

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2**

In the Matter of

Pfizer Pharmaceuticals, LLC,

Barceloneta, Puerto Rico,

Respondent.

Docket No. CAA-02-2016-1206

CONSENT AGREEMENT AND
FINAL ORDER

PRELIMINARY STATEMENT

1. This Consent Agreement and Final Order (“CAFO”) is issued pursuant to Section 113(d) of the Clean Air Act (“CAA”), 42 U.S.C. § 7413(d). The Complainant in this action is the Director of the Caribbean Environmental Protection Division of the United States Environmental Protection Agency, Region 2 (“EPA”), who has been delegated the authority to institute this action. Respondent is Pfizer Pharmaceuticals, LLC (“Respondent”).

2. EPA and the U.S. Department of Justice have determined, pursuant to Section 113(d)(1) of the CAA, 42 U.S.C. § 7413(d)(1), that EPA may pursue this matter through administrative enforcement action.

3. Pursuant to Section 22.13 of the revised Consolidated Rules of Practice, 40 Code of Federal Regulations (“C.F.R.”) § 22.13(b), where parties agree to settlement of one or more causes of action before the filing of a complaint, a proceeding may be simultaneously commenced and concluded by the issuance of a CAFO pursuant to 40 C.F.R. §§ 22.18(b)(2) and (3).

4. It has been agreed by the parties that settling this matter by entering into this CAFO pursuant to 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3) is an appropriate means of resolving specified claims against Respondent without litigation. Compliance with the terms and conditions of this CAFO shall resolve those alleged violations which are set forth below.

STATUTORY BACKGROUND

5. Section 113(d) of the CAA, 42 U.S.C. § 7413(d), provides for the assessment of penalties for violations of Section 112(r) of the CAA, 42 U.S.C. § 7412(r).

6. Section 112(r)(7) of the CAA, 42 U.S.C. § 7412(r)(7), requires the Administrator to promulgate release prevention, detection, and correction requirements regarding regulated

substances in order to prevent accidental releases of regulated substances. EPA promulgated regulations in 40 C.F.R. Part 68 to implement Section 112(r)(7) of the CAA, the former of which set forth the requirements of risk management programs that must be established and implemented at stationary sources subject to this section of the CAA. The regulations at 40 C.F.R. Part 68, Subparts A through G, require owners and operators of stationary sources to, among other things, develop and implement: (a) a management system to oversee the implementation of the risk management program elements; and (b) a risk management program that includes, but is not limited to, a hazard assessment, a prevention program, and an emergency response program. Pursuant to 40 C.F.R. Part 68, Subparts A and G, the risk management program for a stationary source that is subject to these requirements is to be described in a risk management plan ("RMP") that must be submitted to EPA.

7. Sections 112(r)(3) and (5) of the CAA, 42 U.S.C. §§ 7412(r)(3) and (5), require the Administrator to promulgate a list of regulated substances, with threshold quantities. EPA promulgated a regulation at 40 C.F.R. Part 68, Subpart F, which implements Sections 112(r)(3) and (5) of the CAA, and which lists the regulated substances and their threshold quantities.

8. Pursuant to Section 112(r)(7) of the CAA, 42 U.S.C. § 7412(r)(7), and 40 C.F.R. §§ 68.10(a), 68.12, and 68.150, an owner or operator of a stationary source that has more than a threshold quantity of a regulated substance in a process shall comply with the requirements of 40 C.F.R. Part 68 (including, but not limited to, submission of an RMP to EPA), no later than June 21, 1999, or three years after the date on which such regulated substance is first listed under 40 C.F.R. § 68.130, or the date on which the regulated substance is first present in a process above the threshold quantity, whichever is latest.

