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

September 5, 2007

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

Dear mrs Torres:

Re: ADMINISTRATIVE AMENDMENT
PFIZER PHARMACEUTICALS LLC – 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 with the purpose to add, eliminate and correct typographic errors in some conditions of the referenced permit.

1. The third sentence of the third paragraph in the Section I of the permit, Process Description, is substituted only in the English version. It shall read as follows:

   "The gas scrubber is used for compliance with the Pharmaceutical Industry MACT and the condensers or **gas scrubber** for compliance with the Rule 419 of RCAP."

2. Section V of the permit is eliminated.

3. Condition (A)(1) of Section VIII is substituted in the English version only and it shall read as follows:

"Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must comply with the provisions of 40 CFR (Code of Federal Regulations) part 63 subpart A contained in Table 1 of subpart GGG. [§63.1250**(c)**]"

4. Condition (B)(1) of Section VIII of the permit is substituted. The condition shall read as follows:

"For sources subjected to 40 CFR, Part 63, Subpart GGG, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall control Hazardous Air Pollutants (HAP) emissions to the level specified in §63.1252 on and after the compliance dates specified in §63.1250(f). Continuous compliance shall be demonstrated in accordance with the provisions of §63.1258. [40 CFR §63.1252- *Standards: General*]"

6. Condition (D)(1) of the Section VIII is substituted only in the English version. The condition shall read as follows:

"Existing Sources – For each process, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must comply with the requirements in paragraphs (a)(1) and (a) (3) **or paragraphs (a)(2) and (a)(3) of §63.1254**. [40 CFR §63.1254]"

7. Condition (E)(3)(k) of the Section VIII is substituted only in the English version, and it shall read as follows:

"**If** more than 90 percent of the pumps in a group of processes meet the criteria in either paragraph (c)(5) or (6) of §63.1255, the group of processes is exempt from the requirements of paragraph (c)(4) of §63.1255. [40 CFR §63.1255 (c)(9)]"

8. Condition (I)(6)(g) of the Section VIII is added, and shall read as follows:

g. "Anticipated periods of planned routine maintenance of a CCCD subject to §63.1252(h) during the period between the compliance date and the end of the period covered by the first periodic report, and if applicable, the rationale for why the planned routine maintenance must be

performed while a process with a vent subject to §63.1254(a)(3) will be operating [40 CRF §63.1260(f)(7)]."

10. Letter c is changed to letter h to maintain the sequence of the permit in condition VIII(E)(7) only in the English version. It shall read as follows:

"**h**. Periodic reports. According to 40 CFR §63.1255(h)(3), the owner or operator of a source subject to §63.1255 shall submit Periodic Reports."

11. Letter d is changed to letter i to maintain the sequence of the permit in condition VIII(E)(7) only in the English version. It shall read as follows:

"**i**. Monitoring Requirements."

12. Letter e is changed to letter j to maintain the sequence of the permit in condition VIII(E)(7) only in the English version. It shall read as follows:

"**j**. Reporting Requirements."

13. The following conditions are amended to reflect the correct cites only in the English version:

Condition III.17., page 9: The source shall immediately cease to operate or act as stipulated in its Emergency Response Plan (established in Rule 107 ~~I~~ **(C)**), when said plan ....

Condition III.28.a., page 11: ...or any of its terms and conditions has been extended pursuant to Rule 605~~I~~**(c)**(4)(i) or 605~~I~~**(c)**(4)(ii) of the RCAP.

Condition III.31, page 11: .... The permitee must comply with the general obligation requirements of section 112~~I~~**(r)**(1) of the act as follows:....

Condition VII.A.2.vi., final sentence of the condition in the page 21: If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) claims that any portion of such a malfunction, startup, and shutdown plan is confidential business information entitled to protection from disclosure under section 114~~I~~**(c)** of the Act or 40 CFR 2.301, the material....

Condition VIII.A.1., reference of the condition in the page 23: [§63.1250~~I~~**(c)**]

Condition VIII.B.1.c., page 26: Except as provided in paragraph **Ł(c)**(2) of §63.1252, owners and operators of affected sources shall comply with the requirements in paragraph **Ł(c)**(1) of this section for heat exchange systems that cool process equipment or materials used in pharmaceutical manufacturing operations. [40 CFR §63.1252**Ł(c)**]

Condition VIII.B.1.c.i., reference of the condition in the page 26: [40 CFR §63.1252**Ł(c)**(1)]

Condition VIII.B.1.c.ii., reference of the condition in the page 26: [40 CFR §63.1252**Ł(c)**(2)]

Condition VIII.C.3., page 28: ...must comply with the requirements of §63.1253**Ł(c)**.

Condition VIII.E.2.b.iii, page 33: ... shall comply with paragraph **Ł (c)** of §63.1255;

Condition VIII.E.3.a., reference of the condition in the page 36: [40 CFR §63.1255**Ł(c)**(1)]

Condition VIII.E.3.c., page 37: According to 40 CFR §63.1255**Ł(c)**(2)(ii), the instrument reading, ...

Condition VIII.E.3.c.i., reference of the condition in the page 37: [40 CFR §63.1255**Ł(c)**(2)(ii)(A)]

Condition VIII.E.3.c.ii., reference of the condition in the page 37: [40 CFR §63.1255**Ł(c)**(2)(ii)(B)]

Condition VIII.E.3.d., page 37: According to 40 CFR §63.1255**Ł(c)**(2)(iii), each pump and agitator ... the procedure specified in either paragraph **Ł(c)**(2)(iii)(A) or (B) of §63.1255 prior to the next weekly inspection.

