issue was published in the Miami Herald on January 16, 1985.

Copies of the Preliminary Determination and Technical Evaluation have been available for public inspection at the department's Southeast District office in West Palm Beach, Dade County Department of Environmental Resources Management in Miami, and the Bureau of Air Quality Management in Tallahassee.

Comments were received from Mr. I. Goldman with the Southeast District office, West Palm Beach, Palm Beach County, Florida, on January 7, 1985. Mr. Goldman requested that Specific Conditions No. 1, 2, 3, 4, 5, 6, and 8 be revised as shown in his statements. (Attachment A)

The department considered the comments and questions and reply as follows:

Specific Condition:

No. 1: The department has agreed to modify Specific Condition No. 1 for clarification purposes. This Specific Condition shall read:

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)).

No. 2: Mr. Goldman questions the use of 8400 hrs/yr instead of 8760 hrs/yr. Key Pharmaceuticals requested permitted operating time in the application is 24 hrs/day, 7 days/wk, 50 wks/yr. Therefore, the operating hours shall not exceed 8400 hrs/yr.

No. 3 Mr. Goldman's question concerning the capacity or input rate equalling the 40 ton/yr VOC output was considered.

The maximum input rate is 107.6 lbs/hr. For this source, the calculations show 9.7 tons/yr VOC.

Reference: Mr. Lloyd H. Stebbins, letter of October 17, 1984 - Response to incompleteness letter Statement 2. (Attachment B)

- No. 4 For clarification, the department modified this specific condition by combining specific condition 4 and 5 and including the words "opacity test." Specific Condition No. 4 shall read as follows:

The Glatt No. 2 opacity test shall meet all applicable requirements of 40 CFR 60, Appendix A, Reference Method 9. Particulate matter emissions from the Glatt No. 2 shall not exceed 0.3 lb/hr, 25.9 tons/yr or 5% opacity.

- No. 6 This specific condition shall now read as Specific Condition No. 5. The department considered Mr. Goldman's suggestion that the testing for nitrogen oxide emissions be a one time requirement instead of every 5 years.

Specific Condition No. 5 has been modified and shall read as follows:

Nitrogen oxide emissions, as determined by EPA Reference Method 7 described in 40 CFR 60, Appendix A, shall not exceed 0.1 lb No_x emitted per MMBtu heat input. Routine tests for nitrogen oxides will not be required if the initial test shows compliance with this specific condition.

Specific Condition No. 7 shall now read as Specific Condition No. 6.

- No. 8 This Specific Condition shall now read as Specific Condition No. 7. The department has considered Mr. Goldman's comments and has determined that Condition No. 7 will include the words "for VOC" and "of VOC" for clarification; however, all other statements in this Specific Condition will remain the same as stated in the draft permit. This is a reasonable request for this type of operation, and particularly so due to the department's previous lack of operating data from Key Pharmaceuticals.

Specific Condition No. 7 shall read as follows:

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, and

emission tests 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.

Attachments to be incorporated are:

Attachment A: Mr. I. Goldman's comments dated December 31, 1984.
Attachment B: Mr. Lloyd Stebbins letter dated October 17, 1984.

The final action of the Department will be to issue the permit with the changes noted 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 13-091497

Expiration Date: June 30, 1985

County: Dade

Latitude/Longitude: 25° 56' 04"N/
80° 12' 11"W

Project: No. 2 Fluidized Bed
Coating Unit

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 107.6 lb/hr. The unit has a dust collector system and a catalytic incinerator using natural gas 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 co-ordinates of the site are 17-580.6 east and 2868.5 north.

The construction and operation of the No. 4 dryer shall be in accordance with the application for permit to construct, submitted by Mr. Allen F. Gant on August 17, 1984, and the additional information provided in Mr. Lloyd H. Stebbins October 17, 1984 letter. Key Pharmaceuticals, Inc. must also comply with the terms conditions of the consent order OGC No. 84 84-0644 issued.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-091497
Expiration Date: June 30, 1985

GENERAL CONDITIONS:

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

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

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

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

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

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-091497
Expiration Date: June 30, 1985

GENERAL CONDITIONS:

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

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

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

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

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

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

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-091497
Expiration Date: June 30, 1985

GENERAL CONDITIONS:

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

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

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

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

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

13. This permit also constitutes:

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

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

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

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-091497
Expiration Date: June 30, 1985

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 13-091497
Expiration Date: June 30, 1985

SPECIFIC CONDITIONS:

2. The operating hours shall not exceed 8,400 hours per year.
3. The input rate to the Glatt No. 2 shall not exceed 107.6 lb/hr.
4. The Glatt No. 2 opacity test shall meet all applicable requirements of 40 CFR 60, Appendix A, Reference Method 9. Particulate matter emissions from the Glatt No. 2 shall not exceed 0.3 lb/hr, 25.9 tons/yr, or 5% opacity.
5. Nitrogen oxide emissions, as determined by EPA Reference Method 7, 40 CFR 60, Appendix A shall not exceed 0.1 lb NO_x emitted per MMBtu heat input. Routine tests for nitrogen oxides will not be required if the initial test shows compliance with this specific condition.
6. 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.
7. 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, 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.

Issued this 25 day of February, 1985

STATE OF FLORIDA DEPARTMENT OF
ENVIRONMENTAL REGULATION



VICTORIA J. TSCHINKEL, Secretary

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: _____	
DER	Reply Required []	Info. Only []
Date Due: _____	Date Due: _____	

FEB 26 1985

TO: Victoria J. Tschinkel
FROM: Clair Fancy *for B. L. CHE*
DATE: February 25, 1985
SUBJ: Approval of Attached Air Construction Permit

BAQM

RECEIVED

FEB 25 1985

Office of the Secretary

Attached for your approval and signature is one Air Construction Permit for Key Pharmaceuticals, Inc. This is a permit to construct the No. 2 Fluidized Bed Coating Unit at the applicant's existing facility in Miami, Dade County, Florida.

Day 90, after which the permit would be issued by default, is February 26, 1985.

The Bureau recommends your approval and signature.

CF/pa

Attachments

DER
JAN 18 1985
BAQM



Key
Pharmaceuticals,
Inc.

January 16, 1985

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

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

Dear Mr. Fancy:

Attached is a copy of the DER's Notice of Proposed Agency Action on Key Pharmaceutical's Permit Application as it appeared in the Wednesday, January 16, 1985 edition of the Miami Herald, required by Florida Administration Code Rule 17-103.150.

Sincerely,

KEY PHARMACEUTICALS, INC.

Allen F. Gant
Vice President
Production and Engineering



Key
Pharmaceuticals,
Inc.

THE MIAMI HERALD

Wednesday January 16, 1985

A1-17 Legal Notices-Derald

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

The Department gives notice of its intent to issue a permit to Key Pharmaceuticals, Inc. to authorize construction of a fluidized bed coating unit.

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 107.6 lb/hr. The unit has a dust collector system and a catalytic incinerator using natural gas 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 proceedings. 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 Administrative Services, 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 the following locations:

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

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

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

Any person may send written comments on the proposed action to Mr. Clair Fancy 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.
Jan. 16, 1985
Ad. No. 355-125R

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-091497
Expiration Date: June 30, 1985

DER
7 1985
BAQM

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:

The permittee must satisfy the requirements of

or the

1. ~~This permit must comply with consent order OGC case No. 84-0644 as it applies to No. 2 Fluid Bed Coating Unit (Glatt No. 2)~~ 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)).

0644 shall not be operated



12/31/84

DEPARTMENT OF ENVIRONMENTAL REGULATION

ROUTING AND TRANSMITTAL SLIP

ACTION NO

ACTION DUE DATE

1. TO: (NAME, OFFICE, LOCATION)

Bill Thomas

Initial

Date

2.

BAQM

Initial

Date

3.

Initial

Date

4.

Initial

Date

REMARKS:

Comments on
Key Pharmaceuticals
Preliminary
Determination

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

DER
JAN 7 1985
BAQM

FROM:

J. Goldman

DATE

12/31/84

PHONE

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-091497
Expiration Date: June 30, 1985

SPECIFIC CONDITIONS:

2. The operating hours shall not exceed 8,400 hours per year.
why not 8760 hrs/yr since limit is 40 T/yr VOC
3. The input rate to the Glatt No. 2 shall not exceed 107.6 lb/hr. *(is this its capacity or does this input = 40 T/yr VOC output?)*
4. The Glatt No. 2 shall meet all applicable requirements of 40 CFR 60, Appendix A, Reference Method 9. *opacity test*
5. Particulate matter emissions from the Glatt No. 2 shall not exceed 0.3 lb/hr or 5% opacity.
6. Nitrogen oxide emissions, as determined by Reference Method 7, 40 CFR 60, Appendix A shall not exceed 0.1 lb NO_x emitted per MMBtu heat input. *This provision requires testing every 5 years per 17-2. Suggest one time test only.*
7. 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.
8. 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, and emission test reports for particulate matter and visible emissions. *do you really want this for 1-26 T of particulate emissions*
The initial compliance test should use Method 25 as the acceptance test to verify emission factors. *Suggest one time only*
Inventory control can be used, thereafter, to verify emissions. *for VOC of VOC*
however, in case of doubt with the emission factors, the department may request a Reference Method 25, 40 CFR 60, Appendix A.

Suggest combining 4 & 5

*Dee
12/31/84*

No. 0155794

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		¢	
	SPECIAL DELIVERY		¢	
	RESTRICTED DELIVERY		¢	
	OPTIONAL SERVICES	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				
12/21/84				

PS Form 3800, Apr. 1976

PS Form 3811, Jan. 1979	<p>SENDER: Complete items 1, 2, and 3. Add your address in the "RETURN TO" space on reverse.</p>								
	<p>1. The following service is requested (check one.)</p> <p><input checked="" type="checkbox"/> Show to whom and date delivered. ¢</p> <p><input type="checkbox"/> Show to whom, date and address of delivery. ¢</p> <p><input type="checkbox"/> RESTRICTED DELIVERY Show to whom and date delivered. ¢</p> <p><input type="checkbox"/> RESTRICTED DELIVERY. Show to whom, date, and address of delivery. \$ _____</p> <p>(CONSULT POSTMASTER FOR FEES)</p>								
	<p>2. ARTICLE ADDRESSED TO:</p> <p>Mr. Allen F. Gant 50 N.W. 176th St. Miami, FL 33169</p>								
	<p>3. ARTICLE DESCRIPTION:</p> <table border="1"> <tr> <td>REGISTERED NO.</td> <td>CERTIFIED NO.</td> <td>INSURED NO.</td> </tr> <tr> <td></td> <td>0155794</td> <td></td> </tr> </table> <p>(Always obtain signature of addressee or agent)</p>			REGISTERED NO.	CERTIFIED NO.	INSURED NO.		0155794	
	REGISTERED NO.	CERTIFIED NO.	INSURED NO.						
		0155794							
<p>I have received the article described above.</p> <p>SIGNATURE <input type="checkbox"/> Addressee <input checked="" type="checkbox"/> Authorized agent</p> <p><i>SQ Vator</i></p>									
<p>4. DATE OF DELIVERY</p> <p>12-20</p>									
<p>5. ADDRESS (Complete only if requested)</p>									
<p>6. UNABLE TO DELIVER BECAUSE:</p>		<p>CLERK'S INITIALS</p>							

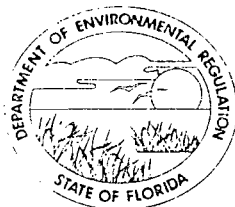


☆GPO : 1979-300-459

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

December 20, 1984

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, located at your 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,

for Bill Thomas

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

CHF/rw

Attachments

cc: Art Bolivar
Roy Duke
Lloyd H. Stebbins
Bill Voshell

BEFORE THE STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

In the Matter of an)
Application for Permit by:)
)
Key Pharmaceuticals, Inc.) DER File No. AC 13-091497
50 NW 176th Street)
Miami, Florida 33619)
)

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 August 17, 1984, 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. The information supplied by Mr. Lloyd H. Stebbins in his October 17, 1984, (letter received October 18) completed the application so that it could be processed by the department. Information submitted by the company shows the operation of the No. 2 Fluidized Bed Coating Unit 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.

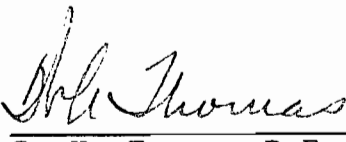
Petitions which are not filed in accordance with the above provisions are subject to dismissal by the Department. In the event a formal hearing is conducted pursuant to Section 120.57(1), all parties shall have opportunity to respond, to present evidence and argument on all issues involved, to conduct cross-examination of witness and submit rebuttal evidence, to submit proposed findings of facts and orders, to file exception 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, Tallahase, 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 Statues.

Executed the 21 day of Dec, 1984, in Tallahassee, Florida.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL REGULATION

for 

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

Copies furnished to:

Allen F. Gant
Art Bolivar
Roy Duke
Lloyd Stebbins
Bill Voshell

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

The Department gives notice of its intent to issue a permit to Key Pharmaceuticals, Inc. to authorize construction of a fluidized bed coating unit.

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 107.6 lb/hr. The unit has a dust collector system and a catalytic incinerator using natural gas for control of emissions. This addition will not have a significant increases 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 Administrative, 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 the following locations:

Dept. of Environmental Regulation
Southeast 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 Mgmt.
909 Southeast 1st Avenue
Brickell Plaza
Miami, Florida 33131

Any person may send written comments on the proposed action to Mr. Clair Fancy 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.

Preliminary Determination
and
Technical Evaluation

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

Miami, Dade County, Florida

Proposed Permit AC 13-091497

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

December 20, 1984

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.

C. Process and Controls

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

The fluidized bed granulator/coating unit yields the intermediate product prior to tablet production. The process involves three stages:

- 1) In order to produce pellets, sugar seeds are charged into the fluidized bed granulator. The bed is fluidized by a high volume air flow, blown through the bottom of the unit. In a separate vessel the active ingredient is mixed with film forming solution, isopropyl alcohol and acetone. This coating solution along with atomizing air is sprayed into the coater through a nozzle system in the unit to form "active coated seeds". The spray process is stopped and the seeds are dried in place using fluidized air. After screening and testing the active coated seeds are stored in drums.
- 2) According to a predetermined schedule the active coated seeds are returned to the fluid bed coater to become the feed for Step 2. During this step a mixture of additional release coating along with atomizing air is injected into the unit. The fluidized bed coater is operated in the same manner as before to produce another intermediate product. This product is also dried in place, tested and stored in bulk containers.

3) According to the planned schedule, these seeds are returned once more to become the feed for the fluidized bed coater. The final pellets are produced by injecting film forming solution and acetone along with atomizing air into the unit. At the end of this step, the pellets are dried in place, tested and stored in bulk until moved to the tablet production process.

The fluid bed system consists of the reaction vessel, the fluid bed coating unit #2 with air inlet, pocket prefilter, heater, solids loading, solids discharge, air outlet, dust collection system, and catalytic incinerator.

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.

The air that exits the No. 2 unit enters the exhaust air filter prior to the air outlet. The dust collecting system for Glatt uses cartridge filters which treat 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 VOC's (process solvents) are evaporated and ducted to the catalytic incineration system that is designed to handle a vent stream with a maximum gas flow rate of 9300 SCFM. The minimum reduction by volume of VOC by the incinerator is guaranteed at 97%. The mixture entering the incinerator is heated by exhaust gases and the gases are ignited due to the heat from the pilot and the heat exchanger.

Combustion takes place in the combustion chamber of the incinerator and continues through the catalyst to maintain combustion efficiency to water and carbon dioxide. Exhaust gases preheat inlet gases in the heat exchanger and the exhaust to the stack.

II. Rule Applicability

State Regulations

The proposed project to construct a No. 2 fluidized bed coating unit 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. 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.

	Emission		Allowable Emission lb/hr	Emission Without Control	
	Max lb/hr	Actual T/yr		lb/hr	T/yr
VOC	2.31	9.7	9.5	46	193.2
PM	0.3	0.25	0.3	6.2	25.9

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 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. 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 13-091497
Expiration Date: June 30, 1985
County: Dade
Latitude/Longitude: 25° 56' 04"N/
80° 12' 11"W
Project: No. 2 Fluidized Bed
Coating Unit

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 107.6 lb/hr. The unit has a dust collector system and a catalytic incinerator using natural gas 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 co-ordinates of the site are 17-580.6 east and 2868.5 north.

