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# Pfizer Global Manufacturing

***José F. Martínez- Toledo, Manager***
*Environmental, Health & Safety – PGM Arecibo*

July 15, 2005

Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
EPA Headquarters
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20004



**Subject:** **Petition to the U.S. Environmental Protection Agency Administrator to Object to the Pfizer Pharmaceuticals, LLC – Arecibo, PR Facility Title V Operating Permit (PFE-TV-2834-09-0297-0004)**

Dear Mr. Johnson:

Pfizer Pharmaceuticals, LLC (hereinafter Pfizer) is hereby filing this Petition with the U.S. Environmental Protection Agency (hereinafter EPA) Administrator to object to the Proposed Title V Operating Permit (hereinafter the Proposed Permit) issued by the Puerto Rico Environmental Quality Board (hereinafter the EQB) to the Pfizer-Arecibo facility (hereinafter the Petition). The Proposed Permit was issued as part of EQB's Interlocutory Resolution R-05-08-10 of March 21, 2005 (hereinafter the Interlocutory Resolution). **Exhibit 1**. The Petition is filed pursuant to Part 70.8(d) of Volume 40 of the Code of Federal Regulations (hereinafter 40 CFR) and Rule 609 of the Regulation for the Control of Atmospheric Pollution (hereinafter the Air Regulation).[1]

Pfizer respectfully requests the EPA Administrator to receive and evaluate the Petition, and to object to the Proposed Permit issued to the Pfizer-Arecibo facility, because EQB did not

[1] Puerto Rico Department of State Regulation No. 5300 of August 28, 1995, as subsequently amended

address the comments Pfizer filed regarding several **applicable requirements,**[2] conditions and limitations of the Draft Title V Operating Permit (hereinafter the Draft Permit) during the public comment period of 40 CFR Part 70.7(h) and Rule 609(a) of the Air Regulation.

## I. INTRODUCTION

### A. Permit Chronology

1. The Pfizer-Arecibo facility presently consists of the following emission units EU-1: Boiler; EU-2: Thermal Oxidizer as a Combustion Unit; EU-3: [Reserved]; EU-4: Chemical Manufacturing Operations; EU-5: Tank Farm; EU-6: Refrigeration and Air Conditioning Equipment; EU-7: Plantwide Applicable Requirements (e.g., Risk Management Program); Insignificant Activities (e.g., emergency power generators, steam stripper, emergency fire extinguishing pumps).

2. On February 5, 1997, Pharmacia & Upjohn Caribe Inc. (at the time the owner of the Pfizer-Arecibo facility) filed a timely and complete Title V Operating Permit Application. On February 11, 1997, EQB issued the "Permit Application Shield", pursuant to Rules 602(a)(2)(v) and 605(b) of the Air Regulation. **Exhibit 2**. On November 7, 2003, EQB issued the Draft Permit and held public hearing on December 8, 2003. Pfizer attended the public hearing and filed comments to the Draft Permit. **Exhibit** 3.

3. On March 11, 2005, Pfizer met with the EQB Air Quality Area and the Director of the Legal Division to inform the EQB of the Company's decision to become a minor source of criteria pollutants. To achieve the minor source category, Pfizer filed a revision to air construction permit PFE-07-0802-1278-I-II-C, and requested the imposition of "**federal**

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2 The term **applicable requirement is** defined in 40 CFR Part 70.2 and Rule 102 of the Air Regulation.

**enforceable**" permit conditions to limit the source's "**potential to emit**"[3] for the nitrogen oxides and sulfur oxides pollutants.[4]

4. On March 16, 2005, Pfizer filed a communication addressed to the President of EQB informing him about the filing of the revision to the construction permit to become a minor source subject to the operation permit requirements of Rule 204 of the Air Regulation instead of the Title V Operating Permit requirements of Part VI of the Air Regulation. **Exhibit 4**.

5. Nonetheless, on March 29, 2005, EQB issued the Interlocutory Resolution and the Proposed Permit.[5]

6. On April 19, 2005, Pfizer timely filed a Motion to Reconsider with the EQB and requested the EQB to suspend the effect of the Proposed Permit and further procedures because, among other reasons, the agency's actions violate due process of law (i) by refusing to act on Pfizer's revision to the air construction permit to become a minor source of criteria pollutants, (ii) by issuing a Proposed Permit with conditions and limitations that adversely affects the Pfizer-Arecibo facility, and (iii) by imposing **applicable requirements** that will affect the source's status of compliance with federal and local rules and regulations. **Exhibit 5**. The Motion to Reconsider is still pending resolution from EQB's Governing Board.

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[3] The terms "**federal enforceable**" and "**potential to emit**" are defined in Rule 102 of the Air Regulation.

[4] On October 2002, the Pfizer-Arecibo facility became a minor source of hazardous air pollutants through the imposition of **federally enforceable** permit conditions to limit the **potential to emit** in air construction permit PFE-07-0802-1278-I-II-C.

[5] A "proposed permit" is the version of the permit that EQB proposes to issue and forwards to the EPA Administrator for review to comply with Rule 609. Rule 102 of the Air Regulation. See, also, Rule 609 of the Air Regulation.

**B. The Interlocutory Resolution**

1. The Interlocutory Resolution approved and incorporated the Examining Panel Report which contains the recommendations of the Examining Officials who presided at the hearing held during the Draft Permit public comment period. **Exhibit 6**.