Condition VIII.E.3.e.i., page 37: When a leak is detected pursuant to paragraph **Ł(c)**(2)(i), **Ł(c)**(2)(iii)(A), ...

Condition VIII.E.3.e.ii., page 37: According to 40 CFR §63.1255**Ł(c)**(3)(ii), the first attempt...

Condition VIII.E.3.f.i., reference of the condition in the page 38: [40 CFR §63.1255**I(c)**(4)(i)]

Condition VIII.E.3.f.ii., reference of the condition in the page 38: [40 CFR §63.1255**I(c)**(4)(ii)]

Condition VIII.E.3.f.iii., reference of the condition in the page 38: [40 CFR §63.1255**I(c)**(4)(iii)]

Condition VIII.E.3.f.iv., page 38: According to 40 CFR §63.1255**I(c)**(a)(iv) ... as required in paragraphs **I(c)**(2)(i) and (ii) ... meeting the criteria in paragraphs **I(c)**(5) and (6) of §63.1255.

Condition VIII.E.3.g., page 38: According to 40 CFR §63.1255**I(c)**(5), each pump or agitator ... of paragraphs **I(c)**(1) through **I(c)**(4)(iii) of §63.1255, ...

Condition VIII.E.3.g.iv., page 39: ... specified in either paragraph **I(c)**(5)(iv)(A) or (B) of ...

Condition VIII.E.3.g.iv.b, reference of the condition in the page 39: [40 CFR §63.1255**I(c)**(5)(iv)(B)]

Condition VIII.E.3.g.v., page 39: Each sensor as described in paragraph **I(c)**(5)(iii) of §63.1255 ... [40 CFR §63.1255**I(c)**(5)(v)]

Condition VIII.E.3.g.vi., reference of the condition in the page 39: [40 CFR §63.1255**I(c)**(5)(vi)(A)]

Condition VIII.E.3.g.vii., page 40: If indications of liquids dripping from the pump/agitator seal exceed the criterium established in paragraph **I(c)**(5)(vi)(A) of ...

Condition VIII.E.3.g.viii., page 40: When a leak is detected pursuant to paragraph **I(c)**(5)(iv)(A) or (B) of ...

Condition VIII.E.3.h., page 40: ...is exempt from the requirements of paragraphs **I(c)**(1) through (3) of §63.1255. [40 CFR §63.1255**I(c)**(6)]

Condition VIII.E.3.j., page 40: ... requirement of paragraphs **Ł(c)**(2)(iii) and **Ł(c)**(5)(iv) of §63.1255 and the daily requirements of paragrap **Ł(c)**(5)(v) of §63 1255, ... [40 CFR §63.1255**Ł(c)**(8)]

Condition VIII.E.3.k., page 40: ... in either paragraph **Ł(c)**(5) or (6) of §63.1255, ... the requirements of paragraph **Ł(c)**(4) of §63.1255. [40 CFR §63.1255**Ł(c)**(9)]

Condition VIII.E.7.b.iv., page 51: ... under the provisions of paragraph **Ł(c)**(7) of §63.1255, ...

Condition VIII.E.7.b.viii.(a), page 51: Design criteria required by paragraph **Ł(c)**(5)(vi)(A) of section ...

Condition VIII.E.7.b.xi., page 51-52: ... elects to monitor as provided under §63.178**Ł(c)**, a list ... period required in §63.178**Ł(c)**(3)(ii) and (iii) ... as provided in §63.178**Ł(c)**(3)(iii), ...

Condition VIII.E.7.c., page 52: For visual inspections of equipment subject to the provisions of paragraphs **Ł(c)**(2)(iii) and **Ł(c)**(5)(iv) of §63.1255, ...

Condition VIII.E.7.d., page 52: ...when each leak is detected as specified in paragraph **Ł(c)** of §63.1255, and ...

Condition VIII.E.7.d.vii., page 53: If the alternative in §63.174**Ł(c)**(1)(ii) is not in use...

Condition VIII.E.7.d.viii., page 53: ... as required in §63.174**Ł(c)**(1)(i) and **Ł(c)**(2)(ii).

Condition VIII.E.7.d.ix., page 53: ... monitoring required in §63.178**Ł(c)**(3)(i) for equipment ... period required in §63.178**Ł(c)**(3)(ii) and (iii).

Condition VIII.E.7.c in page 57 (See point 10 above the letter.) If applicable, the initiation of a monthly monitoring program under either paragraph **Ł(c)**(4)(ii), or paragraph (e)(4)(i) of §63.1255.

Condition VIII.E.7.c.iii, page 57-...monitoring alternatives as described in §63.174**Ł(c)**(1). (See point 10 above the letter.)

Condition VIII.G.5.a., page 61: For control equipment that is used to comply with the provisions of §63.1253(d) or §63.1254**Ł(c)**, Pfizer Pharmaceuticals ...

Condition VIII.H.3., reference of the condition in the page 62: [40 CFR §63.1259**I(c)**]

Condition VIII.I.7.b.ii.4., page 66: When a continuous sampling system is used, the information required in §63.10**I(c)**(5) through (13).

Other terms and conditions not mentioned in this amendment remain effective.

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

Cordially,

Environmental Quality Board

Eugene Scott Amy, Esq.
Vice President

Eng. Angel O. Berríos Silvestre
Associate Member

Carlos W. López Freytes, Esq.
President