COMMONWEALTH OF PUERTO RICO
Office of the Governor
Environmental Quality Board
35 Years of Environmental Management
Air Quality Area

February 5, 2007

MAINA Y TORRES
DIRECTOR / TEAM LEADER
API (CELECOXIB OPERATIONS)
PFIZER PHARMACEUTICALS LLC
CRUCE DAVILA
PO BOX 11247
BARCELONETA PR 00617

Dear mrs Torres:

Re: ADMINISTRATIVE AMENDMENT
PFIZER PHARMACEUTICALS LLL – CRUCE DAVILA
PFE-TV-2833-09-0397-0030-B
BARCELONETA, PUERTO RICO

The Environmental Quality Board includes the **revision** to the permit mentioned above. The revision is authorized under an administrative amendment to transfer the responsibility of part of Pfizer Pharmaceuticals LLC (Cruce Davila) units to Abraxis BioScience Manufacturing LLC (Abraxis) and retain the operational control over other emission units.

Pfizer (leased) will rent to Abraxis (lessor) the chemical operations building, administrative offices, tank farm and some raw material and finished product storehouses located at the west side of the property adquired by Abraxis. The waste water from the chemical plant operated by Pfizer Pharmaceuticals LLC will be discharged (under a lease contract) to the pretreatment system whose owner and operator is Abraxis.

Pursuant to the powers granted to the Environmental Quality Board by the Environmental Public Policy Act, Public Law Number 416 of September 22, 2004, as amended, and after verifying the administrative record and in compliance with the Uniform Administrative Procedures Act, Public Law Number 170 of August 12, 1998, as amended, the US Clean Air Act, the Puerto Rico Environmental Public

ADMINISTRATIVE AMENDMENT
PFIZER PHARMACEUTICALS LLC – CRUCE DAVILA
PFE-TV-2833-09-0397-0030-B
BARCELONETA, PUERTO RICO

Policy Act and the Environmental Quality Board Regulations for the Control of Atmospheric Pollution, the Environmental Quality Board approves the permit and the terms and conditions stipulated therein.

The revision of this permit is being made pursuant to Rule 606(a)(2) of the Regulations for the Control of Atmospheric Pollution.

Pfizer Pharmaceuticals LLC – Cruce Davila will be responsible for the compliance with all conditions and terms of the permit until the transference is completed. The new effective date of this administrative amendment for the units under this permit will be **February 14, 2007**. This permit will expire on **November 10, 2011**.

In San Juan, Puerto Rico, on February 5, 2007.

Eugene Scott Amy
Vice President

Angel O. Berríos Silvestre
Associate Member

Carlos W. Lopez Freytes
President

COMMONWEALTH OF PUERTO RICO / OFFICE OF THE GOVERNOR

ADMINISTRATIVE AMENDMENT
TITLE V OPERATING PERMIT
AIR QUALITY AREA
ENVIRONMENTAL QUALITY BOARD

Permit Number:	**PFE-TV-2833-09-0397-0030-B**
Date of Receipt of the Application:	**March 26, 1997**
Final Issue and/or Effective Date:	**November 10, 2006**
Administrative Amendment Date:	**February 14, 2007**
Expiration Date:	**November 10, 2011**

Pursuant to the provisions of Part VI of the Environmental Quality Board Regulations for the Control of Atmospheric Pollution (RCAP) and the provisions of the Code of Federal Regulations (CFR), Title 40, Part 70

Pfizer Pharmaceuticals LLC (CRUCE DAVILA)
Barceloneta, Puerto Rico

hereinafter the permittee or **Pfizer CRUCE DAVILA**, is authorized to operate a stationary source of air pollutant emissions limited to the units and conditions described in this permit. The permit holder may release air pollutants resulting from processes and activities that are directly related to and/or associated with the emission sources, as required, limited or conditioned by this permit, until its expiration date or until the permit is modified or revoked.

The conditions in this permit shall be enforceable by the federal and state governments. Those requirements that may be enforced only by the state government shall be identified as such in this permit. Copy of this permit must be kept in the aforementioned facility at all times.