The construction and operation of the No. 4 dryer shall be in accordance with the application for permit to construct, submitted by Mr. Allen F. Gant on August 17, 1984, and the additional information provided in Mr. Lloyd H. Stebbins October 17, 1984 letter. Key Pharmaceuticals, Inc. must also comply with the terms conditions of the consent order OGC No. 84 84-0644 issued.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number:AC 13-091497
Expiration Date: June 30, 1985

GENERAL CONDITIONS:

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

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

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

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

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

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-091497
Expiration Date: June 30, 1985

GENERAL CONDITIONS:

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

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

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

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

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

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

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-091497
Expiration Date: June 30, 1985

GENERAL CONDITIONS:

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

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

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

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

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

13. This permit also constitutes:

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

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

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

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-091497
Expiration Date: June 30, 1985

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. This permit must comply with consent order OGC case No. 84-0644 as it applies to No. 2 Fluid Bed Coating Unit (Glatt No. 2). 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 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 13-091497
Expiration Date: June 30, 1985

SPECIFIC CONDITIONS:

2. The operating hours shall not exceed 8,400 hours per year.
3. The input rate to the Glatt No. 2 shall not exceed 107.6 lb/hr.
4. The Glatt No. 2 shall meet all applicable requirements of 40 CFR 60, Appendix A, Reference Method 9.
5. Particulate matter emissions from the Glatt No. 2 shall not exceed 0.3 lb/hr or 5% opacity.
6. Nitrogen oxide emissions, as determined by Reference Method 7, 40 CFR 60, Appendix A shall not exceed 0.1 lb NO_x emitted per MMBtu heat input.
7. 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.
8. 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, 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. Inventory control can be used, thereafter, to verify emissions; however, in case of doubt with the emission factors, the department may request a Reference Method 25, 40 CFR 60, Appendix A.

PERMITTEE:
Key Pharmaceuticals, Inc.

Permit Number: AC 13-09147
Expiration Date: June 30, 1985

SPECIFIC CONDITIONS:

Issued this ___ day of ___ 1985

STATE OF FLORIDA DEPARTMENT OF
ENVIRONMENTAL REGULATION

VICTORIA J. TSCHINKEL, Secretary

___ pages attached.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION IV

345 COURTLAND STREET
ATLANTA, GEORGIA 30365

NOV 28 1984

4AW-AM

file
DER

DEC 03 1984

BAQM

Mr. Steve Smallwood, P.E., Chief
Department of Environmental
Regulation
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, Florida 32301

Dear Mr. Smallwood:

This is to acknowledge receipt of the draft Consent Order for Key Pharmaceuticals, Inc., as transmitted in Mr. William H. Green's letter dated October 24, 1984.

After review of the proposed Order and consideration of the telephoned revisions to Paragraph 16 and 28 of the Order, my staff has advised me that the Order is approvable. Please be advised that so long as Key Pharmaceuticals, Inc., formally executes this Consent Order, complies fully with the terms set out in it, and remains in compliance with the requirements of the Clean Air Act and any requirements promulgated thereto, EPA will not institute an enforcement action against Key Pharmaceuticals, Inc., pursuant to the Clean Air Act.

Should you have any further questions on this matter, please feel free to write or call me at (404) 881-3454 or Ms. Jewell Harper, Assistant Regional Counsel, of my staff at (404) 881-2335.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Thomas W. Devine".

Thomas W. Devine, Acting Director
Air, Pesticides and Toxics Management
Division

cc: William H. Green, Esq.
Hopping, Boyd, Green and Sams
Post Office Box 6526
Tallahassee, Florida 32314

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: Art Volivar (305)858-0601
Dade County Pollution Control

FROM: Lillian L. Jack
Air Permitting

DATE: October 18, 1984

SUBJ: Key Pharmaceuticals

*Dade County - Dept. of Environmental
Resources*

*801 SW Third Avenue
Miami, FL 33131*

Please find enclosed the Process Calculations page discussed per our telephone conversation. I have also enclosed a list of questions/response that DER staff posed to Key Pharmaceuticals during a meeting on July 20, 1984.

It was a pleasure talking with you, and let's keep communications open for any additional information concerning Key Pharmaceuticals.

LJ/ks

PROCESS CALCULATIONS

ASSUMPTIONS

1. Catalytic incinerator efficiency - 95%
2. Dust collector efficiency - 99%
3. All solvents out fluid bed to stack

Solids in - 61.6 lbs per hour

Acetone in - 24.7 lbs per hour

IPA in - 21.3 lbs per hour

Total Process
Input 107.6 lbs per hour

All solvents to incineration
 $21.3 + 24.7 = 46$ lbs per hour

According to the Supplier the incinerator is 95% efficient, therefore, the amount of solvents emitted is $0.05 (46.0) = 2.3$ lbs per hour.

On an annual basis

$$\frac{2.30 \times 24 \times 7 \times 50}{2000} = 9.7 \text{ tons per year VOC}$$

REYNOLDS, SMITH AND HILLS
ARCHITECTS • ENGINEERS • PLANNERS
INCORPORATED

October 17, 1984

DIRECTORS:

IVAN H. SMITH, F.A.I.A.
RALPH W. HEIM, P.E.
JAMES F. SHIVLER, JR., P.E.
WILLIAM J. WEBBER, A.I.A.
ROBERT F. DARBY, A.I.A.
BOB ALLIGOOD, A.I.E.
BEN BUCALO, P.E.
GEORGE M. BARSON, Sc.D., P.E.
K. N. HENDERSON, P.E.
HOWARD B. BOCHIARDY, F.A.I.A.
HENRY LUKE, P.E.
JOSEPH W. GRIFFIN, A.I.A.
JOHN E. COOK

Mr. Clair H. Fancy
Florida Department of Environmental Regulations
Central Air Permitting Section
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, Florida 32301

SUBJECT: Application to Construct
Key Pharmaceuticals, Inc.
Miami, Florida
AEP Number 84143-000

DER
OCT 18 1984
BAQM

Dear Mr. Fancy:

We are forwarding herewith, on behalf of our client, Key Pharmaceuticals, Inc., additional information regarding the Application to Construct the Number 2 Fluidized Bed Coating Unit, to be located at 50 NW 176th Street, Miami, Florida. Also attached are responses to questions raised by D.E.R. during review of the application.

Your timely approval of this application will be appreciated.

Should you have any questions, or require further information, please do not hesitate to telephone me.

Very truly yours,



Lloyd H. Stebbins, P.E., Head
Chemical and Process Department
Environmental Engineering Division

LHS:adh

Enclosure

cc: Mr. A. F. Gant
Key Pharmaceuticals, Inc.

Attached are responses to questions contained in the letter of September 14, 1984, addressed to Mr. A. F. Gant, Key Pharmaceuticals, regarding the No. 2 Fluidized Bed Coating Unit Construction Application. These questions were previously reviewed by Mr. J. Hawkins of RS&H in a telephone conversation with Ms. L. Jack of the D.E.R. on September 28, 1984. The numbering of responses refers to the numbering of the questions in the September 14 letter.

We are also attaching a copy of the revised Met-Pro Proposal (No. 84157D, dated 9/21/84) which should replace the proposal submitted with the application. Revisions to the proposal have been incorporated in the additional information submitted herewith. Also attached is a copy of a Met-Pro letter which provides additional information relative to NOx formation in the catalytic incinerator. Please include this material in the application.

Should you have questions or require further clarification of items herein, please call Mr. John Hawkins, RS&H, (904) 739-2000.

1. The minimum product weight shown is based on an assumed maximum particulate emission of 0.3 lbs/hr. Actual product weight should be near 61.6 lbs/hr.
2. Background calculations are, as shown in permit application under "Process Calculations".

VOC

$$\begin{aligned} \text{VOC} &= 21.3 + 24.7 = 46 \text{ lbs/hr maximum input} \\ &\text{for 95\% incinerator efficiency} \\ (46 \text{ lbs/hr}) (0.05) &= 2.3 \text{ lbs/hr maximum leaving incinerator} \\ \frac{2.3 \text{ lbs/hr} \times 24 \text{ hrs/da} \times 7 \text{ da/wk} \times 50 \text{ wk/yr}}{2000 \text{ lbs/ton}} &= 9.7 \text{ tons/yr} \end{aligned}$$

$$\text{Allowable VOC emissions} = 40 \text{ tons/yr}$$

$$\frac{40 \text{ tons/yr} \times 2000 \text{ lbs/ton}}{(50 \text{ wks/yr}) (7 \text{ da/wk}) (24 \text{ hr/da})} = 9.5 \text{ lb/hr}$$

Potential VOC emissions (uncontrolled)

$$46 \text{ lbs/hr} \times 24 \text{ hrs/da} \times 7 \text{ da/wk} \times 50 \text{ wk/yr} = 386,400 \text{ lbs/yr}$$

$$\frac{386,400 \text{ lbs/yr}}{2000 \text{ lbs/ton}} = 193.2 \text{ tons/yr}$$

Particulates

$$\text{Allowable emissions} = 0.3 \text{ lbs/hr}$$

Based on historical experience with similar fluidized bed coating processes, less than 10% of the particulate input leaves the bed and is admitted to the dust collector. Then, for a 99% efficient dust collector:

$$(61.6 \text{ lb/hr}) (0.1) (0.01) = 0.06 \text{ lb/hr}$$

$$(0.06 \text{ lb/hr}) (24 \text{ hr/da}) (7 \text{ da/wk}) (50 \text{ wk/yr})$$

$$= 504 \text{ lb/yr}$$

$$\frac{504}{2000}$$

$$= 0.25 \text{ ton/year}$$

Please insert these figures under "Emissions" in III. C. Under "Allowable Emission", please insert 0.3 lbs/hr.

Then, for the case of 10% of the particulate leaving the fluidized bed, the "Potential Emission" should be

$$(61.6 \text{ lb/hr}) (0.1) (24 \text{ hr/da}) (7 \text{ da/wk}) (50 \text{ wk/yr})$$

$$= 51,744 \text{ lb/yr}$$

$$\frac{51,744}{2000}$$

$$= 25.9 \text{ tons/year}$$

Please insert these revised figures on the permit application.

3. As noted in the revised Met-Pro proposal, the guaranteed minimum reduction (by volume) of VOC by the incinerator is 97%. This is independent of the VOC input within the design range. It is expected that the efficiency would be higher with lower volumetric throughput, due to increased residence time of the VOC's at the catalyst. The lower indicated temperatures (shown on page 3 of the revised Met-Pro proposal) are catalyst outlet temperatures; the temperature being controlled is the 600 F catalyst inlet temperature. For temperatures above 600 F at the catalyst inlet, the process is self-sustaining, below 600 F, auxiliary burner heat input would be required. In any event, the efficiency guarantee of 97% incineration is still applicable.
4. Fuel is natural gas; fuel analysis data in Section III. E. is not applicable.
5. The dry standard cubic feet and the water vapor content were not provided, since for the actual operating conditions, the air flow rate is much, much greater (approximately 9000%) than required for the combustion of the 46 pounds per hour of VOC. Thus, the water vapor of combustion is relatively insignificant, and the exhaust gas moisture content is close to the moisture content of the inlet air. Please change gas flow rate to 9236 SCFM, to correspond to the revised Met-Pro proposal for 9000 SCFM inlet air. For the dry gas flow, please insert 9030 SCFM. For the water vapor content, please insert 2.2 percent.
6. Process is of a batch nature and a startup occurs with each batch processed. Number of startups is directly related to production rate. Emissions increases do not occur during startups, as catalyst temperature is maintained at 600 F minimum by the auxiliary burner during operation.
7. In regard to Section IV, and referring to the revised Met-Pro proposal, the incinerator design capacity could read "498.8 lbs/hr (instantaneous)", based on Design Case 14, which is for 249.4 pounds per hour each of acetone and IPA. Also, in accordance with the revised Met-Pro proposal, please revise the gas flow rate to 9236 SCFM. For the dry gas flow, please insert 9030. For the primary chamber, the volume shown is correct. The other data requested is not applicable to the catalytic incinerator. You may insert "N/A" in the blank data spaces.

8. Due to the comparatively low temperatures of the catalytic incineration process, NOx production is very small. Please refer to the attached letter of October 5, 1984, from Met-Pro to Key Pharmaceuticals for further discussion. Due to the high excess air, CO emission is not expected. No other criteria pollutant emissions are anticipated.
9. Based on the Met-Pro proposal, the apparent design volume of catalyst per 1000 SCFM is 0.003 cubic feet, based on the design flow rate of 9000 SCFM. As flowrate decreases, the apparent design volume of catalyst per 1000 SCFM would increase.
10. The allowable emission rate shown is based on an emission of 40 tons per year of VOC.
11. Please revise the Start of Construction date to read "January 1, 1985".
12. Please revise the UTM coordinates to read:

East 763000
North 582500



Systems Division

160 CASSELL ROAD • BOX 144 • HARLEYSVILLE, PA 19438 • (215) 723-6751 • TELEX: 846-424

October 5, 1984

Key Pharmaceuticals, Inc.
13900 N.W. 57th Ct.
Miami Lakes, FL 33014

Attention: Mr. Stephen J. Goodstein

Subject: Key P.O. CM17214
Met-Pro No. 47758
Catalytic Incinerator - Miami

Dear Steve:

In response to your question concerning NOx emissions from a catalytic incinerator, please refer to the attached statement taken from Afterburner Systems Study produced by the Shell Development Company and distributed by the National Technical Information Service.

If you have any other questions, please don't hesitate to contact me.

Very truly yours,

A handwritten signature in cursive script that reads "Stephen R. Newcomb".

Stephen R. Newcomb, P.E.
Project Manager

SRN:djh

Attachment

cc: ✓ Mr. John Hawkins
Reynolds, Smith & Hills
6737 Southpoint Drive South
Jacksonville, FL 32201

4.2.6 NO_x Formation in Catalytic Afterburners

The same factors, discussed for thermal afterburners in sections 3.1.2.7 and 3.1.2.8, will contribute to detectable, but normally low, emissions of nitrogen oxides, NO_x, in the stack effluent from a catalytic afterburner. The emission factor for NO_x is expected to be the same as for a thermal afterburner, 0.05-0.1 lb NO_x emitted/MM Btu preheat fuel value required. Because of the lower level of preheat in catalytic afterburners, the concentration of NO_x in the effluent will be lower, typically about 15 ppm. As with thermal afterburners, chemically combined nitrogen in the fume stream is expected to be nearly quantitatively converted to NO_x in the effluent.

TECHNICAL PROPOSAL NO. 84157D

for

KEY PHARMACEUTICALS, INC.
Miami, Florida

by

SYSTEMS DIVISION, MET-PRO CORPORATION
160 Cassell Road, P. O. Box 144
Harleysville, PA 19438

Technical Proposal No. 84157D

KEY PHARMACEUTICALS, INC.

I. INTRODUCTION

The OXYCAT Catalytic Incineration System, designed and fabricated by the Systems Division of Met-Pro Corporation, is engineered to efficiently control hydrocarbon fume emissions from industrial processes. In brief, our process involves three stages:

1) Contaminated Stream Preheat

If required, the industrial exhaust is preheated to a temperature suitable for activation of the combustion reaction over the catalyst. A preheat burner and/or recuperative heat exchanger are used for this purpose.

2) Combustion of Contaminated Stream

The contaminated stream is passed over a catalyst, developed and manufactured at Met-Pro, where combustion takes place at temperatures much lower than conventional thermal incineration designs.

3) Exhaust of Environmentally Safe Products of Combustion

The safe products of combustion ultimately are vented into the atmosphere.

The OXYCAT Catalytic Incineration System is a factory assembled, insulated unit, designed to meet performance specifications and applicable insurance underwriters' requirements. The expected efficiency for hydrocarbon control is 97 per cent when operated in accordance with the specifications of Section IIB of this proposal.

A detailed description of system components, accessories, assembly criteria and performance specifications follows:

II. TECHNICAL DESCRIPTION AND SPECIFICATIONS

A. Scope

Systems Division of Met-Pro Corporation proposes to design and fabricate one Model CXII-9G Catalytic Incineration System to control hydrocarbon emissions from pharmaceutical operations for Key Pharmaceuticals, Inc., Miami, Florida.

The Catalytic Incineration System is designed to handle a vent stream with a maximum volume of 9000 SCFM.