9. The regulations set forth at 40 C.F.R. Part 68 separate the covered processes into three categories, designated as Program 1, Program 2, and Program 3. A covered process is subject to Program 3 requirements, as per 40 C.F.R. § 68.10(d), if: (a) the process does not meet one or more of the Program 1 eligibility requirements set forth in 40 C.F.R. § 68.10(b); and (b) either the process is listed in one of the specific North American Industry Classification System (generally referred to as "NAICS") codes found at 40 C.F.R. § 68.10(d)(1), or the process is subject to the United States Occupational Safety and Health Administration process safety management standard set forth in 29 C.F.R. § 1910.119. As required by 40 C.F.R. § 68.10(c), a facility must register its RMP-covered process as a Program 2 process if it does not meet the requirements of either Program 1 or Program 3.

10. The regulations set forth at 40 C.F.R. § 68.12(d) require that the owner or operator of a stationary source with a Program 3 process undertake certain tasks, including, but not limited to, development and implementation of a management system (pursuant to 40 C.F.R. § 68.15) and the implementation of prevention program requirements.

FINDINGS OF FACT

11. Respondent is the owner and/or operator of a manufacturing facility located at Rd. 2 Km. 58.2, Barceloneta, Puerto Rico (the "Facility"). The Facility uses ammonia (conc. 20% or greater) ("aqueous ammonia") and methylamine gas in two processes for the manufacture of pharmaceuticals.

12. EPA conducted an inspection of the Facility on or about January 31, 2014 to assess compliance with Section 112(r) of the Act and the applicable regulations, including those listed in 40 C.F.R. Part 68 (the "Inspection").

13. On June 23, 2015, EPA issued an information request letter to Respondent regarding compliance with Section 112(r) of the CAA.

14. On July 13, 2015, Respondent submitted a response to the EPA's information request, which provided, among other things, information regarding the aqueous ammonia and methylamine gas stored on site. Respondent subsequently sent a letter dated October 19, 2015 to EPA which provided updated information about the quantities of aqueous ammonia at the Facility from 2012-2015.

15. On March 9, 2016, EPA sent a supplemental information request letter to Respondent regarding the amount of aqueous ammonia stored on site in 2010 and 2011. Pfizer provided a response to EPA's supplemental request on April 21, 2016. Respondent additionally sent a letter dated March 15, 2016 to EPA, which provided updated information about the quantities of methylamine gas in 2012 through 2014.

16. Respondent did not submit an RMP to EPA.

EPA CONCLUSIONS OF LAW

17. Respondent is, and at all times referred to herein was, a "person" within the meaning of Section 302(e) of the CAA, 42 U.S.C. § 7602(e).

18. The Facility is a stationary source pursuant to 40 C.F.R. § 68.3.

19. Aqueous ammonia is a regulated substance pursuant to Section 112(r)(2) and (3) of the CAA and 40 C.F.R. § 68.3.

20. The threshold quantity for aqueous ammonia, as listed in 40 C.F.R. § 68.130, Tables 1 and 2, is 20,000 pounds.

21. Respondent handled and stored, aqueous ammonia in a process at the Facility in quantities exceeding the threshold quantity.

22. Methylamine gas is a regulated substance pursuant to Section 112(r)(2) and (3) of the CAA and 40 C.F.R. § 68.3.

23. The threshold quantity for methylamine gas, as listed in 40 C.F.R. § 68.130, Tables 1 and 2, is 10,000 pounds.

24. Respondent handled and stored, methylamine gas in a process at the Facility in quantities exceeding the threshold quantity.

25. Respondent's failure to submit an RMP regarding the Facility is a violation of the regulations at 40 C.F.R. Part 68.

26. Respondent's failure to comply fully with the requirements of 40 C.F.R. Part 68 regarding the Facility constitute violations of Section 112(r) of the CAA, 42 U.S.C. § 7412(r). Respondent is therefore subject to the assessment of penalties under Section 113(d) of the CAA, 42 U.S.C. § 7413(d).

CONSENT AGREEMENT

27. Based upon the foregoing, and pursuant to Section 113(d) of the CAA and the "Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits" (40 C.F.R. Part 22), Complainant and Respondent hereby agree on the following provisions.