Section I- General Information

I. Facility Information

Name: **PFIZER PHARMACEUTICALS LLC (CRUCE DAVILA)**

Postal Address: **P. O. BOX 11247**

City: **BARCELONETA** State: **PUERTO RICO** Zip Code: **00617**

Name of Facility: **PFIZER PHARMACEUTICALS LLC (CRUCE DAVILA)**

Postal Address of the Facility: **P. O. BOX 11247, BARCELONETA, 00617**

Physical Address: **STATE ROAD 140, KM 64.4, BARCELONETA, P.R. 00617**

Responsible Official: **Maina Y. Torres** Telephone: **(787) 621-5401**
Director/Team Leader, API (Celecoxib Operations)

Contact Person in the Facility: **Mr.Eduardo Cordero, Eng.** Telephone: **(787) 774-7419**
Director/Team Leader, EHS Fax:**(787) 846-7310**

SIC Primary Code: **2833**

II. Process Description

PFIZER PHARMACEUTICALS LLC (CRUCE DAVILA) is an industry dedicated to the chemical synthesis manufacturing of active ingredients pharmaceuticals and finished pharmaceutical formulations. The company is located on state road PR-140, Km 64.4 to the south of highway PR-2, Barceloneta, Puerto Rico.

The original facilities were established in 1973 on 56 *cuerdas*. The physical plant covers approximately 392,000 square feet including four large buildings and several small structures, a tank farm, chemical storage area, solvent recovery area and a wastewater pretreatment plant.

Emissions units of the Chemical Synthesis area include the following activities: reactor loading, steam/gas displacement, loss of pressure, gas venting in empty tanks, gas heating and evolution, gas venting to maintain inert atmosphere, vacuum and atmospheric distillation, and vacuum drying. A series of condensers, a process gas scrubber, and several dust collectors are used as air pollution control equipment. The gas scrubber is used for compliance with the Pharmaceutical Industry MACT and the condensers or dust collectors for compliance with the Rule 419 of RCAP. Pfizer Cruce Dávila maintains the Leak Detection and Repair Program (LDAR) to control the fugitive emissions of the components.

Bulk storage tanks in the tank farm are used to store chemical materials used in the Chemical Synthesis area. Condensers are used as air pollution control equipment.

Storage tanks located in the tank farm are used to accumulate process wastes from the chemical synthesis area, which are regulated under the Resource Conservation and Recovery Act (RCRA). Condensers are used as air pollution control equipment in several of the storage tanks.

SECTION II - DESCRIPTION OF THE EMISSION UNITS

The emission units regulated by this permit are as follows:

Emission Unit	Description of Emission Unit	Control Equipment
EU-Chemical Plant (EU-2)	Prior to beginning any batch, the operator makes sure that the equipment to be used is empty. Immediately the raw materials are charged in the designated vessels. The contents are heated or cooled to the acceptable temperature. When the contents of the vessel reach the desired conditions, the materials are crystallized and then the materials are separated by the centrifuges into wet solids and the mother liquors that will go to the vessels that collect the dangerous waste for final disposition. The operator makes sure that the drying equipment to be used is empty prior to begin processing any batch. The wet solids are loaded into the designated drying equipment to minimize the humidity content to the desired level. The condensate in the drying equipment is transferred to the vessels. The dried material is emptied or unloaded to tote bins or fiber drums and transferred to the Pin Mill PMPA. The operator makes sure that the grinding equipment to be used is empty, prior to begin any batch. Then the material is loaded onto the equipment since the tote bin or fiber drums. On the grinding process finished, the materials are transferred to the fiber drums and sent to the designated storage area. This emission unit uses the gas scrubber as control equipment for compliance with MACT and the condenser for the compliance with the control requirement of the Rule 419 of the RCAP for those equipments that are not MACT affected. At the moment this emission unit does not have waste water (determination point) nor tanks affected by the MACT requirements.	The gas scrubber (for the effect of the compliance with the Pharmaceutical Industry MACT) and the condensers or gas scrubber (for the effect of the Rule 419 of the RCAP)
EU-Tank Farm (EU-7)	This unit consists of bulk storage tanks for chemical substances used in production. Some of these tanks have conservation vents or condensers.	Condensers

SECTION III- GENERAL PERMIT CONDITIONS

1. **Sanctions and Penalties:** The permittee shall be obliged to comply with all the terms, conditions, requirements, limitations, and restrictions established in this permit. Any violation of the terms of this permit shall be subject to administrative, civil or criminal measures, as established under Article 16 of the Environmental Public Policy Act, (Law Number 416 of September 22 of 2004, as amended).