System Components include:

- 1) Gas-Fired Incinerator
- 2) Recuperative Heat Exchanger with Bypass
- 3) Process Blower
- 4) Catalyst Charge
- 5) Complete Control Logic
- 6) Integral Exhaust Stack
- 7) Inlet/Outlet Hydrocarbon Analyzers with Chart Recorder
- 8) Combustion Air Blower
- 9) Inlet Damper System

B. Process Specifications

1) Design

The Model CXII-9G Catalytic Incineration System has been designed in accordance with fourteen projected design conditions. These conditions were projected from information provided by Key Pharmaceuticals, Inc.. These design cases are outlined below. The process temperature is 70 deg. F., and process pressure is assumed to be -1" W.C.

II. TECHNICAL DESCRIPTION AND SPECIFICATIONS . . . cont'd.

B. Process Specifications . . . cont'd.

1) Design . . . cont'd.

Design Case	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Flow Rate (SCFM)	2800	4400	5200	5200	6000	6000	6000	6000	6000	9000	9000	9000	9000	9000
Isopropyl Alcohol (lbs/hr)	99.65	227.6	39.3	58.9	---	39.3	58.9	99.65	249.4	---	39.3	58.9	99.65	249.4
Acetone (lbs/hr)	99.65	227.6	39.3	58.9	111.1	39.3	58.9	99.65	249.4	---	29.3	58.9	99.65	249.4

NOTE: The process data presented above assumes the exhaust stream is composed only of the above referenced gaseous constituents. No liquid or solid phase components can be present in the stream.

2) Operation

Design Case	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Flow Rate (SCFM)	2800	4400	5200	5200	6000	6000	6000	6000	6000	9000	9000	9000	9000	9000
Dilution Air Required (SCFM)	800	3800	0	0	0	0	0	0	3000	0	0	0	0	
Catalyst Outlet Temp. (°F)	1207	1208	770	853	800	747	820	969	1207	600	698	747	848	1207

- NOTE:
1. Process inlet temperature assumed to be 70 deg. for all design cases.
 2. Pressure assumed to be -1.0 in. H2O for all design cases.
 3. Catalyst inlet temperature is 600 deg. F for all design cases.
 4. Catalyst control temperature is 600 deg. for all design cases.
 5. Maximum allowable catalyst outlet temperature is 1250 deg. F.
 6. When the heat exchanger outlet temperature exceeds the catalyst control temperature, a controlled volume of process air will bypass the coldside of the heat exchanger and re-enter the unit upstream of the catalyst, to maintain 600 degrees F at the catalyst inlet.
 7. A minimum of 600 deg. F. will be maintained at catalyst inlet. Burner input would be required when temperature drops below 600 deg. F.

II. TECHNICAL DESCRIPTION AND SPECIFICATIONS . . . cont'd.

B. Process Specifications . . . cont'd.

3) Operating Requirements . . . cont'd.

- Process Blower . . . 1. 460 V, 3 phase, 60 Hz
 2. 50 HP (37.25 Kwh)
 3. Start-up - 45.3 BHP (33.75 Kwh)
 4. Operation (Minimum)
 32 BHP (23.8 Kwh)
 5. Operation (Maximum)
 40.3 BHP (30.0 Kwh)

- Burner 1. Natural Gas Fuel at 1000 BTU/SCF
 2. Start-up - 4.5 mm BTU/hr
 (4500 SCFH)

Design Case	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Fuel (mm BTU/hr)	Pilot .05-.18	Pilot .05-.18	0.59	0.24	0.57	0.81	0.48	Pilot .05-.18	Pilot .05-.18	2.46	1.8	1.98	0.83	Pilot .05-18

- NOTES: 1. The preheat burner is designed to automatically turn down to an output capacity of .18 mm BTU/hr. It is projected that if the solvent loading is relatively constant, burner input would not be required to maintain the minimum catalyst inlet temperature. Heat for process preheat would be recovered from the heat liberated by the combustion reaction. As a means of energy savings, the burner can be turned down to pilot operation (0.05 mm BTU/hr) by a manual selector switch at the control panel.
2. Start-up conditions assumed to be 6000 SCFM at 32 deg. F. and 0" W.C.

4) Utilities

- Fuel Natural Gas at 1000 BTU/SCF
 Electricity 460 V, 3 Phase, 60 Hz
 Plant Air (Damper Actuation) . . 100 psig

III. SYSTEM COMPONENTS

A. Combustion Chamber

The combustion chamber would be fabricated of carbon steel with continuously welded joints. The sides would be reinforced with stiffeners at suitable intervals. The section would be internally insulated with a thermally expandable insulation material. The skin temperature of the unit would be approximately 140 Deg. F under normal operation.

B. Catalyst

The catalyst accelerates and promotes the combustion reaction. It does not enter into the reaction and is not dissipated. The catalyst contains finely dispersed particles of precious metals embedded on a ceramic monolith support structure.

The catalyst would be installed in one Type 304 stainless steel basket 49" W x 52" H x 19" D and weighs 1500 pounds. The catalyst basket is easily removable from the combustion chamber and an access door would be provided for catalyst removal.

C. Combustion System and Controls

1) Combustion System Package

A gas-fired burner manufactured by Eclipse, or approved equal, would be used to preheat process gases to their catalytic oxidation temperature. The burner, is located in the combustion chamber upstream of the reaction zone.

A completely prepped gas valve train mounted and supported on the unit would be provided. Met-Pro valve trains are designed to meet FM insurance requirements. Valve train components include:

- a) Pressure regulator
- b) Gas cocks
- c) Low fuel pressure switch
- d) High fuel pressure switch
- e) Motorized safety shut-off valve
- f) Gas control valve and control motor

III. SYSTEM COMPONENTS continued

C. Combustion System and Controls continued

2) Control Panel

The control panel would meet all the requirements of the National Electrical Manufacturer's Association (NEMA) and all pertinent classifications as listed in the National Electrical Code (NEC) pertaining to control panels. Mounted within the NEMA 12 panel enclosure would be the following:

- a) Indicating Controller
- b) Control Transformer
- c) Fused Disconnect Switch
- d) Purge Timer
- e) Alarm Relay
- f) Alarm and Silencing Button
- g) Pilot Lights
- h) Pushbuttons
- i) Miscellaneous Terminal Blocks, Fuses, etc.
- j) Flame Safeguard
- k) Motor Starters
- l) Analyzers/Recorder (Separate NEMA 4 cabinet)

3) Other Accessories

- a) High Temperature Limit
- b) Thermocouples
- c) UV Flame Detector
- d) Process Air Sensor
- e) Unit Junction Box

In the event of flame failure, low or high fuel pressure, blower failure, or incinerator exceeding high temperature limit, the control system will automatically switch into the shut-down mode.

D. Unit Transitions

Inlet and outlet transitions would be provided for process gas handling. Transitions would be fabricated from stainless steel minimum 12 Bwg. with inlet flange connection provided.

III. SYSTEM COMPONENTS continued

E. Recuperative Heat Exchanger

A nominally 60% thermally efficient recuperative heat exchanger would be provided to reduce the fuel requirements of the catalytic unit during normal operation. This section would recover flue gas heat and use it to preheat the process gases prior to entering the burner/combustion section. The resultant process preheat would allow for minimum heat input by the burner and significant fuel savings.

The gas-to-gas exchanger would be a shell and tube type unit with two 304 stainless steel tube bundles. The bundles are arranged in series such that process makes two tube passes and one shell pass. The tube bundles would be an integral part of the incinerator, and would consist of nominal one inch diameter tubes, double convolute expansion joints, and tube sheets. Unit shell side of the heat exchanger would be an integral part of the catalytic incinerator with similar construction to the combustion chamber.

F. Unit Base

The main runs of the unit skid would consist of two structural beams approximately 5.5 feet apart. The main runs would be approximately 17 feet long. Cross member beams, a minimum of four feet apart would be provided. Unit would stand approximately 14 feet high, 5.5 feet wide, and 17 feet long (dimensions do not include ductwork, outlet stack, or process fan). Unit weight is approximately 40,000 pounds.

G. Unit Stack

An exhaust stack 32" diameter and 11'0" in length is provided for flue gas outlet. Top of the stack is approximately 28' above pad. The exhaust stack is fabricated of stainless steel, minimum 12 Bwg.

H. Heat Exchanger Cold Side Bypass Assembly

A 16" diameter duct, fabricated of 304 stainless steel would be provided to allow for a controlled

III. SYSTEM COMPONENTS . . . cont'd.

H. Heat Exchanger Cold Side Bypass Assembly . . . cont'd.

volume of process air to bypass the cold side of the heat exchanger and enter the combustion chamber upstream of the catalyst section inlet. The bypass duct would be equipped with a pneumatically operated volume control damper. Bypass air volume control would be initiated by a temperature signal. All fabricated ductwork would be minimum 16 Bwg.

I. Hydrocarbon Analyzation Equipment

Two (2) Beckman Model 400 Hydrocarbon Analyzers, or approved equal, would be provided to measure solvent concentration in the gas stream entering the incinerator and in the exhaust stream leaving the incinerator.

One (1) Beckman Model 8720 Two Channel Chart Recorder would also be provided.

J. Dilution Air Tee-Section

During periods when solvent loading is high, and the catalyst outlet temperature exceeds 1200 deg. F., fresh air would be admitted to the inlet stream for process dilution. When this condition occurs, the fresh air inlet damper would open to admit outside air. This damper would be normally closed, however, is projected to open at the extreme solvent loading conditions referenced in Section II.B.1 of this proposal. Dilution air addition would be controlled by a temperature controller downstream of the catalyst section.

K. Process Blower

The blower would be finish mounted on a unitary base with motor, motor base, and V-belt drive. Additional features include Type C sparkproof flanged inlets and outlets, drain, access door, OSHA belt guard, and opposed blade outlet damper.

Blower would be rated for 9000 ACFM at 70 deg. F. and 20" W.C.S.P. Blower would be supplied by New York Blower, or approved equal.

III. SYSTEM COMPONENTS . . . cont'd.

L. Combustion Air Blower

The blower would be finish mounted on a unitary base with motor, motor base, and V-belt drive. Additional features include Type C sparkproof flanged inlets and outlets, drain, access door and OSHA belt guard.

Blower would be rated for 1100 ACFM at 70 deg. F. and 5" W.C.S.P. Blower would be supplied by New York Blower, or approved equal.

IV. SHIPMENT SCHEDULE

The estimated shipping completion based upon similar units would be 16 to 22 weeks after drawing approval. The required time for installation of the unit upon reaching the job site would be approximately two (2) weeks, depending upon weather conditions, labor and proper site preparation.

V. ASSEMBLY, PAINTING AND SHOP TESTING

- A. The system is designed for field assembly. Most components of the proposed equipment would be assembled in our shop prior to shipment. The equipment would be shipped as completely assembled as practical; however, where over-the-road shipping limitations apply, partial disassembly may be required. Purchaser is invited to examine the equipment in its partially assembled state, subject to Met-Pro scheduling requirements for manufacturing space. Degree of assembly would be dependent upon shop area available.
- B. The control panel would be completely prewired. All panel components would be checked by controlled simulation testing, and results thoroughly analyzed to assure smooth, efficient system start-up.
- C. The burner valve train would be completely prepiped. All incinerator, skid mounted, components would be prewired to a terminal block in the junction box, mounted on the unit. Wiring between this terminal and the terminal strip in the control panel would be by others.
- D. Shop testing is limited to electrical and mechanical devices, and actual process conditions would not be simulated.
- E. Items purchased by Met-Pro such as fans and valves would retain manufacturer's standard prime and finish. Met-Pro would not be responsible for field painting of any kind.
- F. Met-Pro engineering standards on surface preparation would be in accordance with SSPC-SP 1-63, Solvent Cleaning. All carbon steel surfaces would be primed with a 1.5-2.0 mil. thick CECO-357 standard gray paint.

VI. START-UP ASSISTANCE

A total of five (5) man-days of service to assist in the start-up of the catalytic incinerator are included as part of this proposal. Additional assistance may be scheduled. Appendix I of this proposal details Met-Pro Service Fee Schedules.

In order to facilitate scheduling of Systems Division field services, notification of two (2) weeks prior to start-up is required.

VII. ITEMS AND SERVICES NOT INCLUDED

1. IRI (FIA) or FM or other insurance approvals are not included in this proposal. Met-Pro valve trains and system controls are designed according to recognized insurance company standards. Final approvals are handled through regional offices at location of installation. Met-Pro will provide drawings and other necessary information required to assist the customer in obtaining this approval.
2. Building modifications or lighting fixtures including engineering, thereof.
3. Installation or erection.
4. Structural steel platforms, ladders or foundations.
5. Interconnecting wiring and piping of service connections or analyzation equipment.
6. Field painting of any kind.
7. LEL Monitoring system.
8. Any procedure or requirements in obtaining a permit for the operation of the incineration system will be the customer's responsibility. Met-Pro will supply the necessary information on the incineration system for the customer to apply for approval.
9. Local disconnects.
10. Heat tracing of utility lines and valves.

VIII. SOUND LEVEL SPECIFICATIONS

Met-Pro shall not provide nor will be responsible for any testing, evaluating, certifying or reporting of sound level measurements of equipment supplied for the catalytic incineration system. The expected db(A) levels under normal operating conditions should not exceed the present OSHA standards. Information concerning sound levels will be submitted as received from the respective equipment supplier.

IX. DEFINITION OF APPROVED EQUALS

The term "approved equal" is applied in this proposal to facilitate any changes or additions to the process design. All equipment would be as described subject to design feasibility, design changes, or market availability. Met-Pro reserves the right to use "approved equals" as they see fit in the manufacture of the catalytic incineration system.

X. ENGINEERING DRAWINGS AND DATA (3 of each)

Process & Instrumentation Diagram (approval)	- 6 weeks ARO
Dimensioned Outline Drawing (approval)	- 6 weeks ARO
Electrical Schematics	- 6 weeks after P&I
Assembly and Erection Drawings	- 30 days before Unit Shipment
Installation Manuals	- 30 days before Unit Shipment
Operation/Maintenance Manuals	- With Unit
Catalog Cuts	- With Unit
Performance Curves	- With Unit

The release of engineering drawings and reproducible sepias or tracings of the catalytic unit to the customer are to be used solely for the purpose of operating equipment supplied by Met-Pro. The drawings or facsimiles thereof remain the property of Met-Pro and pertain to patents or pending patent applications related to the catalytic incineration system.

Any drawings or manuals supplied to the customer above a total of six (6) of that particular drawing or manual shall be at additional cost to the customer. The cost will be \$10.00 per drawing and \$50.00 per manual if ordered before shipment of the unit to the purchaser. The cost of drawings and manuals ordered after unit shipment will be quoted at time of order.

XI. SYSTEM PERFORMANCE

Met-Pro Corporation, Systems Division, guarantees that the catalytic incineration system will provide a minimum 97% reduction (by volume) of the volatile organic contaminants present in the process exhaust stream. This guarantee is to be confirmed by acceptance tests described below, conducted within three (3) months of start-up or six (6) months of shipment whichever occurs first. Guarantee is contingent on purchaser following Met-Pro recommended operating procedures and on operation to the process specifications given in Section II.B of this proposal.

System performance is specifically contingent upon none of the following catalyst inhibitors being present in the process exhaust:

Phosphorus, Bismuth, Lead, Arsenic,
Sulfur, Antimony, Mercury, Iron Ox-
ide, Tin, Silicon, Zinc, Halogens,
or inert particulate.

Systems Division additionally warrants performance of this system provided purchaser installs it in accordance with drawings either made or approved by Systems Division and provided purchaser in turn warrants all interconnecting piping, wiring, ductwork, and other purchaser-furnished materials and components.

Replacement of equipment due to damage, or failure caused by the improper operation of the unit will be the responsibility of the purchaser.

Catalytic incineration system performance shall be verified by a mutually agreed upon third party at purchaser's expense. Performance testing shall be conducted as outlined by EPA document, 450/a-78-04, "Guideline Series - Measurement of Volatile Organic Compounds". Any alternate procedures for such testing shall be by mutual agreement between Systems Division and the purchaser.

XI. SYSTEM PERFORMANCE continued

System efficiency shall be determined by the following equation:

$$EFF = \frac{(CB \times VOLB) - (CA \times VOLA)}{(CB \times VOLB)} \times 100$$

Where:

- EFF = The system emission efficiency in percent.
 - CB* = The concentration of gaseous organics in the effluent gas before the system in parts per million by volume.
 - CA* = The concentration of gaseous organics in the effluent gas after the system in parts per million by volume.
 - VOLA** = The volumetric flow rate of the effluent gas after the system, in dry standard cubic meters per second.
 - VOLB** = The volumetric flow rate of the effluent gas before the system, in dry standard cubic meters per second.
-

*CA and CB shall be determined by EPA Reference Method 25.