2. The Interlocutory Resolution included the Proposed Permit, ordered the EQB Air Quality Area to incorporate in the Proposed Permit the recommendations of the Examining Panel Report, forwarded the Proposed Permit to EPA, commenced the EPA 45-day review period, established the 60-day public objection period after EPA's 45-day review period, and indicated that the Proposed Permit could be issued as the Final Title V Operating Permit. The Proposed Permit also established other procedures to be followed by EPA in the event the agency objects to the Proposed Permit or any of its conditions or limitations.

**C. The Proposed Permit**

1. The Proposed Permit includes **applicable requirements**, conditions and limitations that do not correspond to the current operations of the Pfizer-Arecibo facility. These operational conditions are known by EQB and are the basis for Pfizer's revision to the air construction permit. The Proposed Permit included **applicable requirements**, conditions and limitations for which Pfizer filed comments and objections during the Draft Permit public comment period. The issuance of the Proposed Permit in its current form as the final Title V Operating Permit will adversely affect the operations of the Pfizer-Arecibo facility and will result in the facility being in immediate non-compliance with the permit's conditions.

## II. LEGAL BASIS FOR THE PETITION

### A. The Public Petitions to the EPA Administrator Pursuant to 40 CFR Part 70.8

1. Pursuant to 40 CFR Part 70.8(d), if the EPA Administrator does not object in writing to the Proposed Title V Operating Permit within the 45-day review period, any person may petition the Administrator to make such objection. Such petition shall be made within 60 days after the expiration of the Administrator's 45-day review period. Any such petition shall be based on objections to the permit that were raised with reasonable specificity during the public comment period (unless it was impracticable to raise such objections within that period) or unless the grounds for such objections arose after such period.[6]

2. EQB issued the Proposed Title V Operating Permit for the Pfizer-Arecibo facility on March 29, 2005. EPA did not object in writing to the Pfizer-Arecibo facility Proposed Permit within its 45-day review period, which period expired on May 16, 2005. Pfizer is a **person** according to Rule 102 of the Air Regulation.[7] The Pfizer-Arecibo facility attended the hearing held by EQB during the Draft Permit public comment period. Pfizer raised comments and objections to several conditions and limitations included in the Draft Permit. Pfizer is a person who can petition the EPA Administrator to object to the Proposed Permit.

## III. APPLICABLE REQUIREMENTS, CONDITIONS AND LIMITATIONS OF THE PROPOSED PERMIT FOR WHICH THE PETITION IS FILED

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[6] Rule 609(e)(1) of the RCAP states: *"If the Administrator does not object in writing under section (d) of Rule 609, any person may petition the Administrator within sixty (60) days after the expiration of the Administrator's 45-day review period to make such objection. Any such petition shall be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided for in section (a) of Rule 609, unless the petitioner demonstrates that it was impracticable to raise such objections within such period, or unless the grounds for such objection arose after such period. "*

[7] The term **"person"** is defined as *"any person natural or juridical, or group of persons, private or public including agencies, government bodies, municipalities and public quasi-public corporations."*

The conditions and limitations of the Draft Permit that Pfizer respectfully requests the EPA Administrator to object to are included in **Exhibit 7. Exhibit 7** is incorporated and made part of this Petition. The comments and objections to such conditions and limitations were raised by Pfizer at the public hearing on the Draft Permit with reasonable specificity. EQB's decision not to consider any of Pfizer's comments and to issue the Proposed Permit will adversely affect the Pfizer-Arecibo facility's operations and compliance status.

**WHEREFORE,** Pfizer respectfully requests the EPA Administrator to receive and evaluate this Petition, and pursuant to 40 CFR Part 70.8(d) and Rule 609(e) of the Air Regulation, object to the Proposed Permit's **applicable requirements**, conditions, and limitations as outlined in **Exhibit 7** of this Petition.

**RESPECTFULLY SUBMITTED.**

PFIZER PHARMACEUTICALS, LLC.

Enclosures

c. Ms. Kathleen Callahan
Regional Administrator
Region II

Carlos López Freytes, Esq.
President
Environmental Quality Board

**Pfizer Pharmaceuticals LLC**
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# Pfizer Global Manufacturing

COPY FOR YOUR INFORMATION

**Rafael Castro, *Director***
*Environmental, Health and Safety - PGM Arecibo*

January 18, 2007

**CERTIFIED MAIL: 7005 0390 0002 4840 4008**

Alan J. Steinberg, Regional Administrator
United States Environmental Protection Agency
Region 2
290 Broadway
New York, NY 10007-1866

**Re: Petition to the U.S. Environmental Protection Agency Administrator to Object to the Pfizer Pharmaceuticals, LLC – Arecibo, PR Facility Title V Operating Permit (PFE-TV-2834-09-0297-0004)**

Dear Mr. Steinberg:

On July 2005, Pfizer Pharmaceuticals LLC Arecibo (PPLLCA) filed a Petition with the U.S. Environmental Protection Agency (hereinafter EPA) to object to the Proposed Title V Operating Permit (hereinafter the Proposed Permit) issued by the Puerto Rico Environmental Quality Board PREQB). The purpose of this letter is to withdraw the petition since the PREQB issued a final Title V Operating Permit to PPLLCA in August 2005 which was subsequently replaced with a Minor Source Operating permit in February 2006."

If you have any questions regarding this matter, please call me at 787-650-0478.

Cordially,

Rafael Castro, Director
Environmental Health & Safety

RC

cc: Steven Riva, EPA Region 2 Air Permitting Branch
Matthew D. Garamone, Pfizer Inc.