2. **Right of Entry:** Pursuant to the provisions of Rules 103 and 603(c)(2) of the RCAP, the permittee shall grant access to EQB representatives to its facilities, upon presentation of credentials, to perform the following:

   a) Enter upon any premises where an emission source is located, or where air emission-related activities are conducted, or where records must be kept under the conditions of the permit, the agreement with the RCPA, or the US Clean Air Act;

   b) Have access to and copy, at reasonable times, any records that must be kept under the conditions of the permit, the agreement with the RCPA or the US Clean Air Act;

   c) Inspect and examine any facilities, equipment (including air monitoring and pollution control equipment), practices or operations (including methods used for quality control) regulated or required under the permit, and perform emission and fuel sampling;

   d) As authorized by the Act and the Regulations sample substances or parameters, at reasonable times, for the purpose of assuring compliance with the permit or applicable requirements.

3. **Sworn Statement:** All reports required pursuant to Rule 103(D) of the RCAP (to wit, semiannual sampling reports and annual certification of compliance), shall be submitted together with a sworn statement or affidavit of the Responsible Official or authorized representative. Such sworn statement shall attest to the truthfulness, correctness, and completeness of such records and reports.

4. **Data Availability:** As provided by rule 104 of the RCAP, all emissions data obtained by or submitted to the EQB, including data reported pursuant to Rule 103 of the RCAP, and any data otherwise obtained, shall be available for public inspection and may also be made available to the public in any additional ways that the EQB may deem appropriate.

5. **Emergency Plan:** Pursuant to Rule 107 of the RCAP, the permittee shall have an Emergency Response Plan available, which must be consistent with adequate safety practices, and which provides for the reduction or retention of facility emissions

during periods classified by the EQB as air pollution alerts, warnings, or emergencies. These plans will include the reduction to be achieved for each source and the means by which such reduction will be accomplished. These plans will be available for inspection by any authorized EQB representative, at any time.

6. **Control Equipment:** The permittee shall comply with Rule 108 of the RCAP, as follows:

A. All air pollution control equipment or control measures shall provide for continuous compliance with applicable rules and regulations. Such equipment or measures shall be installed, maintained, and operated according to those conditions imposed by this Title V Permit, within the operational limits specified by the manufacturer.

B. The material collected from the air pollution control equipment shall be disposed of in accordance with applicable rules and regulations. The removal, handling, transport, storage, treatment or disposal shall be done in such a way that it will not produce environmental degradation, and in accordance with applicable rules and regulations.

C. The EQB may require the installation and maintenance of additional, complete, and separate air pollution control equipment of a capacity equal to the capacity of the primary control equipment, when deemed appropriate to safeguard the health and welfare of human beings. Furthermore, the Board may require that such additional air pollution control equipment be operated continuously and together with the primary air pollution control equipment.

D. All air pollution control equipment shall be operated at all times when the source being controlled is in operation.

E. In case of a shutdown of air pollution control equipment for the necessary scheduled maintenance, the Board shall be informed of the intention to shut down such equipment, at least three days prior to the planned shutdown. Such prior notice shall include, but is not limited to:

(1) Identification of the specific source to be removed from service, including its location and permit number.

(2) The expected length of time that the air pollution control equipment will be out of service.

(3) The nature and quantity of the air pollutants that are likely to be emitted during the control equipment shutdown period.

(4) Special measures to be taken to minimize the duration of the control equipment shutdown period, such as the use of irregular personnel and additional equipment.

(5) The reasons why it will be impossible or impractical to shut down the operations of the facility during the repair period.

F. To the extent possible, maintain and operate any affected source and associated air pollution control equipment at all times, including startup, shutdown and malfunction periods, and shall do so in a manner that is consistent with the original manufacturer's design specifications, and in compliance with applicable rules and regulations and permit conditions.

7. **Certification of Compliance:** As specified under Rule 602 (c)(2)(ix)(C) of the RCAP, the permittee shall submit each year a compliance certification to both the Board and the EPA[1], no later than ninety (90) days after the date of anniversary of this permit. The certification shall include the information required under Rule 603 (c) of the RCAP.

8. **Location Approval:** Pursuant to Rule 201 of the RCAP, nothing in this permit shall be construed as authorizing the location or construction of a major stationary source, or the significant modification of a major stationary source, without first obtaining a location approval from the EQB, and without showing compliance with the National Ambient Air Quality Standards (NAAQS). This permit does not authorize the construction of a new minor source without first obtaining a construction permit as provided under Rule 203 of the RCAP.

9. **Open Burning:** Pursuant to Rule 402 of the RCAP, no permittee shall cause or permit the open burning of refuse in the premises except as provided in paragraph (E) of said rule which authorizes fire fighting training or investigation of fire fighting techniques. The permit holder shall:

a) Keep records of training or investigation-related fire fighting activities. These records shall be available upon request.

a) Submit to the Board, on an annual basis, a schedule of the training or investigation-related fire fighting activities and notify the Board seven days in advance of the date of each activity.