**VOLA and VOLB shall be determined by EPA Reference Method 2.

APPENDIX I

Met-Pro Field Service

A. DEFINITION OF A NORMAL WORKING DAY

A "working day" as used in this schedule excludes Saturdays, Sundays, Holidays, the hours prior to 7:00 a.m. or after 6:00 p.m., and does not exceed eight (8) hours in any twenty-four (24) hour period. Overtime rates shall be applied on an hourly basis if it is a continuation of a "working day". If an additional visit to a work site, beyond the working day is required, a four (4) hour minimum overtime charge shall apply.

B. FEE SCHEDULE

Service Technicians:

1) Half-day (less than 4 hours)	\$225.00
2) Daily (4-8 hours)	\$400.00
3) Overtime (Monday thru Friday)	\$ 75.00/hour
4) Saturday*	\$ 75.00/hour
5) Sunday and Holiday**	\$100.00/hour

Service Engineer or Engineering Person:

1) Half-day (less than 4 hours)	\$350.00
2) Daily (4-8 hours)	\$575.00
3) Overtime (Monday thru Friday)	\$100.00/hour
4) Saturday*	\$100.00/hour
5) Sunday and Holiday**	\$125.00/hour

APPENDIX I

C. EXPENSES

In addition to the above rates, all expenses, such as telephone telegraph, meals, hotel expense and travel expense, including airplane, train or car rental incurred incident to the service will be billed at actual cost as accounted for by vendor. Time and expense will be computed from the time service personnel depart from their regular schedule until they return to that schedule. When a Met-Pro Corporation automobile is utilized in providing services, it will be billed at approximately the current IRS recognized rate (currently \$0.21/mile). If a Met-Pro truck is utilized in providing services, it will be billed at double the rate for autos.

* A four (4) hour minimum overtime charge shall apply.

** An eight (8) hour minimum overtime charge shall apply.

PS Form 3811, Jan. 1978

SENDER: Complete items 1, 2, and 3.
Add your address in the "RETURN TO" space on reverse.

1. The following service is requested (check one.)

Show to whom and date delivered..... ¢

Show to whom, date and address of delivery..... ¢

RESTRICTED DELIVERY
Show to whom and date delivered..... ¢

RESTRICTED DELIVERY
Show to whom, date, and address of delivery. \$

(CONSULT POSTMASTER FOR FEES)

2. ARTICLE ADDRESSED TO:

Mr. Allen F. Gant
50 Northwest 176th St.
Miami, Florida 33169

3. ARTICLE DESCRIPTION:

REGISTERED NO.	CERTIFIED NO.	INSURED NO.
	0156564	

(Always obtain signature of addressee or agent)

I have received the article described above.

SIGNATURE Addressee Authorized agent

4. DATE OF DELIVERY _____ POSTMARK _____

5. ADDRESS (Complete only if requested)

6. UNABLE TO DELIVER BECAUSE: _____ CLERK'S INITIALS _____

RETURN RECEIPT, REGISTERED, INSURED AND CERTIFIED MAIL

GPO : 1979-300-459

No. 0156564

RECEIPT FOR CERTIFIED MAIL

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

PS Form 3800, Apr. 1976

SENT TO
Mr. Allen F. Gant
STREET AND NO.

P.O., STATE AND ZIP CODE

POSTAGE	\$
CERTIFIED FEE	¢
SPECIAL DELIVERY	¢
RESTRICTED DELIVERY	¢
OPTIONAL SERVICES	
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	9/14/84

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

September 14, 1984

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 13-091497; Request for Additional Information

The department has reviewed your application to construct and has determined that additional information is needed to complete this review. At this time, the application is incomplete. Please respond to the following questions and comments as soon as possible so that our review may continue.


1. The application (Section III.B) indicates a minimum product weight of 61.3 lbs/hr. What is the maximum product weight?
2. Provide background process calculations (Section III.C) for particulates, all potential emissions, and all allowable emissions. Is there any auxiliary equipment for this operation with the potential to generate emissions? If so, identify and show all calculations.
3. The efficiency guarantee for the catalytic incinerator equals 97% according to page 16 of Met-Pro Proposal 84157. Provide a manufacturer's guarantee for the proposed operating conditions of 9300 scfm, acetone of 24.7 lbs/hr and 21.3 lbs/hr of isopropyl alcohol. What is the efficiency at the lower indicated temperatures and the hours of operation at these lower temperatures?
4. Provide fuel analysis data as required in Section III.E of the application.
5. Provide the dry standard cubic feet per minute and the water vapor content as required in Section III.H.

Mr. Allen F. Gant
Page Two
September 14, 1984

6. Provide information on the number of start-ups per year and the duration and emission increases due to the start-ups. Show all calculations.
7. Provide Section IV Incinerator information to include the design capacity for the incinerator, the dscfm (dry standard cubic feet per minute) and the required data for the incinerator primary chamber.
8. During incineration, is there any NO_x formed? Is there any CO emitted? Any other criteria pollutants emitted? If so, provide all calculations.
9. What design volume of catalyst ft³/1000 scfm? What is changed with increased SCFM?
10. Section III.C shows an allowable emission rate for VOC. Provide the applicable emission standard and all calculations.
11. Construction can not commence without receipt of a valid permit to construct. Please revise your start of construction and completion date in Section II.B of the application.
12. The UTM units and latitude/longitude do not coincide. Please recheck and resubmit.

When we have received all of the required information, we will continue processing your application. If you have any questions, please call Lillian Jack, Review 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

cc: Lloyd H. Stebbins
Nancy Wright
Roy Duke

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

Phone call 9/28/84, 11:30 AM
John Hawkins

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



BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

Art Volman

September 14, 1984

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 13-091497; Request for Additional Information

The department has reviewed your application to construct and has determined that additional information is needed to complete this review. At this time, the application is incomplete. Please respond to the following questions and comments as soon as possible so that our review may continue.

1. The application (Section III.B) indicates a minimum product weight of 61.3 lbs/hr. What is the maximum product weight? max input 107.6 lbs/hr
2. Provide background process calculations (Section III.C) for particulates, all potential emissions, and all allowable emissions. Is there any auxiliary equipment for this operation with the potential to generate emissions? If so, identify and show all calculations.
3. The efficiency guarantee for the catalytic incinerator equals 97% according to page 16 of Met-Pro Proposal 84157. Provide a manufacturer's guarantee for the proposed operating conditions of 9300 scfm, acetone of 24.7 lbs/hr and 21.3 lbs/hr of isopropyl alcohol. ~~What is the efficiency at the lower indicated temperatures and the hours of operation at these lower temperatures?~~
4. Provide fuel analysis data as required in Section III.E of the application. *Natural GAS*
5. Provide the dry standard cubic feet per minute and the water vapor content as required in Section III.H.


OK

Mr. Allen F. Gant
Page Two
September 14, 1984

6. Provide information on the number of start-ups per year and the duration and emission increases due to the start-ups. Show all calculations. *(none)*
7. Provide Section IV Incinerator information to include the design capacity for the incinerator, the dscfm (dry standard cubic feet per minute) and the required data for the incinerator primary chamber.
8. During incineration, *How much is emitted based on the max. capacity?* is there any NO_x formed? Is there any CO emitted? Any other criteria pollutants emitted? If so, provide all calculations. *1300° Range low residence*
- Send* 9. What design volume of catalyst ft³/1000 scfm? What is changed with increased SCFM? *What is the design range?*
- Send* 10. Section III.C shows an allowable emission rate for VOC. Provide the applicable emission standard and all calculations.
11. Construction can not commence without receipt of a valid permit to construct. Please revise your start of construction and completion date in Section II.B of the application.
12. The UTM units and latitude/longitude do not coincide. Please recheck and resubmit.

When we have received all of the required information, we will continue processing your application. If you have any questions, please call Lillian Jack, Review 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

cc: Lloyd H. Stebbins
Nancy Wright
Roy Duke

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

Nº 76041

RECEIPT FOR APPLICATION FEES AND MISCELLANEOUS REVENUE

Received from Key Pharmaceuticals, Inc. Date August 17, 1984


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

Applicant Name & Address Same as above.

Source of Revenue _____

Revenue Code 001031 Application Number AC 13-091497

By Patricia B. Adams


 KEY PHARMACEUTICALS, INC.
50 N.W. 176TH STREET
MIAMI, FLORIDA 33169-0670
(305) 652-2276

Check Number 46127
Date _____

Invoice No.	Invoice Date	Amount	Description	Discount	Net Amount
	8-7-84		Permit fee for construction permit for Glatt II.		\$100.00

Attached check is for items listed above - Detach this voucher before depositing check.

▲
LAST LINE SHOWN
IS TOTAL

 KEY PHARMACEUTICALS, INC.
50 N.W. 176TH STREET
MIAMI, FLORIDA 33169-0670
SOUTHEAST FIRST NATIONAL BANK OF MIAMI
MIAMI, FLORIDA

Check Number Date 08-10-84 Exactly *****100. Dollars and 00 Cents

FLORIDA STATE DEPARTMENT OF ENVIRONMENTAL REGULATION
2600 BLAIRSTONE ROAD
TALLAHASSEE, FLORIDA 32301

Amount
\$ ***100.00

Pay to
the
Order of

BY Michael Johnson
BY Paul L. Wimbly

DEPARTMENT OF ENVIRONMENTAL REGULATION

ROUTING AND TRANSMITTAL SLIP

ACTION NO.

ACTION DUE DATE

1. TO: (NAME, OFFICE, LOCATION)

Lillian Jack

INITIAL

DATE

2.

INITIAL

DATE

3.

INITIAL

DATE

4.

INITIAL

DATE

REMARKS:

RE: Key Pharm.

- ① Will Any NO_x be formed by the incinerator?
- ② Will there be any CO emitted?
- ③ Will any other criteria pollutants be emitted?

Col nec 9/7/84

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:

DATE

PHONE

REYNOLDS, SMITH AND HILLS

ARCHITECTS • ENGINEERS • PLANNERS
INCORPORATED

August 9, 1984

DIRECTORS:

IVAN H. SMITH, F.A.I.A.
RALPH W. HEIM, P.E.
JAMES F. SHIVLER, JR., P.E.
WILLIAM J. WEBBER, A.I.A.
ROBERT F. DARBY, A.I.A.
BOB ALLIGOOD, A.I.E.
BEN BUCALO, P.E.
GEORGE M. BARSON, Sc.D., P.E.
K. N. HENDERSON, P.E.
HOWARD B. BOCHIARDY, F.A.I.A.
HENRY LUKE, P.E.
JOSEPH W. GRIFFIN, A.I.A.
JOHN E. COOK

Mr. Clair H. Fancy
Florida Department of Environmental Regulations
Central Air Permitting Section
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, Florida 32301

SUBJECT: Application to Construct
Key Pharmaceuticals, Inc.,
Miami, Florida
AEP Number 84143 000

DER

AUG 17 1984

BAQM

Dear Mr. Fancy:


We are forwarding herewith, on behalf of our client, Key Pharmaceuticals, Inc., an application to construct the Number 2 Fluidized Bed Coating Unit, to be located at 50 NW 176th Street, Miami.

Attached to this letter is a listing of the questions as noted by us, which were raised by Ms. Forthman, Mr. Palagyi, Mr. Svec and Ms. Wright of the DER at a meeting in Tallahassee on July 20, 1984. The response immediately follows each question. We trust that we have satisfactorily responded to each item of concern.

Your timely approval of this application will be appreciated.

Should you have any questions, or require further information, please do not hesitate to telephone me.

Very truly yours,



Lloyd H. Stebbins, P.E., Head
Chemical and Process Department
Environmental Engineering Division

LHS:adh

Enclosure

cc: Mr. A. F. Gant
Key Pharmaceuticals, Inc.

ATTACHMENT

Following is a listing of the items questioned by DER in the July 20, 1984, meeting in Tallahassee:

1. DER would require written guarantee of the efficiency of the catalytic incinerator from the manufacturer.

RESPONSE:

A copy of the Met-Pro proposal, showing the written guarantee of efficiency will be attached to permit application. This has been noted in Item D on Page 5 of the permit application. Met-Pro guarantees the unit to operate at 97% efficiency based on volume. In turn, an overall efficiency of 95% based on weight has been used in all the calculations.

2. Key would be required to present a plan as to how we would prove to DER that we are staying under a 40 ton per year discharge limit.

RESPONSE:

The 40 ton upper limit would be maintained by monitoring stack gases for hydrocarbons (see Page 8 of Met-Pro quote). There are two Beckman 400 Hydrocarbon Analyzers (or equal) to measure both inlet and outlet solvent concentrations. Other process parameters will be obtained from FDA records for each operating cycle.

3. Key would have to present data showing ongoing efficiency of the incinerator.

RESPONSE:

The Beckman 400's are attached to a two pen Beckman 8720 recorder to provide hard copy of hydrocarbon levels in and out of the incinerator.

4. Key must present to DER documentation from manufacturer that guarantees 99% particulate efficiency.

RESPONSE:

A letter from Torit is attached, indicating a guarantee that the TD4600 cartridge type unit used with Glatt II is at least 99% efficient for 1 micron dust. This has been noted to Item D on Page 5 of the permit application. Please note that the dust collector discharge is to the incinerator, and not to atmosphere. Any appreciable amount of dust entering the incinerator will foul the catalyst.

5. Show reasons for such a wide range of stack temperature (425°F to 700°F) as presented in permit.

RESPONSE:

The range of stack gas temperatures occurs only based on the input conditions given for the quote. If solvent levels are high, stack gas temperature can go up to 700°F. When solvent levels are lower (such as final coat or when bed jams up), the temperatures are lower (e.g., 425°F). In actual running, stack gases will be about 500°F to 550°F.

6. Does Key require variance for height of stack from Dade County?

RESPONSE:

Key will require approval for the stack as well as the unit from building and zoning department of Dade County. If a variance is required, it will be applied for but the height should not warrant it.

7. DER requires that we specify the primary chamber volume of the incinerator.

RESPONSE:

The primary chamber is the combustion chamber and is 41"x37"x78"=68.5 cu.ft. This has been added to the permit application.

8. DER requires more information on fuel usage that was specified as "pilot only" on the permit.

RESPONSE:

Based on burning acetone and/or isopropyl alcohol at design conditions (see Page 2 of quote), there is enough heat from the heat of combustion to auto ignite incoming solvents in the air stream, therefore not requiring natural gas as fuel (i.e., pilot only). Natural gas will be used only to maintain temperatures if solvent levels drop off substantially or during start-up. More details on gas usage have been added to Item E on Page 5 of the permit application.

9. On Page 6 of the permit, resolve discrepancy of "feet per second" numbers (one place shows 37 to 48 FPS, another place shows 37 to 40 FPS).

RESPONSE:

The stack velocity should be 37 to 48 fps in both cases. This has been corrected on the permit application.



Key
Pharmaceuticals,
Inc.

