

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region 2

In the matter of:

TAPI Puerto Rico, Inc.
Highway 3, Km, 76.3
C Street, Humacao Industrial Park
Humacao, PR 00791.

Respondent

Proceeding under Section 113 of the
Clean Air Act, 42 U.S.C. § 7413

Docket No.CAA-02-2011-1204

Administrative Complaint under Section 113
of the Clean Air Act, 42 U.S.C. § 7413

U.S. ENVIRONMENTAL
PROTECTION AGENCY-REG. II
2011 OCT 21 A 10:15
REGIONAL HEARING
CLERK

ANSWER TO ADMINISTRATIVE COMPLAINT

TO THE HONORABLE PRESIDING OFFICER:

TAPI Puerto Rico, Inc. ("TAPI") respectfully answers the Complaint:

STATUTORY AUTHORITY

1. The allegations of paragraph one (1) and two (2) on the "Jurisdiction" section of the Administrative Complaint ("Complaint") (Section I) is the United States Environmental Protection Agency's ("EPA") interpretation on the nature of the action, and as such, do not require a responsive pleading. Nevertheless, they are denied insofar as a responsive pleading may be warranted insofar as the allegation is used as a basis to state the claims of violations alleged in the Complaint in reference to the bulk pharmaceutical manufacturing facility located at Highway 3, Km. 76.3, C Street, Humacao Industrial Park, Humacao, Puerto Rico ("the Facility").

2. The allegations of paragraphs three (3) through nine (9) on the "Applicable Statutes and Regulations" section of the Complaint (Section II) and paragraphs ten (10) through sixteen (16) of the "Definitions" Section (Section III) include statements of law upon which

EPA has elected to set forth its jurisdictional claims and as such do not require a responsive pleading from the TAPI. Nevertheless, they are denied insofar as a responsive pleading may be warranted insofar as the allegation is used as a basis to state the claims of violations alleged in the Complaint.

FINDINGS OF VIOLATIONS

3. The allegation included in paragraph number seventeen (17) of the Complaint includes statements of law upon which EPA has elected to set forth its jurisdictional claims and as such do not require a responsive pleading from the TAPI. Nevertheless, they are denied insofar as a responsive pleading may be warranted insofar as the allegation is used as a basis to state the claims of violations alleged in the Complaint.

4. The allegations included in paragraph number eighteen (18) of the Complaint are admitted. It is affirmatively alleged that TAPI continues to own and operate the Facility.

5. The allegation included in paragraph number nineteen (19) of the Complaint is admitted.

7. The allegation included in paragraph number twenty (20) of the Complaint is admitted.

6. The allegations included in paragraph number twenty one (21) of the Complaint are statements and/or issues of law and as such do not require a responsive pleading from the TAPI. Nevertheless, they are denied insofar as the allegation is used as a basis to state the claims of violations alleged in the Complaint.

8. The allegations included in paragraph number twenty two (22) of the Complaint are admitted.

9. The allegations included in paragraph number twenty three (23) of the Complaint are hereby denied, as drafted.

10. The allegations included in paragraph number twenty four (24) of the Complaint are hereby denied, as drafted.

11. The allegations included in paragraph number twenty five (25) of the Complaint are hereby denied, as drafted.

12. The allegations included in paragraph number twenty six (26) of the Complaint are hereby denied, for lack of information or knowledge with respect to the veracity and/or mendacity of such allegations.

13. The allegation included in paragraph number twenty seven (27) of the Complaint is admitted.

14. The allegation included in paragraph number twenty eight (28) of the Complaint is admitted.

15. The allegations included in paragraph number twenty nine (29) of the Complaint are denied, as drafted.

16. The allegations included in paragraph number thirty (30) of the Complaint are admitted.

17. The allegations included in paragraph number thirty one (31) of the Complaint are admitted.

18. The allegations included in paragraph number thirty two (32) of the Complaint it is admitted insofar as to that the EPA issued Administrative Compliance Order. The rest of the allegations of paragraph are denied, as drafted.

19. The allegations included in paragraph number thirty three (33) of the Complaint are admitted.

20. The allegations included in paragraph number thirty four (34) of the Complaint are admitted insofar as TAPI was in compliance with Part 68 at the time of the second inspection. The rest of the allegations in this paragraph are denied, as drafted.