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[1] The certification to the EQB shall be mailed to: Manager, Air Quality Area, P.O. Box 11488, Santurce, PR, 00910. The certification to the EPA shall be mailed to: Chief, Permitting Section, Air Program Branch, EPA Region II, 290 Broadway, New York, NY, 10007.

10. **Fugitive Emissions of Particulate Matter:** Pursuant to Rule 404 of the RCAP, no permittee shall cause or permit:

    a) any materials to be handled, transported or stored in a building or its appurtenances, or a road to be used, constructed, altered, repaired or demolished without taking reasonable precautions to prevent particulate matter from becoming airborne.

    b) visible emissions of fugitive dust beyond the boundary line of the property on which the emissions originate.

11. **Objectionable odors:** Pursuant to Rule 420 of the RCAP, no permittee shall cause or permit the emission to the atmosphere of matter that produces *objectionable or disagreeable* odors that can be perceived in an area other than that designated for industrial purposes. The permittee shall show compliance with Rule 420 (A)(1) as follows:Iif objectionable odors are detected beyond the area designated for industrial purposes and complaints are received, the permittee shall investigate and take measures to minimize or eliminate the objectionable odors, as needed [State enforceable condition only.]

12. **Permit Renewal Applications:** Pursuant to Rule 602(a)(1)(iv) of the RCAP, the permittee shall submit a permit renewal application to the EQB at least 12 months prior to its expiration date. The responsible official shall certify each of the forms required pursuant to paragraph (c)(3) of Rule 602 of the RCAP.

13. **Permit Duration:** Pursuant to Rule 603 of the RCAP, the following terms shall govern for the duration of this permit:

    a) Expiration: This authorization shall have a fixed term of five (5) years. The expiration date will be automatically extended until the Board approves or denies a renewal application (Rule 605(c)(4)(ii) of the RCAP) but only in those cases where the permittee submits a complete renewal application at least twelve (12) months before the expiration date. (Rule 603 (a)(2), Rule 605 (c)(2) and Rule 605 (c)(4) of the RCAP)

    b) Permit Shield: As specified under Rule 605 I(4)(i) of the RCAP, the permit shield may be extended until the time it is renewed if a timely and complete renewal application is submitted.

    c) In the case that this permit is is subject to any challenge by third parties, the permit shall remain in effect until the time it is revoked by a court of law with jurisdiction in the matter.

14. **Recordkeeping Requirements:** Pursuant to Rule 603(a)(4)(ii) of the RCAP, the permittee must keep records of all required sampling data and support information

for 5 years from the date of the sampling, measurement, report or sampling application.

15. **Sampling Reporting Requirements:** Pursuant to Rule 603(a)(5)(i) of the RCAP, the permittee must submit reports of any required sampling every six months, or more frequently if required by the EQB or any other applicable requirement. All instances of deviations from permit requirements must be clearly identified in such reports. All required reports must be certified by a responsible official consistent with Rule 602(c)(3) of the RCAP.

16. **Reporting of Deviations Due to Emergency:** Pursuant to Rule 603(a)(5)(ii)(a) of the RCAP, any deviation attributable to upset conditions (such as sudden failure or rupture) or emergency as defined in Rule 603(e) of the RCAP must be reported within two working days. Said notification may be used as an affirmative defense should any action be brought against the permittee. If the permittee asserts the emergency defense in an action for compliance, the permittee shall have the burden of proof to show that the deviation was a result of an emergency and that the Board was adequately notified. If such deviation for emergency were to extend beyond 24 hours, the affected units may be operated until the end of the cycle or 48 hours, whichever comes first. The Board may only extend the operation of an existing source of emission beyond 48 hours if the source were to show, to the Board's Satisfaction, that the National Ambient Air Quality Standards (NAAQS) would not be exceeded and it would not constitute a risk to public health.

17. **Notification of Deviations (Hazardous Air Pollutants):** The source shall immediately cease to operate or act as stipulated in its Emergency Response Plan (established in Rule 107 I), when said plan has demonstrated that there is no significant impact in premises other than those designated for industrial use. (State enforceable condition only.) Pursuant to Rule 603 (a)(5)(ii)(b) of the RCAP, the Board shall be notified within 24 hours of any deviation that results in a release of emissions of hazardous air pollutants that continues for more than one hour in excess of the applicable limit. In case of a release of any regulated air pollutant that continues for more than 2 hours in excess of the applicable limit, the Board shall be notified within 24 hours of the deviation. The permittee shall, also, within 7 days of the deviation, submit to the EQB a written detailed report including the probable causes, time and duration of the deviation, remedial action taken, and steps that are being undertaken to prevent a reoccurrence.