DER

AUG 17 1984

BAQM

August 10, 1984

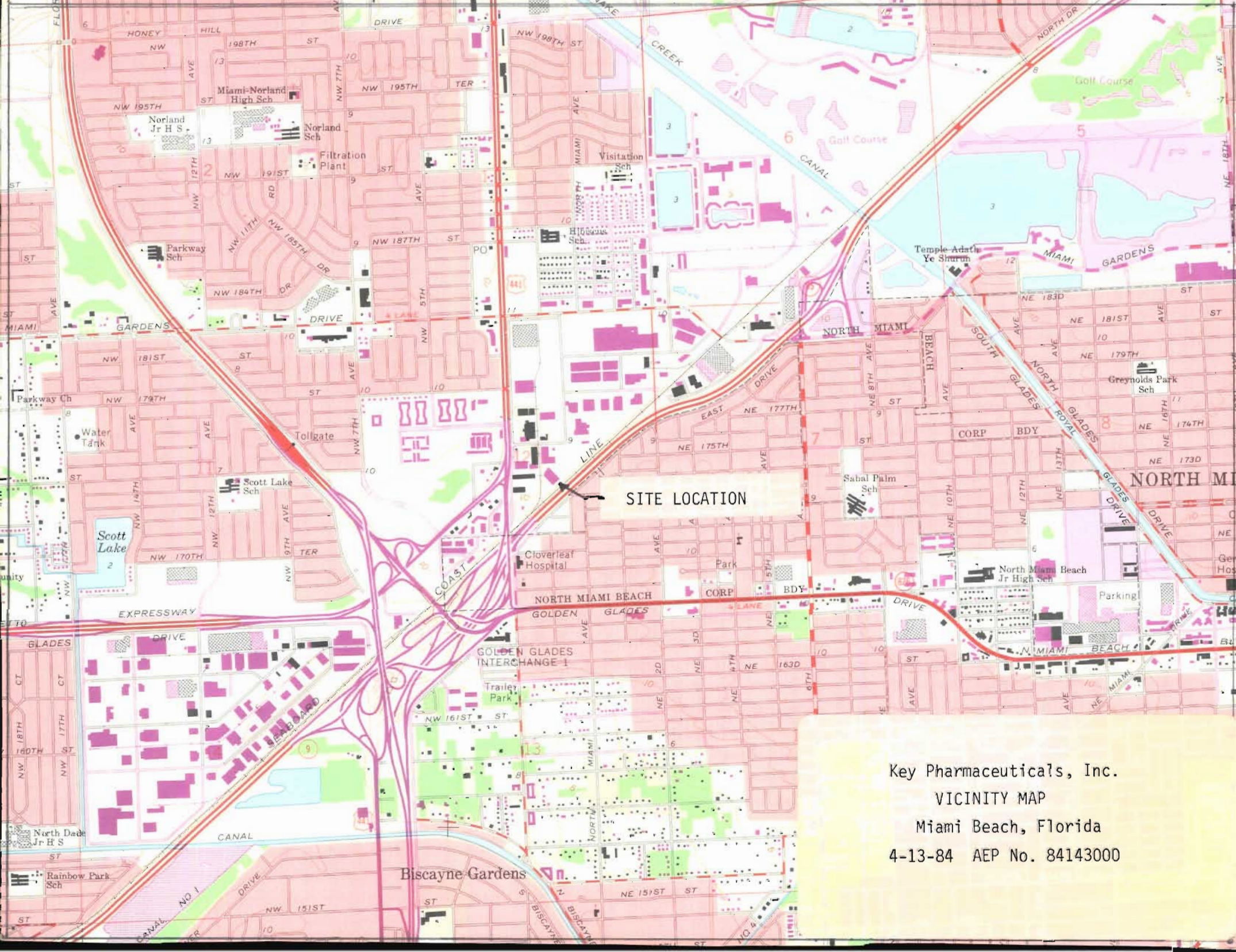
Florida Department of Environmental Regulation
2600 Blairstone Road
Tallahassee, Florida 32301

TO WHOM IT MAY CONCERN:

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

Yours truly,

D. M. Bell
Senior Vice President
Operations



SITE LOCATION

Key Pharmaceuticals, Inc.
VICINITY MAP
Miami Beach, Florida
4-13-84 AEP No. 84143000

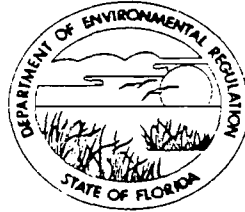
AC 13-091497

STATE OF FLORIDA

DEPARTMENT OF ENVIRONMENTAL REGULATION

NORTHEAST DISTRICT

3426 BILLS ROAD
JACKSONVILLE, FLORIDA 32207



DER

AUG 17 1984

BAQM

BOB GRAHAM
GOVERNOR

VICTORIA J. TSCHINKEL
SECRETARY

G. DOUG DUTTON
DISTRICT MANAGER

APPLICATION TO OPERATE/CONSTRUCT AIR POLLUTION SOURCES

SOURCE TYPE: Air Pollution [X] New¹ [] Existing¹

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) No. 2 Fluidized Bed Coating Unit

SOURCE LOCATION: Street 50 NW 176th Street City Miami

UTM: East 579830 North 2868480

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)

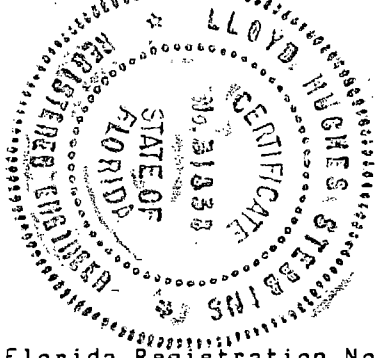
Date: 8/15/84 Telephone No. 305/652-2276

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 *Lloyd H. Stebbins*

Lloyd H. Stebbins
Name (Please Type)

Reynolds, Smith and Hills
Company Name (Please Type)

P O Box 4850, Jacksonville, FL 32201
Mailing Address (Please Type)

Florida Registration No. 31838 Date: 8-15-84 Telephone No. 904/739-2000, Ext. 2201

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.

Sugar seeds are added to a fluid bed coating unit. They are fluidized by high volume air through the base. A slurry of active ingredient plus solvents is sprayed onto the seeds through nozzles. Additional sustained release coatings with solvents are added. The material is inspected for quality, containerized and used in further processing into tablets not involving solvents.

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

Start of Construction Sept. 10, 1984 Completion of Construction Jan 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.)

\$280,000

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

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? | <u>Yes</u> |
| a. If yes, has "offset" been applied? | <u>N/A</u> |
| b. If yes, has "Lowest Achievable Emission Rate" been applied? | <u>N/A</u> |
| c. If yes, list non-attainment pollutants. | <u>Ozone</u> |
| 2. Does best available control technology (BACT) apply to this source?
If yes, see Section VI. | <u>No</u> |
| 3. Does the State "Prevention of Significant Deterioration" (PSD)
requirement apply to this source? If yes, see Sections VI and VII. | <u>No</u> |
| 4. Do "Standards of Performance for New Stationary Sources" (NSPS)
apply to this source? | <u>No</u> |
| 5. Do "National Emission Standards for Hazardous Air Pollutants"
(NESHAP) apply to this source? | <u>No</u> |
| H. Do "Reasonably Available Control Technology" (RACT) requirements apply
to this source? | <u>No</u> |
| a. If yes, for what pollutants? | <u></u> |
| b. If yes, in addition to the information required in this form,
any information requested in Rule 17-2.650 must be submitted. | |

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

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

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

Description	Contaminants		Utilization Rate - lbs/hr	Relate to Flow Diagram
	Type	% Wt		
Acetone	VOC		24.7	"B"
Isopropyl Alcohol	VOC		21.3	"B"
Non-Volatile Solids	Particulates		61.6	"B"

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

- Total Process Input Rate (lbs/hr): 107.6
- Product Weight (lbs/hr): 61.3 Minimum

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 Emission Rate per Rule 17-2	Allowable Emission lbs/hr	Potential ⁴ Emission		Relate to Flow Diagram
	Maximum lbs/hr	Actual T/yr			lbs/yr	T/yr	
VOC	2.31	9.7	N.A.	9.5	386,400	193.2	"A"
Particulates	0.3	1.26	N.A.		252,000	126.0	"A"

¹See Section V, Item 2.

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

³Calculated from operating rate and applicable standard.

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

C. 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)
Catalytic Incinerator	VOC	95	N/A	Suppliers
Met-Pro CX-9				Design *
9300SCFM				
Torit TD4600	Particulates	99		Suppliers
Dust Collector				Design **

* See Page 16 of Met-Pro Proposal 84157 (Attached)

** See letter from Torit Corporation (Attached)

E. Fuels

Type (Be Specific)	Consumption*		Maximum Heat Input (MMBTU/hr)
	avg/hr	max./hr	
Pilot Only (Natural Gas)	0.05 - 0.18	0.18	0.18
Start Up	5.6	5.6	5.6

*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.

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

Stack Height: 12 ft. Stack Diameter: 3 ft.
 Gas Flow Rate: 9300 SCFM DSCFM Gas Exit Temperature: 425 to 700 °F.
 Water Vapor Content: % Velocity: 37 to 48 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						43.7	
Uncontrolled (lbs/hr)						46.0	

Description of Waste Waste Acetone & Isopropyl alcohol are incinerated to water & carbondioxide

Total Weight Incinerated (lbs/hr) 43.7 Design Capacity (lbs/hr)

Approximate Number of Hours of Operation per day 24 day/wk 7 wks/yr. 50

Manufacturer Met-Pro

Date Constructed Begin 9/16/84 Model No. CS-9

	Volume (ft) ³	Heat Release (BTU/hr)	Fuel		Temperature (°F)
			Type	BTU/hr	
Primary Chamber	68.5				
Secondary Chamber	N/A				

Stack Height: 12 ft. Stack Diameter: 3ft Stack Temp. 425 to 700°F

Gas Flow Rate: 9300 SCFM DSCFM* Velocity: 37 to 48 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) Catalytic Incinerator

Brief description of operating characteristics of control devices: Process solvents are evaporated and ducted to the incinerator where the mixture is heated by exhaust gases. The gases are ignited due to the heat from the pilot and the heat exchanger. Combustion takes place in the combustion chamber and continues through the catalyst to maintain combustion efficiency to water and carbon dioxide. Exhaust gases preheat inlet gases in the heat exchanger and then exhausts to the stack.

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

N/A

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

SECTION V: SUPPLEMENTAL REQUIREMENTS

Please provide the following supplements where required for this application.

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

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

SECTION VI: BEST AVAILABLE CONTROL TECHNOLOGY

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

Yes No

Contaminant	Rate or Concentration

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

Yes No

Contaminant	Rate or Concentration

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

Contaminant	Rate or Concentration

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

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

*Explain method of determining

- 5. Useful Life:
- 7. Energy:
- 9. Emissions:

- 6. Operating Costs:
- 8. Maintenance Cost:

Contaminant

Rate or Concentration

Contaminant	Rate or Concentration

10. Stack Parameters

- a. Height: ft. b. Diameter: ft.
- c. Flow Rate: ACFM d. Temperature: °F.
- e. Velocity: FPS

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

1.

- a. Control Device: b. Operating Principles:
- c. Efficiency:¹ d. Capital Cost:
- e. Useful Life: f. Operating Cost:
- g. Energy:² h. Maintenance Cost:
- i. Availability of construction materials and process chemicals:
- j. Applicability to manufacturing processes:
- k. Ability to construct with control device, install in available space, and operate within proposed levels:

2.

- a. Control Device: b. Operating Principles:
- c. Efficiency:¹ d. Capital Cost:
- e. Useful Life: f. Operating Cost:
- g. Energy:² h. Maintenance Cost:
- i. Availability of construction materials and process chemicals:

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:

¹Explain method of determining efficiency.

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

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:¹

Contaminant

Rate or Concentration

(8) Process Rate:¹

b. (1) Company:

(2) Mailing Address:

(3) City:

(4) State:

(5) Environmental Manager:

(6) Telephone No.:

(7) Emissions:¹

Contaminant

Rate or Concentration

(8) Process Rate:¹

10. Reason for selection and description of systems:

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

SECTION VII - PREVENTION OF SIGNIFICANT DETERIORATION

A. Company Monitored Data

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

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

Other data recorded _____

Attach all data or statistical summaries to this application.

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

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

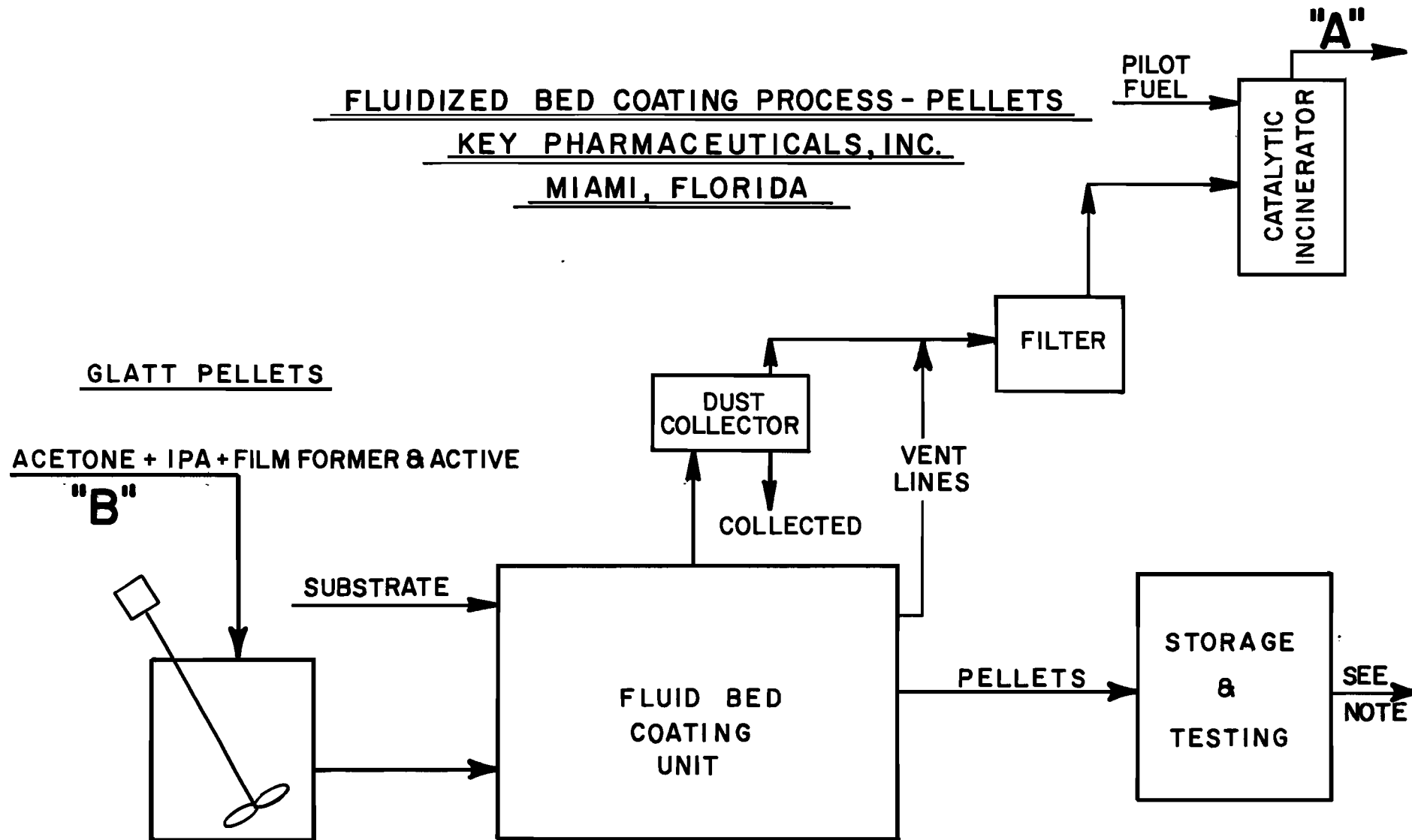
Attach list of emission sources. Emission data required is source name, description of point source (on NEDS point number), UTM coordinates, stack data, allowable emissions, and normal operating time.

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.