28. For the purpose of this proceeding and in the interest of an expeditious resolution of this matter, pursuant to 40 C.F.R. § 22.18(b)(2), Respondent (a) admits the jurisdictional basis for this matter, (b) admits the Findings of Fact set forth above, (c) consents to the assessment of the civil penalty set forth below, (d) consents to the issuance of the attached Final Order, and (e) waives its right to contest the allegations and its right to appeal the attached Final Order.

29. Respondent neither admits nor denies the EPA Conclusions of Law set forth above.

30. This CAFO and any provision herein shall not be construed as an admission in any criminal or civil action or other administrative proceeding, except in an action or proceeding to enforce or seek compliance with the provisions of this CAFO.

31. Respondent hereby certifies that the Facility does not currently have any processes which have regulated substances above RMP threshold quantities.

32. Respondent consents to the issuance of this Consent Agreement and consents for the purposes of settlement to the payment of the civil penalty cited herein.

33. Respondent agrees to pay a civil penalty in the total amount of \$190,000.00, as described below. Such payment shall be made by cashier's or certified check or by Electronic

Fund Transfer ("EFT"). Payment of the penalty must be received by EPA on or before thirty (30) calendar days after the effective date of the Final Order, which as described in the Final Order as the date of filing with the Regional Hearing Clerk, U.S. Environmental Protection Agency, Region 2, New York, New York.

If the payment is made by check, then the check shall be made payable to the "Treasurer, United States of America" and shall be mailed to:

U.S. Environmental Protection Agency
Fines and Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, MO 63197-9000

The check shall be identified with a notation listing the following: "In the Matter of: Pfizer Pharmaceuticals, LLC" and shall bear thereon "Docket Number CAA-02-2016-1206."

If Respondent chooses to make the payment by EFT, then Respondent shall provide the following information to its remitter bank:

Amount of Payment:
SWIFT address: FRNYUS33, 33 Liberty Street, New York, NY 10045
Account Code for Federal Reserve Bank of New York receiving payment:
68010727
Federal Reserve Bank of New York ABA routing number: 021030004
Field Tag 4200 of the Fedwire message should read:
"D 68010727 Environmental Protection Agency"
Name of Respondent: Pfizer Pharmaceuticals, LLC
Case Number: CAA-02-2016-1206

Whether the payment is made by check or by EFT, the Respondent shall promptly thereafter furnish reasonable proof that the payment has been made to:

Jocelyn Scott
Assistant Regional Counsel
Office of Regional Counsel
U.S. Environmental Protection Agency, Region 2
290 Broadway, 17th Floor
New York, New York 10007-1866

and

Karen Maples
Regional Hearing Clerk

U.S. Environmental Protection Agency- Region 2
290 Broadway, 16th Floor
New York, New York 10007-1866.

Payment must be received pursuant to the provisions above.

34. If Respondent fails to make full and complete payment of the civil penalty that it is required to pay by this CAFO, this case may be referred by EPA to the United States Department of Justice and/or the United States Department of the Treasury for collection. In such an action, pursuant to Section 113(d)(5) of the CAA, 42 U.S.C. § 7413(d)(5), and 31 U.S.C. § 3717, Respondent shall pay the following amounts:

- a. Interest. If Respondent fails to make payment, or makes partial payment, interest shall accrue on any unpaid portion of the assessed penalty at the rate established pursuant to 31 U.S.C. § 3717 and 26 U.S.C. § 6621 from the payment due date.
- b. Handling Charges. Pursuant to 31 U.S.C. § 3717(e)(1), a handling charge of fifteen dollars (\$15.00) shall be paid per month, or any portion thereof, if any portion of the assessed penalty is not paid within thirty (30) days of the payment due date.
- c. Attorney Fees, Collection Costs, Nonpayment of Penalty. If Respondent fails to pay the amount of an assessed penalty on time, pursuant to Section 113(d)(5) of the CAA, 42 U.S.C. § 7413(d)(5), in addition to such assessed penalty and interest and handling assessments, Respondent shall also pay the United States' enforcement expenses, including but not limited to attorney fees and costs incurred by the United States for collection proceedings, and a quarterly non-payment penalty for each calendar quarter during which such a failure to pay persists. Such non-payment penalty shall be ten percent (10%) of the aggregate amount of Respondent's outstanding penalties and non-payment penalties accrued from the beginning of such quarter.