18. **Deviations:** Pursuant to Rule 603(a)(5)(ii)(c) of the RCAP, all other deviations must be reported in the permittee's semiannual report unless the permit or applicable requirement requires more frequent reporting.

19. **Severability Clause:** Pursuant to Rule 603(a)(6) of the RCAP, the permit clauses are severable. In the event of a successful challenge to any part of the permit in an administrative or judicial forum, or should any of the clauses of the permit be

declared invalid, said determination shall not affect the remaining clauses contained herein, including those that deal with emission limits, terms and conditions, whether specific or general, and sampling requirements, and maintenance of records and reports.

20. **Noncompliance with the Permit:** Pursuant to Rule 603(a)(7)(i) of the RCAP, the permittee must comply with all the conditions of the permit. Any permit noncompliance constitutes a violation of the Regulations and shall be grounds for enforcement action, sanctions, revocation, termination, modification, reissuance of the permit, or for denial of a permit renewal application.

21. **Non-permissible Defense:** Pursuant to Rule 603(a)(7)(ii) of the RCAP, the permittee may not allege as defense in an enforcement action, that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of the permit.

22. **Modification and Revocation of the Permit:** Pursuant to Rule 603(a)(7)(iii) of the RCAP, the permit may be modified, revoked, reopened, reissued or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance or termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit conditions.

23. **Property Rights:** Pursuant to Rule 603(a)(7)(iv) of the RCAP, this permit does not create or convey any property rights of any sort, or any exclusive privilege.

24. **Obligation to Furnish Information:** Pursuant to Rule 603(a)(7)(v) of the RCAP, the permittee shall furnish the EQB, within a reasonable time, any information that the EQB may request to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit or to determine compliance with the permit. Upon request, the permittee shall also furnish to the EQB copies of records required to be kept by the permit.

25. **Change of Operating Scenario:** Pursuant to Rule 603(a)(10) of the RCAP, the permittee shall, contemporaneously with making a change from one operating scenario to another, record in a log the scenario under which it is operating. This record shall be kept in the facilities at all times.

26. **Final Action:** Pursuant to Rule 605(d) of the RCAP, no permit shall be deemed issued by default as a result of the EQB's failure to take final action on a permit application within 18 months. The EQB's failure to take final action on a permit application within 18 months should be treated as a final action solely for the purpose of obtaining judicial review in state court.

27. **Administrative Amendments and Permit Modifications:** Pursuant to Rule 606 of the RCAP, no amendments or changes may be made to the permit without first

complying with the administrative amendment and permit modification requirements established by the RCAP.

28. **Permit Reopening:** Pursuant to Rule 608(a)(1) of the RCAP, the permit may be reopened and reviewed for any of the following circumstances:

a. When additional requirements under any law or regulation become applicable to the permittee with a remaining permit term of three (3) or more years. Such a reopening shall be completed eighteen (18) months after promulgation of the applicable requirement. No such reopening is required if the effective date of the requirement is later than the date on which the permit is due to expire, unless the original permit or any of its terms and conditions has been extended pursuant to Rule 605I(4)(i) or 605I(4) (ii) of the RCAP.

b. When the EQB or the EPA determines that the permit contains a material mistake or that inaccurate statements were made in establishing the emission standards or other terms or conditions of the permit.

c. When the EQB or the EPA determines that the permit must be revised or revoked to assure compliance with the applicable requirements.

29. **Change of Name or Ownership:** This permit is issued to **Pfizer Pharmaceuticals LLC (Cruce Dávila).** Should the name of the company or facility change, or should it be transferred to a different owner, the new responsible official shall submit an administrative amendment that complies with the requirements of Rule 606 of the RCAP.

30. **Renovation / Demolition Activities:** The permittee must comply with the provisions under 40 CFR §61.145 and §61.150 and Rule 422 of the RCAP when carrying out any renovation or demolition in its facilities.