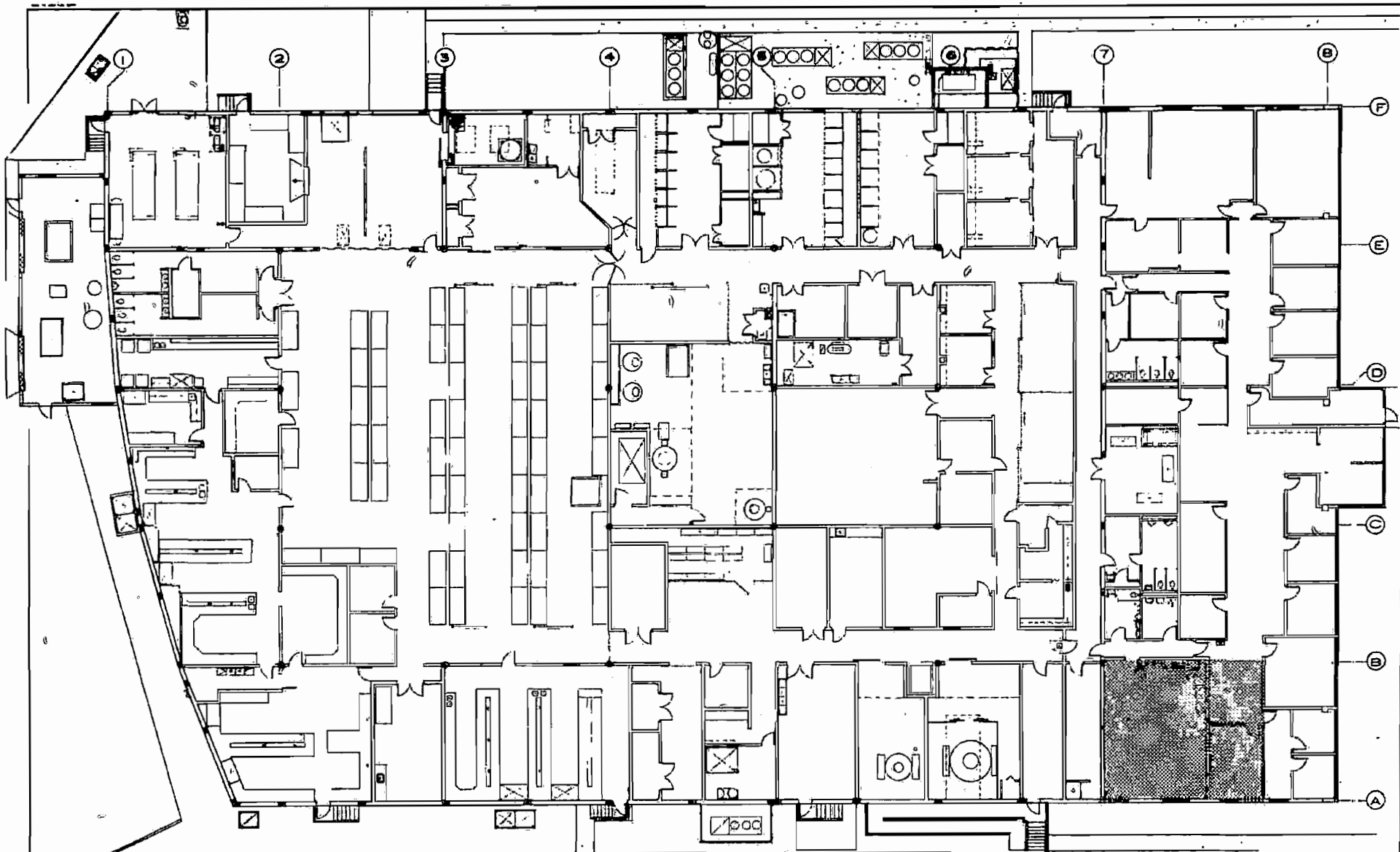
H. Attach scientific, engineering, and technical material, reports, publications, journals, and other competent relevant information describing the theory and application of the requested best available control technology.

FLUIDIZED BED COATING PROCESS - PELLETS
KEY PHARMACEUTICALS, INC.
MIAMI, FLORIDA



NOTE:

THE MATERIAL IS INSPECTED FOR QUALITY, CONTAINERIZED AND USED IN FURTHER PROCESSING NOT INVOLVING SOLVENTS.



FLUID BED NO. 2

KEY PHARMACEUTICALS, INC.

MIAMI, FLORIDA



LOCATION



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

Air Handling

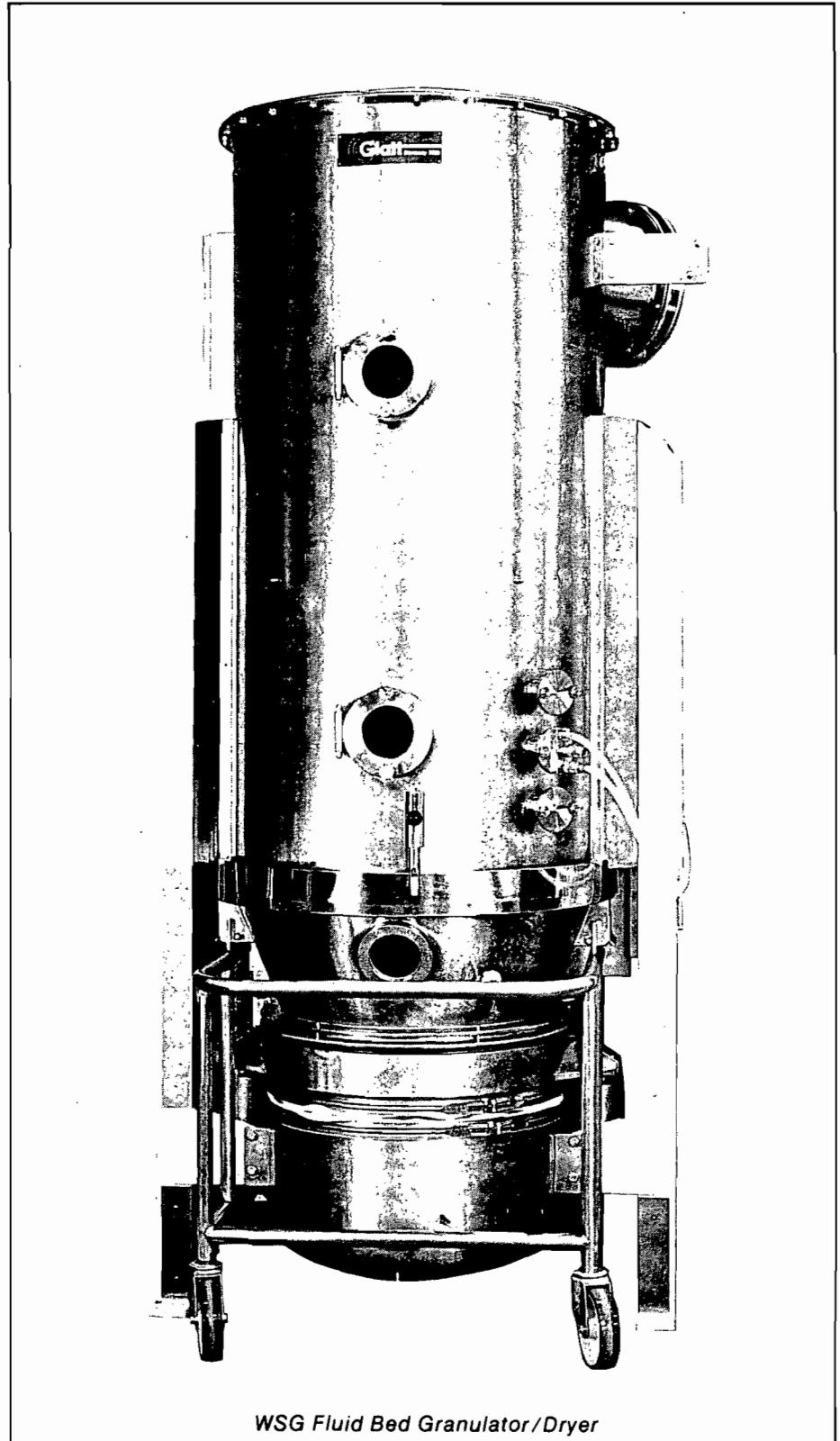
- remote fan for quieter, safer, and cleaner operation
- 80 micron pocket prefilter
- efficient, high capacity galvanized steel heating coils

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



WSG Fluid Bed Granulator/Dryer

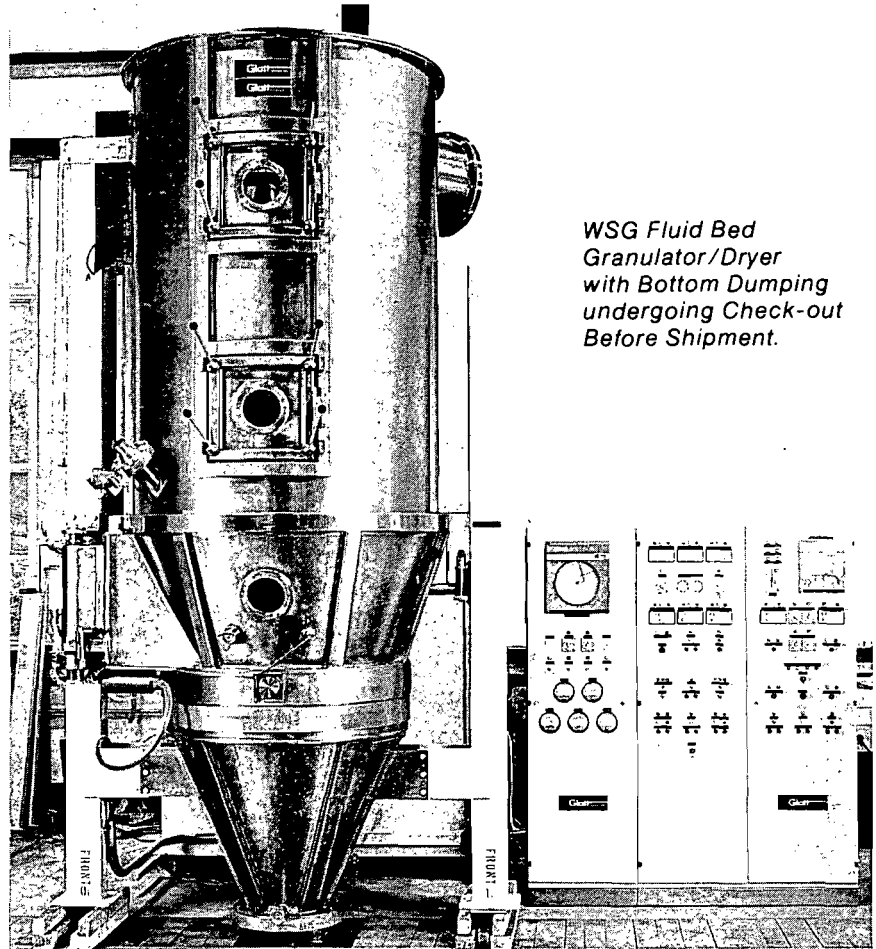
Safety

- 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

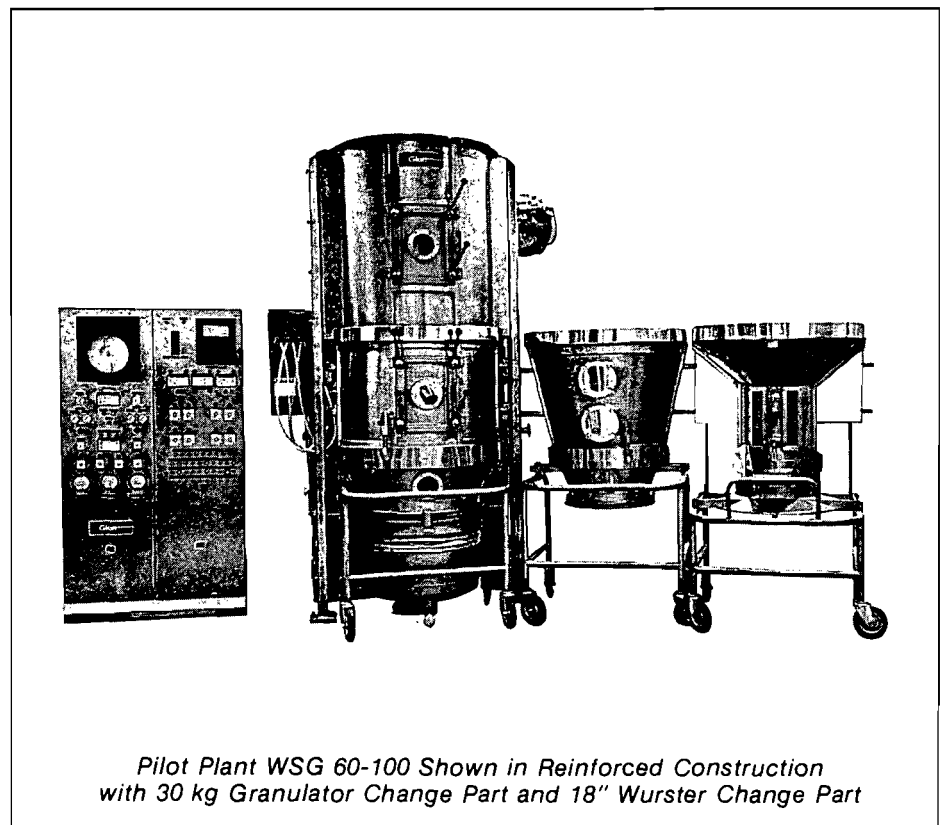
Process Control

- 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

- 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



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



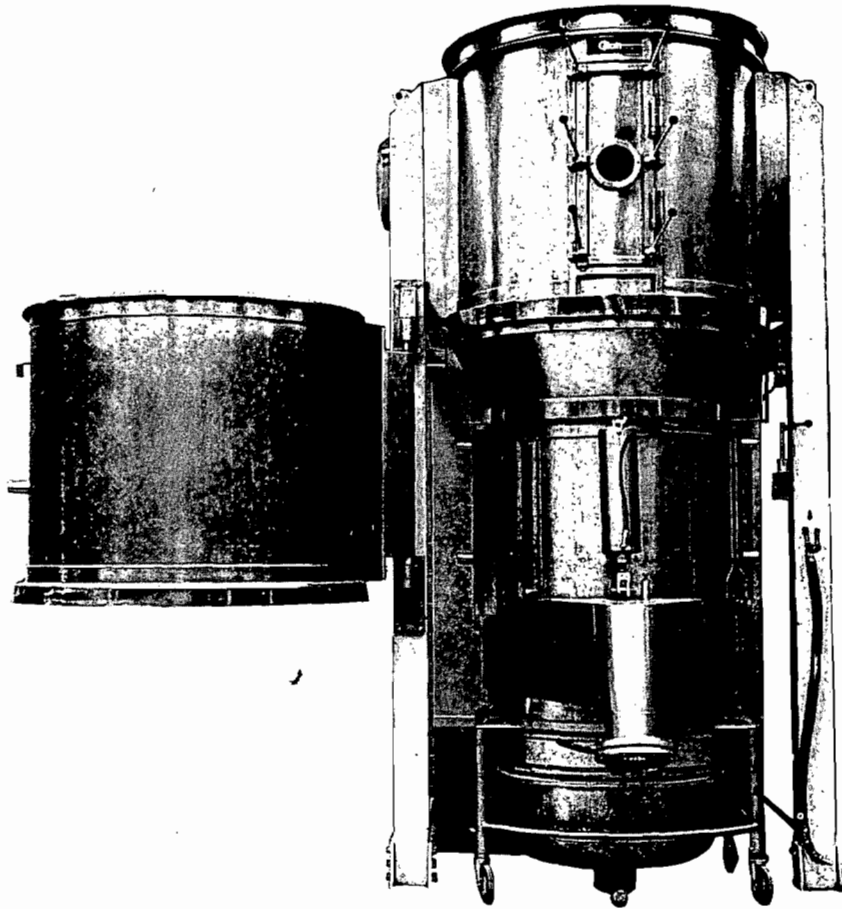
Pilot Plant WSG 60-100 Shown in Reinforced Construction with 30 kg Granulator Change Part and 18" Wurster Change Part