35. The penalty specified in Paragraph 33, above, shall represent civil penalties assessed by EPA and shall not be deductible for purposes of state or federal taxes.

General Provisions

36. This CAFO is being voluntarily and knowingly entered into by the parties in full settlement of Respondent's alleged violations of the CAA set forth above in the Findings of Fact and EPA Conclusions of Law.

37. This CAFO shall not relieve Respondent of its obligation to comply with all applicable provisions of federal, State, or local law, nor shall it be construed to be a ruling on, or

determination of, any issue related to any federal, State, or local permit. This CAFO shall not affect the right of the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law other than injunctive or equitable relief for the violations alleged herein. Except for the alleged violations resolved herein, compliance with this CAFO shall not be a defense to any actions subsequently commenced pursuant to federal laws and regulations administered by EPA, and it is the responsibility of Respondent to comply with such laws and regulations.

38. This CAFO and any provision herein is not intended to be an admission of liability in any adjudicatory or administrative proceeding except in an action, suit, or proceeding to enforce this CAFO or any of its terms and conditions.

39. For purposes of this matter, Respondent explicitly waives any right to request a hearing as to the matters addressed herein and/or contest any allegations in this Consent Agreement and explicitly waives any right to appeal the attached Final Order.

40. Each party hereto shall bear its own costs and attorneys' fees in the action resolved by this CAFO.

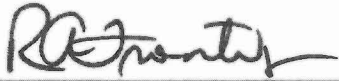
41. This CAFO shall be binding on Respondent and its successors and assignees.

42. Each of the undersigned representatives to this CAFO certifies that he or she is duly authorized by the party whom he or she represents to enter into the terms and conditions of the CAFO and to bind that party to it.

43. Respondent consents to service upon Respondent of a copy of this CAFO by any EPA employee, in lieu of service made by the EPA Region 2 Regional Hearing Clerk.

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For Respondent
Pfizer Pharmaceuticals, LLC.



Signature

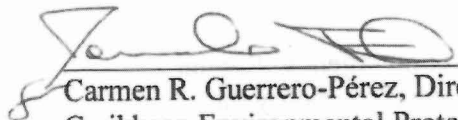
Date: 30-SEP-2016

RAMON FRONTANES
Name (Printed or Typed)

PRESIDENT
Title (Printed or Typed)

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For Complainant
U.S. Environmental Protection Agency, Region 2



Carmen R. Guerrero-Pérez, Director
Caribbean Environmental Protection
Division, Region 2

Date: Sept 29, 2016

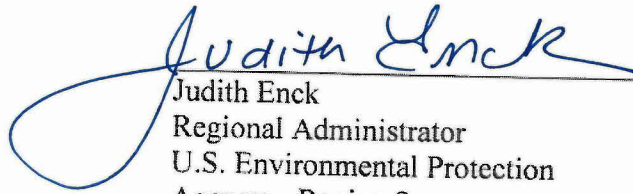


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FINAL ORDER

The Regional Administrator of the U.S. Environmental Protection Agency, Region 2, ratifies the foregoing Consent Agreement. The Consent Agreement, entered into by the Complainant and Respondent to this matter, is hereby approved, incorporated herein, and issued as a Final Order. The effective date of this Order shall be the date of filing with the Regional Hearing Clerk, U.S. Environmental Protection Agency, Region 2, New York, New York.



Judith Enck
Regional Administrator
U.S. Environmental Protection
Agency – Region 2
290 Broadway
New York, New York 10007-1866

Date: 9/30/16