31. **Risk Management Plan:** If during the effective date of this permit, the permittee were subject to 40 CFR Part 68, said permittee must submit a Risk Management Plan in accordance with the schedule of compliance in 40 CFR Part 68.10. If during the effectiveness of this permit, the permittee were subject to 40 CFR Part 68, as part of the annual certification of compliance required under 40 CFR Part 70, said permittee must include a certification of compliance with the requirements of Part 68, including recordkeeping and Risk Management Plan. The permittee must comply with the general obligation requirements of section 112I(1) of the act as follows:

a) Identify the risks that may result in accidental leaks using appropriate risk evaluation techniques.

b) Design, maintain, and operate a safe facility.

c) Minimize the consequences of accidental leaks, should they occur.

32. Emergency Generators:

a) The operation of each generator identified as insignificant activity is limited to 500 hours per year.

b) The permittee shall keep a record of the hours of operation and fuel use of each generator. This record shall be available for inspection by Board and EPA personnel.

33. Fire pumps:

a) The operation of each fire pump is limited to 500 hours per year.

b) The permittee shall keep a record of the hours of operation and fuel use of each fire pump. This record shall be available for inspection by Board and EPA personnel.

34. Weatherproofing of Roof Surfaces: Pursuant to Rule 424 of the RCAP, the permittee shall not cause or permit hot tar or any other weatherproofing material containing organic compounds to be applied without the prior authorization of the Board. The use of used oils or hazardous wastes for weatherproofing is prohibited. State enforceable only.

35. Compliance Clause: Compliance with the permit shall in no way exempt the permittee from complying with all other state and federal laws, regulations, permits, administrative orders or applicable judicial decrees.

36. Calculation of Emissions: On April 1st of each year, the permittee shall send the estimate of real or permissible emissions for the previous calendar year. The estimate of emissions shall be provided in the forms prepared by the EQB for such purposes. The responsible official will certify that all the information submitted is correct, true and representative of the permitted activity. On June 30 of each year, or earlier, the permittee shall pay for the emissions of the previous calendar year.

37. Annual Fee: The permittee shall submit an annual payment based on real emissions of regulated pollutants at a rate of $37.00 per ton unless the Board determines a different fee based on the provisions of Rule 610(b)(2)(iv) of the RCAP. Payment shall be made on June 30 of each year or earlier.

38. Reservation of Rights or Reserved Rights: Except as expressly provided in this Title V permit:

a) Nothing herein shall bar the Board or the EPA from taking administrative or legal action to enforce the terms of the Title V permit, including, but not limited to, the right to request an injunction, impose statutory penalties and fines.

b) Nothing herein shall be construed as a limitation of the rights of the Board or the EPA to take any criminal action against the permit holder or any other person.

c) Nothing herein shall be construed as a limitation of the authority of the Board or the EPA to take any action in response to conditions that constitute a substantial and imminent danger to the health or well being of the public or the environment.

d) Nothing herein shall be construed as a limitation of the right of the permittee to an administrative hearing and judicial review of a termination/ revocation/ denial action pursuant to the Environmental Public Policy Act and Regulations.

39. **Amendments or New Regulations:** Should a new regulation be established or an existing regulation be amended (state or federal) and if it is determined that it applies to your facility, you must comply with the stipulations of said regulation or amendment once it becomes effective.

40. **General Obligation:** Under Section 112(r) of the US Clean Air Act, Pfizer Pharmaceuticals LLC (Cruce Dávila) has a general duty to identify hazards that may result in accidental releases of a controlled substance or any other extremely hazardous substance of a process by using generally accepted assessment techniques and designing, maintaining and operating a safe facility and minimizing the consequences of accidental releases, if they should occur, as required under 112(r)(1) of the US Clean Air act and Rule 107 (D) of the RCAP.

41. **Industrial, Commercial or Institutional Boilers and Process Heaters:** All existing sources having or operating industrial, commercial or institutional boilers and process heaters are subject to the National Emission Standards for Hazardous Air Pollutants for industrial, commercial or institutional boilers and process heaters in Subpart DDDDD of 40 CFR. The affected sources must comply with the emission limits of this subpart no later than 3 years after the date of publication of the final rule in the Federal Register, unless it is determined that said regulation is not applicable or Pfizer Pharmaceuticals LLC (Cruce Dávila) has an extension of compliance with the emission standards that is consistent with 40 CFR §63.6(i) in which case it must comply with said requirements by the date specified in the extension of compliance granted. Unless it is determined that said regulations are not applicable to it, Pfizer Pharmaceuticals LLC (Cruce Dávila) must comply with the notification provisions of 40 CFR §63.7545 according to the schedule in 40 CFR §63.7545 and 40 CFR part

63, Subpart A. According to §63.7495(d) of 40 CFR, some of the notifications must be submitted before Pfizer Pharmaceuticals LLC (Cruce Dávila) is required to comply with the emission limits and work practice standards of 40 CFR part 63 subpart DDDDD.