Optional Three-piece 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.)*

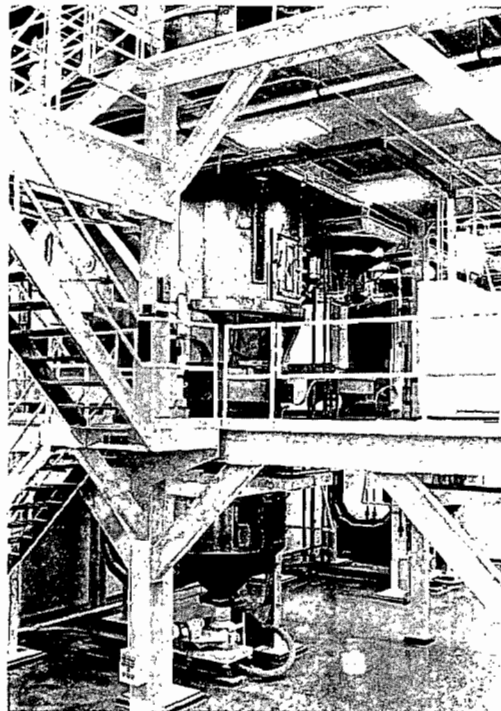
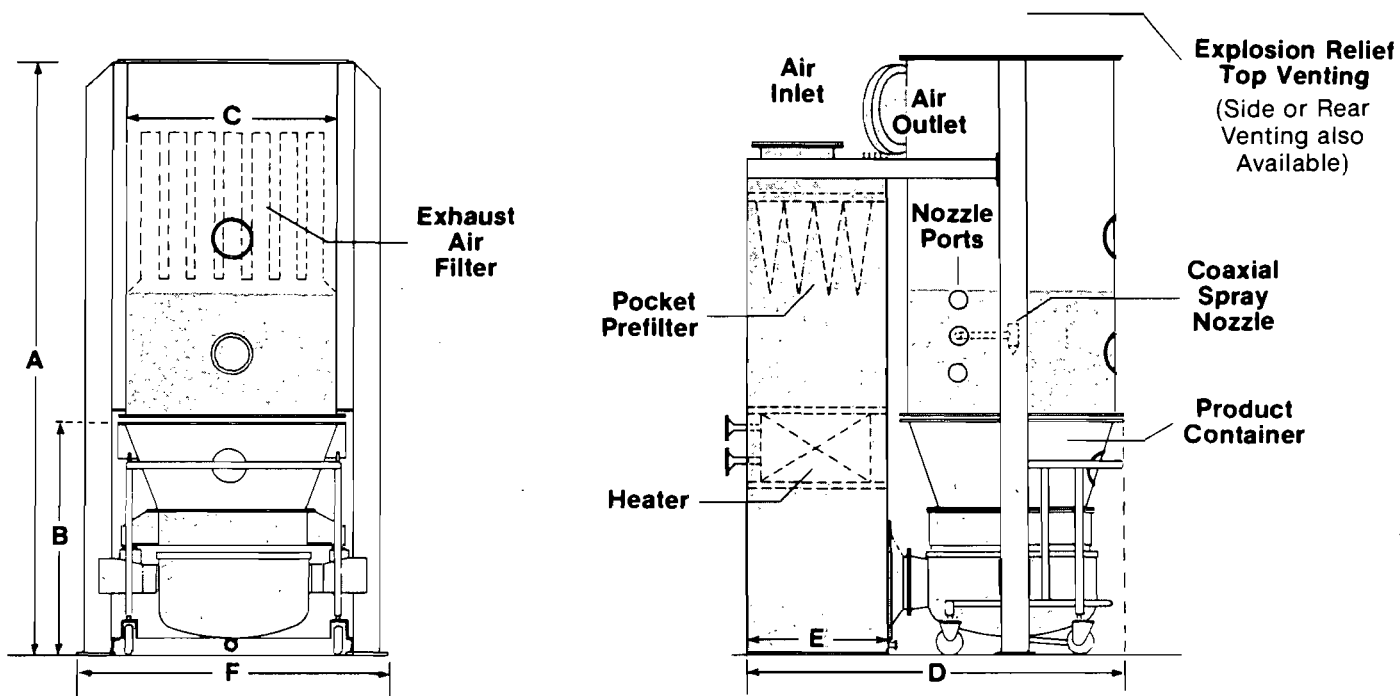


Photo shows a full view of two WSG 1000-1500 granulators showing the three service levels of the machine. The upper level accesses the exhaust air filter housing and bulk material loading facility. The middle section is the process floor where the expansion housing, 3000 liter product container and automatic 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	Details Available On Request
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	
heating capacity in BTU's per hour		64,000	120,000	240,000	360,000	440,000	720,000	840,000	1,008,000	
D I M E N S I O N S i n M M	A	2400	2700	3000	3200	3500	4000	4200	5000	
	B	870	915	985	1175	1375	1590	1760	1980	
	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

PROCESS CALCULATIONS

ASSUMPTIONS

1. Catalytic incinerator efficiency - 95%
2. Dust collector efficiency - 99%
3. All solvents out fluid bed to stack

Solids in - 61.6 lbs per hour

Acetone in - 24.7 lbs per hour

IPA in - 21.3 lbs per hour

Total Process
Input 107.6 lbs per hour

All solvents to incineration
 $21.3 + 24.7 = 46$ lbs per hour

According to the Supplier the incinerator is 95% efficient, therefore, the amount of solvents emitted is $0.05 (46.0) = 2.3$ lbs per hour.

On an annual basis

$$\frac{2.30 \times 24 \times 7 \times 50}{2000} = 9.7 \text{ tons per year VOC}$$

torit



Environmental Control, Inc.
P. O. 530723
Miami Shores, Florida 33153
Tele: 305-895-6696

August 1, 1984

Key Pharmaceuticals
PO Box 693670
Miami, Florida, 33168

DER

AUG 17 1984

BAQM

Attn: Steve Goodstein

Re: Dust Samples Submitted

Gentlemen:

In regards to the dust samples that you submitted to the Torit laboratory in Minnesota for analysis we are pleased to report the following:

On dust sample # 2842 (Theoplylline Dust) the average particle size was 3.30 microns with the smallest particle size at 0.8 microns.

This sample was not hygroscopic, but it was agglomerated and somewhat sticky. In addition the bulk density appeared to be quite light

On dust sample # 2843 (Theo-Dur Dust) the average particle size was between 6.7 & 165 microns, with the smallest particles slightly under 0.8 microns.

This sample also was not hygroscopic, but was agglomerated with approx. 50% of the small particulate being straw like in appearance approximately 7 microns wide x 20-40 microns long.

At a 1.5:1 air to cloth ratio the Ultra Web filters in all of your Torit TD collectors should exceed 99% efficiency on particles as small as 0.10 of a micron, far below the average particle size tested. May I point out that we cannot certify this efficiency if other than Torit's Ultra Web filters are used in the TD collectors.

If additional testing or information is required, please do not hesitate to contact me.

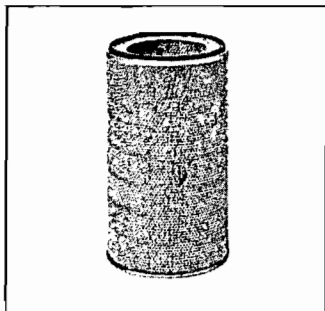
Yours truly,

Norman Gabe, President

DUST COLLECTORS

NEW FILTRATION TECHNOLOGY

The new TD 4600 is based on a unique combination of technologies. It involves the application of cartridge-type filters to a continuous-duty dust collection system. It offers you many advantages for



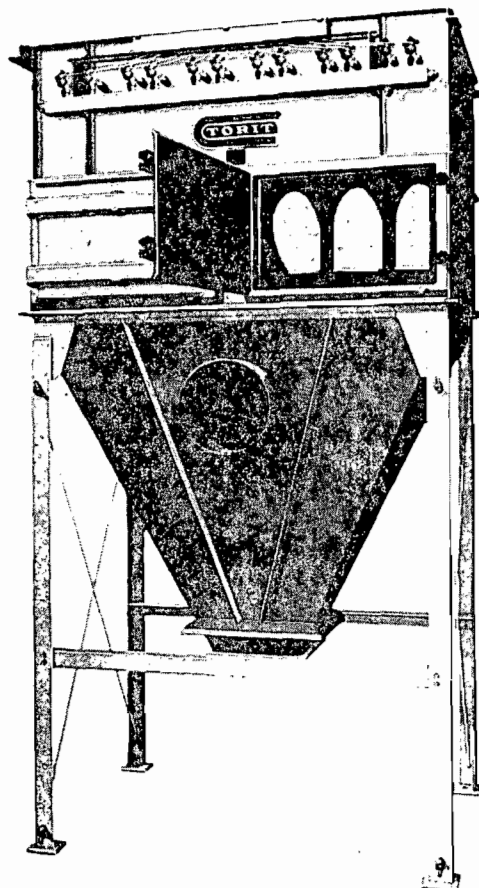
treating large volumes of dust-laden air on a continuing basis: highly efficient filtration; increased filtering area for lower air-to-media ratios; increased ease of maintenance and operation; and substantially decreased collector headroom.

EFFECTIVE FINE PARTICLE CONTROL

The use of pleated, non-woven filter media is the key to the TD 4600's filtering efficiency. Dust-laden air enters through the inlet of the collector—heavy particles fall immediately into the hopper bottom. As the air is drawn in through the filter cartridges, dust is deposited on the outside of the filtering media. With 24 filter cartridges, the system has 4416 square feet of filter area, almost *four times* as much as a conventional tube house of the same size. The generous filter area means low filtration velocity and high efficiency when handling sub-micron particulate.

CONTINUOUS PULSE-JET CLEANING

The TD 4600's filter cartridges are cleaned automatically and continually—the system remains on-line at all times. Continuous filtration means full-time pollution control and longer life for manufacturing equipment. A remotely-mounted solid state timer controls the cycle time. Solenoid valves introduce jets of high-pressure air into each pair of filter cartridges in turn, through the venturi opening above each cartridge. The resulting reverse air flow cleans the filter cartridges. Dust removed from the filters settles to the bottom of the collector. As each pair of cartridges is cleaned in succession, the remaining 22 continue their operation. Extremely high dust loadings are handled easily.



EASY-TO-HANDLE FLEXIBILITY

The TD 4600 requires up to 25% less headroom than conventional tube houses—the highly efficient filter cartridges are 26" long, instead of standard 96" cloth tubes. Its compact size gives you great flexibility in location. Also, the TD 4600 does the job with 24 cartridges, instead of the 100 or more filters in tube houses of the same size.

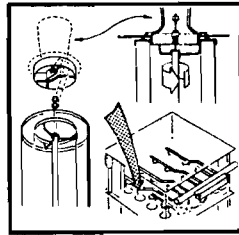
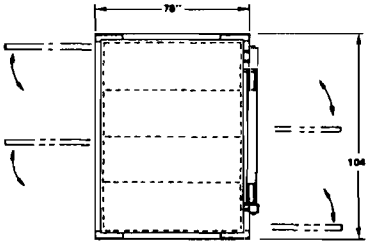
The TD 4600 is delivered to you in major assemblies. The system is available with different blower pack combinations for single-unit or multiple-unit applications. Its hopper can be fitted for 55-gallon drums, or for a rotary air lock adapter. The TD is made with the same high quality TORIT puts into all its dust collection systems: air-tight all-steel construction, sealed seams, and gasketed doors and fittings. The TD 4600 filter cartridge system is a major innovation in effective air pollution control, from TORIT.



DUST COLLECTORS

FILTER CARTRIDGE SYSTEMS/TD 4600

Quick-change feature allows fast cartridge removal and installation.



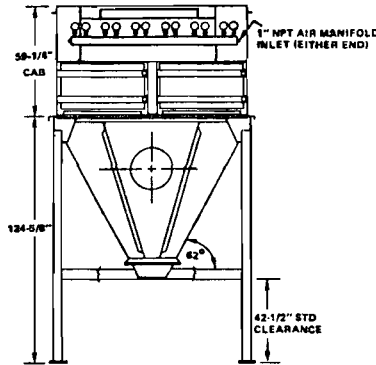
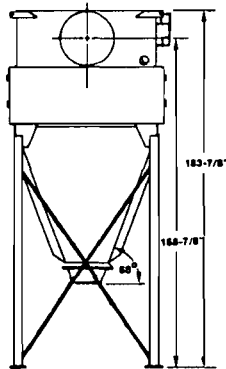
SPECIFICATIONS

Actual Filter Area	5424 sq. ft.
Number of Valves	12
Number of Filter Cartridges	24
Filter Cartridge		
Dimensions	12¾" OD x 8¾" ID x 26" long
Number of Hopper Outlets	1
Hopper Outlet Size	14¼" square
Hopper Size	139 cu. ft.
Shipping Weight	est. 3010 lbs.
Wind Load Rating	100 m.p.h.
Seismic Rating	Zone 3

Specifications subject to change without notice.

NOTES

- Inlet sizes available in 1-inch increments from 9" ID to 22" ID with built-on deflectors. Please specify.
- Standard legs provide 42½" clearance under the hopper flange. Bolt-on legs for special height requirements are available.
- TD systems must be attached to 90-100 PSIG in-plant compressed air supply for cleaning mechanism to function.
- Valves and control system operate on 120v, 60-cycle power.
- TD units are painted with blue acrylic enamel.
- Roof slope 2 inches.



OPTIONAL EQUIPMENT

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

PERFORMANCE TESTED

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

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



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

TECHNICAL PROPOSAL NO. 84157

for

KEY PHARMACEUTICALS, INC.
Miami, Florida

by

SYSTEMS DIVISION, MET-PRO CORPORATION
160 Cassell Road, P. O. Box 144
Harleysville, PA 19438

Technical Proposal No. 84157

KEY PHARMACEUTICALS, INC.

I. INTRODUCTION

The OXYCAT Catalytic Incineration System, designed and fabricated by the Systems Division of Met-Pro Corporation, is engineered to efficiently control hydrocarbon fume emissions from industrial processes. In brief, our process involves three stages:

1) Contaminated Stream Preheat

If required, the industrial exhaust is preheated to a temperature suitable for activation of the combustion reaction over the catalyst. A preheat burner and/or recuperative heat exchanger are used for this purpose.

2) Combustion of Contaminated Stream

The contaminated stream is passed over a catalyst, developed and manufactured at Met-Pro, where combustion takes place at temperatures much lower than conventional thermal incineration designs.

3) Exhaust of Environmentally Safe Products of Combustion

The safe products of combustion ultimately are vented into the atmosphere.

The OXYCAT Catalytic Incineration System is a factory assembled, insulated unit, designed to meet performance specifications and applicable insurance underwriters' requirements. The expected efficiency for hydrocarbon control is 97 per cent when operated in accordance with the specifications of Section IIB of this proposal.

A detailed description of system components, accessories, assembly criteria and performance specifications follows:

II. TECHNICAL DESCRIPTION AND SPECIFICATIONS

A. Scope

Systems Division of Met-Pro Corporation proposes to design and fabricate one Model CXII-9G Catalytic Incineration System to control hydrocarbon emissions from pharmaceutical operations for Key Pharmaceuticals, Inc., Miami, Florida.

The Catalytic Incineration System is designed to handle a vent stream with a maximum volume of 9300 SCFM.

System Components include:

- 1) Gas-Fired Incinerator
- 2) Recuperative Heat Exchanger
- 3) Process Blower
- 4) Catalyst Charge
- 5) Complete Control Logic
- 6) Integral Exhaust Stack
- 7) Inlet/Outlet Hydrocarbon Analyzers with Chart Recorder

B. Process Specifications

1) Design

The Model CXII-9G Catalytic Incineration System has been designed in accordance with two projected design conditions. These conditions were projected from information provided by Key Pharmaceuticals, Inc.. These design cases are outlined below. The process temperature is 75 deg. F., and process pressure is assumed to be 0" W.C.

	Design Case I	Design Case II
Volumetric Flow Rate SCFM	7925	7925
Total Solvent Loading (lb/hr)	537.7	240
Isopropyl Alcohol (lb/hr)	239.8	240
Acetone (lb/hr)	297.9	0

NOTE: The process data presented above assumes the exhaust stream is composed only of the above referenced gaseous constituents. No liquid or solid phase components can be present in the stream.

II. TECHNICAL DESCRIPTION AND SPECIFICATIONS . . . cont'd.

B. Process Specifications . . . cont'd.

2) Operation

Design Case	I	II
Volume (SCFM)	7925	7925
Dilution Air Req'd. (SCFM) . . .	1375	0
Temperature (Deg. F)	75	75
Pressure (in. H2O)	0	0
Solvent Species and Loading . . .	same as design specifications	
Catalyst Inlet Temp. (Deg. F) . .	600	600
Catalyst Outlet Temp. (Deg. F) .	1230	949
Catalyst Control Temp. (Deg. F) .	600	600
Max. Allowable Catalyst Outlet Temp. (Deg. F).	1250	1250

- NOTE: 1. When the heat exchanger outlet temperature exceeds the catalyst control temperature, a controlled volume of process air will bypass the coldside of the heat exchanger and re-enter the unit upstream of the catalyst, to maintain 600 degrees F at the catalyst inlet.
2. A minimum of 600 deg. F. will be maintained at catalyst inlet. Burner input would be required when temperature drops below 600 deg. F.

3) Operating Requirements

- Process Blower . . 1. 460 V 3 phase, 60 Hz
2. 60 HP (44.7 Kwh)
3. Start-up - 45.3 BHP (33.75 Kwh)
4. Operation (Design Case I)
51.46 BHP (38.34 Kwh)
5. Operation (Design Case II)
45.3 BHP (33.75 Kwh)
- Burner 1. Natural Gas Fuel at 1000 BTU/SCF
2. Start-up - 5.6 mm BTU/hr (5600 SCFH)
3. Operation (Design Case I)
0.05-0.18 mm BTU/hr (50-180 SCFH)
4. Operation (Design Case II)
0.05-0.18 mm BTU/hr (50-180 SCFH)

may want to go 208V

II. TECHNICAL DESCRIPTION AND SPECIFICATIONS . . . cont'd.

B. Process Specifications . . . cont'd.

3) Operating Requirements . . . cont'd.