COUNT 1

21. The allegations included in paragraph number thirty five (35) of the Complaint are denied.

22. The allegations included in paragraph number thirty six (36) of the Complaint are denied.

23. The allegations included in paragraph number thirty seven (37) of the Complaint are denied.

24. The allegations included in paragraph number thirty eight (38) of the Complaint are admitted.

25. The allegations included in paragraph number thirty nine (39) of the Complaint are admitted.

26. The allegations included in paragraph number forty (40) of the Complaint are denied.

27. The allegations included in paragraph number forty one (41) of the Complaint are denied.

28. The allegations included in paragraph number forty two (42) of the Complaint are admitted insofar as to EPA's review of the Change of Control Procedure. The rest of the allegations are denied, as drafted.

29. The allegation included in paragraph number forty three (43) of the Complaint is admitted.

30. The allegation included in paragraph number forty four (44) of the Complaint is admitted.

31. The allegation included in paragraph number forty five (45) of the Complaint is admitted.

32. The allegations included in paragraph number forty six (46) of the Complaint are denied, as drafted.

33. The allegations included in paragraph number forty seven (47) of the Complaint are denied, as drafted.

NOTICE OF PROPOSED ORDER ASSESSING A CIVIL PENALTY

34. The first, second, third, fifth and sixth paragraphs of Section V of the Complaint includes statements and conclusions of law upon which EPA has elected to set forth its claims and as such do not require a responsive pleading from the TAPI. Nevertheless, they are denied insofar as a responsive pleading may be warranted. The fourth paragraph and proposed penalties for the allegations in the Complaint are hereby expressly denied.

PROCEDURES GOVERNING THIS ADMINISTRATIVE LITIGATION

35. The allegations included in Section VI of the Complaint are statements and/or issues of law and as such do not require a responsive pleading from TAPI. Nevertheless, they are denied insofar as a responsive pleading may be warranted.

INFORMAL SETTLEMENT CONFERENCE

36. The allegations included in Section VII of the Complaint are statements and/or issues of law and as such do not require a responsive pleading from TAPI. Nevertheless, they are denied insofar as a responsive pleading may be warranted.

**RESOLUTION OF THIS PROCEEDING WITHOUT HEARING OR
CONFERENCE**

37. The allegations included in Section VIII of the Complaint are statements and/or issues of law and as such do not require a responsive pleading from TAPI. Nevertheless, they are denied insofar as a responsive pleading may be warranted.

38. Unless otherwise specified, any and all allegations not expressly admitted in connection to the Complaint should be deemed denied for all practical and legal matters.

AFFIRMATIVE DEFENSES

1. TAPI realleges all of its responsive pleadings, as included in this document, and incorporates the same to this section of affirmative defenses.

2. The Complaint was not served to a officer, partner a managing or general agent or other personal authorized by Federal or Commonwealth law to receive service of process for TAPI in violation of Section 22.5(b)(1)(ii)(A) of Title 40 of the Code of Federal Regulations (C.F.R.) relative to the Consolidated Rules of Practice Governing Administrative Procedures of Civil Penalties and the Revocation/Termination of Permits.

3. The Complaint was not served together with a copy of the Consolidated Rules of Practice Governing Administrative Procedures of Civil Penalties and the Revocation/Termination of Permits in violation of Section 22.5(b)(1)(i) of 40 C.F.R.

4. The Complaint fails to state facts and a claim upon which relief may be granted as claimed by EPA therein and against TAPI.

5. Penalties alleged in the Complaint are improper and/or unwarranted.

6. EPA is not entitled to the penalties requested in the Complaint and/or to any other type of penalties.

7. TAPI respectfully reserves the right to amend the Answer to the Complaint and to include one or more affirmative defenses, after conducting proper discovery procedures which shall include written interrogatories, request for production and inspection of documents and the taking of several depositions.

8. TAPI expressly reserves the right to raise additional defenses and/or to amend those already raised upon completion of the discovery proceedings in the instant case.

WHEREFORE, the TAPI respectfully requests this Honorable Presiding Officer, to take notice of the aforementioned, deny and dismiss the Complaint in all its parts given the insufficiency of service of process required by Section 22.5(b)(1)(ii)(A) of the Consolidated Rules of Practice Governing Administrative Procedures of Civil Penalties and the Revocation/Termination of Permits. In the alternative, TAPI hereby respectfully requests a hearing.

RESPECTFULLY SUBMITTED.

I HEREBY CERTIFY: That on this same date, a true and exact copy of the foregoing document was sent, through regular mail, to; Carolina Jordán-García, Office of Regional Counsel, U.S. Environmental Protection Agency, Region 2, 1492 Ponce de León Ave., Centro Europa Building, Suite 417, Santurce, Puerto Rico 00907-4127.

In San Juan, Puerto Rico, this 20th day of October, 2011.

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