42. **Reports:** All reports required by the Board must be addressed to: Manager, Air Quality Area, Box 11488, Santurce, P.R. 00910.

43. **Off-Permit Changes:** Pursuant to Rule 607(b)(1), Pfizer Pharmaceuticals LLC (CRUCE DAVILA) can make changes without obtaining a permit review if such changes are not mentioned or prohibited under this permit, unless said changes constitute modifications under Title I of the US Clean Air Act.

i. Each such change shall meet all applicable requirements and shall not violate any existing permit term or condition.

ii. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must provide contemporaneous written notice to the Board and the EPA of each such change except for changes that qualify as insignificant under paragraph I(1) of Rule 602. Such written notice shall describe each such change, including the date, any change in emissions, pollutants emitted and any applicable requirement that would apply as a result of the change.

iii. The change shall not qualify for the shield under paragraph (d) of Rule 603.

iv. The permittee shall keep a record describing changes made at the source that could result in emissions of a regulated air pollutant subject to an applicable requirement, but not otherwise regulated under the permit, and the emissions resulting from those changes.

44. **Storage Tanks:** Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall keep records of the distilled fuel (diesel) storage tanks listed as insignificant activities showing the dimensions of the storage tanks and an analysis showing the capacity of the storage tanks pursuant to §60.116(b) of 40 CFR. Said documents shall be available for review by Board technical personnel and will be kept in the facility for the life of each tank.

SECTON IV - ALLOWABLE EMISSIONS

The emissions that are described in the following table represent the potential emissions of the facility at the time of the permit application and shall be used for fee payment purposes only. In agreement with the Resolution R-97-47-1, the emissions calculations will be based on the actual emissions of the Pfizer Pharmaceuticals LLC (Cruce Dávila), although calculations based on permissible emissions of the source will be accepted. If Pfizer Pharmaceuticals LLC (Cruce Dávila) wants to make the calculations being based on permissible emissions they will pay the same fee (charge) by tons that the sources that the

calculations make being based on actual emissions. In addition, when Pfizer Pharmaceuticals LLC (Cruce Dávila), applies for a modification, administrative amendments or minor permit modification to the Title V permit, will only have to pay the payment by ton based on the increase in emissions by caused ton, if some, by the change and not it totality of the positions in agreement with the Rule 610(a) of the RCAP.

Pollutants	Permissible Emissions (tons/year)
PM_{10}	5
VOC	551
HAP's	198.4

SECTION V - SUBMISSION OF REPORTS

Pursuant to Rule 112(B) of the RCAP, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must submit a certification of compliance for the previous calendar year before April 1 of each year, with all the requirements specified in this permit. Said certification must be signed by the responsible official who will certify its validity pursuant to Rule 602 (c)(3) of the RCAP.

SECTION VI - PERMIT CONDITIONS

A. Requirements for the Entire Facility

1. Tank ST-14 B [PFE-09-0801-1905-I-C]:

i. Authorized emissions represent the storage of 2,878,193 gallons per year of 70% isopropyl alcohol (IPA) in tank ST-14 B.

ii. Will keep a monthly record with the following information:

a. Monthly amount of stored solvent, in gallons.
b. The materials safety data sheet (MSDS)
c. Evidence of solvent purchase.

It shall be available at all times in the facility for review by Board technical personnel.

2. Gas scrubber [PFE-01-09-0898-0077-I-C]:

i. The facility must operate and maintain all air pollution control mechanisms, such as gas scrubbers in order to comply with regulations in effect and these shall be operated at all times when the source being controlled is in operation.

ii. The flow meter in the gas scrubber must be calibrated annually in compliance with condition 2(i) of this section. The calibration results and the methodology used shall be kept accessible at the plant for evaluation by our technical personnel, as they deem pertinent.

B. Requirements for Each Emission Unit

The table below summarizes the applicable requirements and the test methods for all emission units identified in Section II of this permit.

1. EU-Chemical Plant (EU-2)

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reporting Frequency
VOC emission limit	VOC	3 15	Pounds per hour Pounds per day	N/A	N/A	N/A	N/A
Process Source Limit	Particulate Mater (PM)	Value will be determined using the table in Rule 407 (a)	output lbs/ input lbs-hr	Records	Daily	Record Book	Biannually

A. VOC EMISSION LIMIT:

(i) Pursuant to Rule 419 of the RCAP, the permittee shall not permit the emission of 3 lbs/hr or 15 lbs/day of VOC from any item, machine, equipment or any other device unless it is provided with a control system, pollution prevention and reduction mechanism or programs or both, as approved or required by the Board. [State enforceable condition only.]