Burner . . . cont'd.

- NOTES: 1. The preheat burner is designed to automatically turn down to an output capacity of .18 mm BTU/hr. It is projected that if the solvent loading is relatively constant, burner input would not be required to maintain the minimum catalyst inlet temperature. Heat for process preheat would be recovered from the heat liberated by the combustion reaction. As a means of energy savings, the burner can be turned down to pilot operation (0.05 mm BTU/hr) by a manual selector switch at the control panel.
2. Start-up conditions assumed to be 7925 SCFM at 70 deg. F. and 0" W.C.

4) Utilities

Fuel Natural Gas at 1000 BTU/SCF
Electricity 460 V, 3 Phase, 60 Hz
Plant Air (Damper Actuation) . . 100 psig

(what is approximate consumption SCFM) ?

III. SYSTEM COMPONENTS

A. Combustion Chamber

The combustion chamber would be fabricated of carbon steel with continuously welded external joints. The sides would be reinforced with stiffeners at suitable intervals. The section would be internally insulated with a thermally expandable insulation material. The skin temperature of the unit would be approximately 140 Deg. F under normal operation.

B. Catalyst

The catalyst accelerates and promotes the combustion reaction. It does not enter into the reaction and is not dissipated. The catalyst contains finely dispersed particles of precious metals embedded on a ceramic monolith support structure.

The catalyst would be installed in one Type 304 stainless steel basket. The catalyst loaded basket is 69" x 41" x 18" and weighs 1900 pounds. The catalyst basket is easily removable from the combustion chamber and an access door would be provided for catalyst removal.

C. Combustion System and Controls

1) Combustion System Package

A gas-fired burner manufactured by Eclipse, or approved equal, would be used to preheat process gases to their catalytic oxidation temperature. The burner, is located in the combustion chamber upstream of the reaction zone.

A completely prepiped gas valve train mounted and supported on the unit would be provided. Met-Pro valve trains are designed to meet FM insurance requirements. Valve train components include:

- a) Pressure regulator
- b) Solenoid vent valve
- c) Gas cocks
- d) Low fuel pressure switch
- e) High fuel pressure switch
- f) Motorized safety shut-off valve
- g) Solenoid blocking valve
- h) Gas control valve and control motor

III. SYSTEM COMPONENTS continued

C. Combustion System and Controls continued

2) Control Panel

The control panel would meet all the requirements of the National Electrical Manufacturer's Association (NEMA) and all pertinent classifications as listed in the National Electrical Code (NEC) pertaining to control panels. Mounted within the NEMA XII panel enclosure would be the following:

- a) Indicating Controller
- b) Control Transformer
- c) Fused Disconnect Switch
- d) Purge Timer
- e) Alarm Relay
- f) Alarm and Silencing Button
- g) Pilot Lights
- h) Pushbuttons
- i) Miscellaneous Terminal Blocks, Fuses, etc.
- j) Flame Safeguard
- k) Motor Starter
- l) Analyzers/Recorder (Separate NEMA XII cabinet)

3) Other Accessories

- a) High Temperature Limit
- b) Thermocouples
- c) UV Flame Detector
- d) Process Air Sensor
- e) Terminal Strip for remote panel installation
- f) Automatic Shut-Down

In the event of flame failure, low or high fuel pressure, blower failure, or incinerator exceeding high temperature limit, the control system will automatically switch into the shut-down mode.

- g) Pushbutton for manual shut-down

D. Unit Transitions

Inlet and outlet transitions would be provided for process gas handling. Transitions would be fabricated from stainless steel minimum 12 Bwg. with inlet flange connection provided.

III. SYSTEM COMPONENTS continued

E. Recuperative Heat Exchanger

A nominally 60% thermally efficient recuperative heat exchanger would be provided to reduce the fuel requirements of the catalytic unit during normal operation. This section would recover flue gas heat and use it to preheat the process gases prior to entering the burner/combustion section. The resultant process preheat would allow for minimum heat input by the burner and significant fuel savings.

The gas-to-gas exchanger would be a shell and tube type unit with two 304 stainless steel tube bundles. The bundles are arranged in series such that process makes two tube passes and one shell pass. The tube bundles would be an integral part of the incinerator, and would consist of nominal one inch diameter tubes, double convolute expansion joints, and tube sheets. Unit shell side of the heat exchanger would be an integral part of the catalytic incinerator with similar construction to the combustion chamber.

F. Unit Base

The main runs of the unit skid would consist of two structural beams approximately 4.5 feet apart. The main runs would be approximately 16 feet long. Cross member beams, a minimum of four feet apart would be provided. Unit would stand approximately 27 feet high, 4.5 feet wide, and 16 feet long (length does not include inlet ductwork assembly). Unit weight is approximately 21,800 pounds.

G. Unit Stack

An exhaust stack 3'0" diameter and 12'0" in length is provided for flue gas outlet. The exhaust stack is fabricated of stainless steel, minimum 12 Bwg.

H. Heat Exchanger Cold Side Bypass Assembly

A 16" diameter duct, fabricated of 304 stainless steel would be provided to allow for a controlled

III. SYSTEM COMPONENTS . . . cont'd.

H. Heat Exchanger Cold Side Bypass Assembly . . . cont'd.

volume of process air to bypass the cold side of the heat exchanger and enter the combustion chamber upstream of the catalyst section inlet. The bypass duct would be equipped with a pneumatically operated volume control damper. Bypass air volume control would be initiated by a temperature signal. All fabricated ductwork would be minimum 12 Bwg.

I. Hydrocarbon Analyzation Equipment

Two (2) Beckman Model 400 Hydrocarbon Analyzers, or approved equal, would be provided to measure solvent concentration in the gas stream entering the incinerator and in the exhaust stream leaving the incinerator.

One (1) Beckman Model 8720 Two Channel Chart Recorder would also be provided.

J. Dilution Air Tee-Section

During periods when solvent loading is high, and the catalyst outlet temperature exceeds 1250 deg. F., outside air would be admitted to the inlet stream for process dilution. When this condition occurs, the outside air isolation damper would open to admit outside air; this damper would be normally closed, however, is projected to open at the extreme solvent loading conditions referenced in Section II.B.1 of this proposal. Dilution air addition would be controlled by a temperature controller downstream of the catalyst section.

K. Process Blower

The blower would be finish mounted on a unitary base with motor, motor base, and V-belt drive. Additional features include flanged inlets and outlets, drain, access door, OSHA belt guard, and opposed blade outlet damper.

Blower would be rated for 9388 ACFM at 75 deg. F. and 21" W.C.S.P. Blower would be supplied by New York Blower, or approved equal.

IV. SHIPMENT SCHEDULE

4 to 5 1/2 Mo.

The estimated shipping completion based upon similar units would be 16 to 22 weeks after drawing approval. The required time for installation of the unit upon reaching the job site would be approximately two (2) weeks, depending upon weather conditions, labor and proper site preparation.

could Met-Pro supply
installation labor for
unit?

V. ASSEMBLY, PAINTING AND SHOP TESTING

- A. The system is designed for field assembly. Most components of the proposed equipment would be assembled in our shop prior to shipment. The equipment would be shipped as completely assembled as practical; however, where over-the-road shipping limitations apply, partial disassembly may be required. Purchaser is invited to examine the equipment in its partially assembled state, subject to Met-Pro scheduling requirements for manufacturing space. Degree of assembly would be dependent upon shop area available.
- B. The control panel would be completely prewired. All panel components would be checked by controlled simulation testing, and results thoroughly analyzed to assure smooth, efficient system start-up.
- C. The burner valve train would be completely prepiped. All incinerator, skid mounted, components would be prewired to a terminal block in the junction box, mounted on the unit. Wiring between this terminal and the terminal strip in the control panel would be by others.
- D. Shop testing is limited to electrical and mechanical devices, and actual process conditions would not be simulated.
- E. Items purchased by Met-Pro such as fans and valves would retain manufacturer's standard prime and finish. Met-Pro would not be responsible for field painting of any kind.
- F. Met-Pro engineering standards on surface preparation would be in accordance with SSPC-SP 1-63, Solvent Cleaning. All carbon steel surfaces would be primed with a 1.5-2.0 mil. thick CECO-357 standard gray paint.

VI. START-UP ASSISTANCE

A total of five (5) man-days of service to assist in the start-up of the catalytic incinerator are included as part of this proposal. Additional assistance may be scheduled. Appendix I of this proposal details Met-Pro Service Fee Schedules.

In order to facilitate scheduling of Systems Division field services, notification of two (2) weeks prior to start-up is required.

VII. ITEMS AND SERVICES NOT INCLUDED

1. IRI (FIA) or FM or other insurance approvals are not included in this proposal. Met-Pro valve trains and system controls are designed according to recognized insurance company standards. Final approvals are handled through regional offices at location of installation. Met-Pro will provide drawings and other necessary information required to assist the customer in obtaining this approval.
2. Building modifications or lighting fixtures including engineering, thereof.
3. Installation or erection.
4. Structural steel platforms, ladders or foundations.
5. Interconnecting wiring and piping of service connections or analyzation equipment.
6. Field painting of any kind.
7. LEL Monitoring system.
8. Any procedure or requirements in obtaining a permit for the operation of the incineration system will be the customer's responsibility. Met-Pro will supply the necessary information on the incineration system for the customer to apply for approval.
9. Local disconnects.
10. Heat tracing of utility lines and valves.

VIII. SOUND LEVEL SPECIFICATIONS

Met-Pro shall not provide nor will be responsible for any testing, evaluating, certifying or reporting of sound level measurements of equipment supplied for the catalytic incineration system. The expected db(A) levels under normal operating conditions should not exceed the present OSHA standards. Information concerning sound levels will be submitted as received from the respective equipment supplier.

IX. DEFINITION OF APPROVED EQUALS

The term "approved equal" is applied in this proposal to facilitate any changes or additions to the process design. All equipment would be as described subject to design feasibility, design changes, or market availability. Met-Pro reserves the right to use "approved equals" as they see fit in the manufacture of the catalytic incineration system.

X. ENGINEERING DRAWINGS AND DATA (3 of each)

Process & Instrumentation Diagram (approval)	- 6 weeks ARO
Dimensioned Outline Drawing (approval)	- 6 weeks ARO
Electrical Schematics	- 6 weeks after P&I
Assembly and Erection Drawings	- 30 days before Unit Shipment
Installation Manuals	- 30 days before Unit Shipment
Operation/Maintenance Manuals	- With Unit
Catalog Cuts	- With Unit
Performance Curves	- With Unit

The release of engineering drawings and reproducible sepias or tracings of the catalytic unit to the customer are to be used solely for the purpose of operating equipment supplied by Met-Pro. The drawings or facsimiles thereof remain the property of Met-Pro and pertain to patents or pending patent applications related to the catalytic incineration system.

Any drawings or manuals supplied to the customer above a total of six (6) of that particular drawing or manual shall be at additional cost to the customer. The cost will be \$10.00 per drawing and \$50.00 per manual if ordered before shipment of the unit to the purchaser. The cost of drawings and manuals ordered after unit shipment will be quoted at time of order.

XI. SYSTEM PERFORMANCE

Met-Pro Corporation, Systems Division, guarantees that the catalytic incineration system will provide a minimum 97% reduction (by volume) of the volatile organic contaminants present in the process exhaust stream. This guarantee is to be confirmed by acceptance tests described below, conducted within three (3) months of start-up or six (6) months of shipment whichever occurs first. Guarantee is contingent on purchaser following Met-Pro recommended operating procedures and on operation to the process specifications given in Section II.B of this proposal.

System performance is specifically contingent upon none of the following catalyst inhibitors being present in the process exhaust:

Phosphorus, Bismuth, Lead, Arsenic,
Sulfur, Antimony, Mercury, Iron Ox-
ide, Tin, Silicon, Zinc, Halogens,
or inert particulate.

Systems Division additionally warrants performance of this system provided purchaser installs it in accordance with drawings either made or approved by Systems Division and provided purchaser in turn warrants all interconnecting piping, wiring, ductwork, and other purchaser-furnished materials and components.

Replacement of equipment due to damage, or failure caused by the improper operation of the unit will be the responsibility of the purchaser.

Catalytic incineration system performance shall be verified by a mutually agreed upon third party at purchaser's expense. Performance testing shall be conducted as outlined by EPA document, 450/a-78-04, "Guideline Series - Measurement of Volatile Organic Compounds". Any alternate procedures for such testing shall be by mutual agreement between Systems Division and the purchaser.

XI. SYSTEM PERFORMANCE continued

System efficiency shall be determined by the following equation:

$$EFF = \frac{(CB \times VOLB) - (CA \times VOLA)}{(CB \times VOLB)} \times 100$$

Where:

- EFF = The system emission efficiency in percent.
- CB* = The concentration of gaseous organics in the effluent gas before the system in parts per million by volume.
- CA* = The concentration of gaseous organics in the effluent gas after the system in parts per million by volume.
- VOLA** = The volumetric flow rate of the effluent gas after the system, in dry standard cubic meters per second.
- VOLB** = The volumetric flow rate of the effluent gas before the system, in dry standard cubic meters per second.

*CA and CB shall be determined by EPA Reference Method 25.

**VOLA and VOLB shall be determined by EPA Reference Method 2.

APPENDIX I

Met-Pro Field Service

A. DEFINITION OF A NORMAL WORKING DAY

A "working day" as used in this schedule excludes Saturdays, Sundays, Holidays, the hours prior to 7:00 a.m. or after 6:00 p.m. and does not exceed eight (8) hours in any twenty-four (24) hour period. Overtime rates shall be applied on an hourly basis if it is a continuation of a "working day". If an additional visit to a work site, beyond the working day is required, a four (4) hour minimum overtime charge shall apply.

B. FEE SCHEDULE

Service Technicians:

1) Half-day (less than 4 hours)	\$225.00
2) Daily (4-8 hours)	\$400.00
3) Overtime (Monday thru Friday)	\$ 75.00/hour
4) Saturday*	\$ 75.00/hour
5) Sunday and Holiday**	\$100.00/hour

Service Engineer or Engineering Person:

1) Half-day (less than 4 hours)	\$350.00
2) Daily (4-8 hours)	\$575.00
3) Overtime (Monday thru Friday)	\$100.00/hour
4) Saturday*	\$100.00/hour
5) Sunday and Holiday**	\$125.00/hour

APPENDIX I

C. EXPENSES

In addition to the above rates, all expenses, such as telephone telegraph, meals, hotel expense and travel expense, including airplane, train or car rental incurred incident to the service will be billed at actual cost as accounted for by vendor. Time and expense will be computed from the time service personnel depart from their regular schedule until they return to that schedule. When a Met-Pro Corporation automobile is utilized in providing services, it will be billed at approximately the current IRS recognized rate (currently \$0.21/mile). If a Met-Pro truck is utilized in providing services, it will be billed at double the rate for autos.

* A four (4) hour minimum overtime charge shall apply.

** An eight (8) hour minimum overtime charge shall apply.

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. _____ PURSUANT TO
CHAPTER 403, FLORIDA STATUTES

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. _____ 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 ____ day
of _____, 1984.

ATTEST:

KEY PHARMACEUTICALS, INC.

Assistant Secretary

By: _____
Vice President

BEFORE THE STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL REGULATION

STATE OF FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATION,)	IN THE OFFICE OF THE
)	SOUTHEAST FLORIDA
Complainant,)	DISTRICT
)	
vs.)	OGC CASE NO. <u>84-0644</u>
)	
KEY PHARMACEUTICALS, INC.,)	
)	
Respondent.)	
<hr/>		

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:

<u>Milestone</u>	<u>Compliance Date</u>
(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 shall be the average level of emissions that would be associated with normal operations of the facility at maximum capacity after the installation of permanent pollution control equipment on Glatt #2, and assuming a 90% reduction of non-chlorinated hydrocarbon emissions from the sources listed in paragraph 4. above.

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.

29. This Consent Order may only be modified by the written agreement of both parties.

FOR THE RESPONDENT

DATE: _____

DONE AND ORDERED this _____ day of _____, 1984, in West Palm Beach, Florida.

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

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