(ii) The permittee shall comply with the above condition using the gas scrubber and the condensers in the emission units described as EU-Chemical Plant (EU-2).

(iii) The permittee shall operate all air pollution control equipment at all times when emissions in excess of the limits established in Rule 419 of the RCAP are or may be generated during the manufacturing process.

B. PROCESS SOURCE LIMITS:

(i) The permittee shall determine the maximum amount of particulate matter emissions from a process source using the Table in Rule 407 (A). Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall not cause or permit the emission of particulate matter in excess of that amount from uncontrolled emissions of a process source for any one-hour period. [Rule 407 of the RCAP].

(ii) The permittee shall read and record the water flow in the gas scrubber as specified in the Pharmaceutical Industry MACT. Pfizer (CRUCE DAVILA) shall calibrate annually the water flow meter and shall keep the record with the data and calibration methodology and made accessible to Environmental Quality Board personnel. The records shall be kept at the facility for five (5) years. [Rule 603 (A)(4)(ii) of the RCAP]

(iii) The permittee shall demonstrate compliance with the above requirements by maintaining the water flow for the gas scrubber.

2. General Conditions for EU-Chemical Plant (EU-2)

(i) Heat exchangers using *THERMINOL* (E-82-01, E-82-02, E-84-01 y E-84-02) may be used instead of gas scrubbers (S-303). The permittee must show by means of good engineering practices that the heat exchangers have a removal efficiency of 93%. The Board reserves the right to request an efficiency test, at its discretion. [Condition 6 of PFE-09-1100-2112-II-C]

(ii) The water flow meter in the gas scrubber shall be calibrated annually. The calibration results and methodology must be kept accessible at the plant for evaluation by our technical personnel, as required. [Condition 4 of PFE-01-09-0898-0077-I-C]

(iii) The dust collector designed to control particulate matter emissions must be provided with a pressure drop gauge to determine the operational efficiency of the control unit, which must be calibrated at least twice a year. The calibration results shall be kept in an accessible location in the facility for evaluation by our technical personnel, as required. A daily record of the readings of this gauge

shall be kept. The pressure load must comply with the limits stipulated by the manufacturer. [PFE-09-0899-1287-I-C]

3. EU-TANK FARM (EU-7)

A. VOC EMISSION LIMITS FOR TANKS THAT ARE NOT COVERED UNDER RULE 417 OF THE RCAP:

(i) Pursuant to Rule 419 of the RCAP, the permittee shall permit the emission of 3 lbs/hr or 15 lbs/day of VOC from any item, machine, device or any other equipment unless it is provided with a control system, pollution prevention and reduction mechanism or programs or both, as approved or required by the Board. [State enforceable only]

(ii) Pursuant to Rule 419(F)(6), tanks used to store VOC with a capacity of less than 40,000 gallons, provided such storage tanks are equipped with a conservation vent, a flame arrestor, or any other equipment whose emissions control effect is equivalent to these, shall be exempt from this Rule.

SECTION VII ALTERNATIVE OPERATING SCENARIOS

A. Scenario 1: Operation and Maintenance Requirements (40 CFR subpart A, §63.6)-EU-2 and EU-7

Should Pfizer Pharmaceuticals LLC (CRUCE DAVILA) experience malfunctions in control equipment during product manufacturing, especially during startup and shutdown, this scenario would allow it to continue operating during said malfunctions.

1. At all times, including periods of startup, shutdown and malfunction,[2] Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must operate and maintain any affected source, including associated air pollution control equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. During a period of malfunction, startup, or shutdown, this general duty to minimize emissions requires that Pfizer Pharmaceuticals LLC (CRUCE DAVILA) reduce emissions from the affected source to the greatest extent which is consistent with safety and good air pollution control practices. The general duty to minimize emissions during a period of malfunction, startup, or shutdown does not require

[2] According §63.2 of 40 CFR, a malfuction means any sudden, infrequent, and not reasonably preventable failure of air pollution control and monitoring equipment, process equipment, or a process to operate in a normal or usual manner which causes, or has the potential to cause, the emission limitations in an applicable standard to be exceeded. Failures that are caused in part by poor maintenance or careless operation are not malfunctions.