

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2

U.S. Environmental
Protection Agency-Reg 2

2014 MAY 13 PM 2: 02

In the Matter of:

Pfizer Pharmaceuticals LLC

Respondent

In a proceeding under Section 113(d)
of the Clean Air Act, 42 U.S.C. § 7413(d)

REGIONAL HEARING
CLERK

CONSENT AGREEMENT
AND
FINAL ORDER

CAA-02-2012-1220

PRELIMINARY STATEMENT

This Consent Agreement and Final Order (CAFO) resolves an administrative penalty proceeding commenced on September 29, 2012, by the filing of a Complaint and Notice of Opportunity for a Hearing (Complaint) by the Complainant, the Director of the Caribbean Environmental Compliance Division (CEPD) for the United States Environmental Protection Agency (EPA) Region 2, against Respondent Pfizer Pharmaceuticals LLC (Pfizer or Respondent), pursuant to Section 113(d), 42 U.S.C. § 7413(d), of the Clean Air Act (CAA or Act), 42 U.S.C. § 7401 *et seq.*, and EPA's Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (CROP), 40 C.F.R. Part 22.

In addition, this CAFO simultaneously commences and concludes an administrative penalty proceeding brought by the Complainant against Respondent for violations discovered after the Complaint was issued, pursuant to Section 113(d) of the CAA, and Rules 22.13(b) and 22.18(b) of the CROP.

The Consent Agreement is signed by the Complainant and Respondent, and the Final Order is issued by the Region 2 Regional Administrator. As set forth in the "Jurisdictional Allegations" section of the Consent Agreement, the Complainant is duly authorized to sign consent agreements and the Regional Administrator is duly authorized to issue final orders.

CONSENT AGREEMENT

General Provisions

1. EPA has determined that Pfizer violated the CAA and its implementing regulations at its plant located in State Road 2, Km. 58.2, Barceloneta, Puerto Rico (the Facility). In general, the violations involve Respondent's failure to comply with Sections 112 and 114, 42 U.S.C. §§ 7412 and 42 U.S.C. §§ 7414 of the Act, and 40 C.F.R. Part 63, Subpart H, the "HON MACT" regulations (HON MACT or Subpart H).

2. The specific violations identified by EPA are set forth below in the section of the Consent Agreement entitled "Conclusions of Law." The Complainant and Respondent enter into this Consent Agreement and propose the attached Final Order to resolve an administrative civil penalty proceeding that was commenced by EPA's Complaint, dated September 29, 2012 (herein referred to in Conclusions of Law, Counts 1 - 5), and to simultaneously commence and conclude an administrative penalty proceeding concerning those specific violations disclosed by Pfizer (herein referred to in Conclusions of Law, Counts 6 - 8), as contemplated by CROP 22.13(b) and 22.18(a) - (b).

3. Therefore, for the purposes of this administrative penalty proceeding, and to avoid the expense of protracted litigation, Respondent:

- a. admits the jurisdictional allegations set forth in paragraphs 9-13 below in the section of this Consent Agreement entitled "Jurisdictional Allegations;"

- b. neither admits nor denies the recitations set forth in the section of this Consent Agreement entitled “Legal Background;”
- c. neither admits nor denies the findings of fact set forth in the section of his Consent Agreement entitled “Findings of Fact;”
- d. consents to the payment of the civil penalty specified in the section of this Consent Agreement entitled “Settlement,” on the terms specified in that section;
- e. consents to the issuance of the attached Final Order; and
- f. waives any right to contest the allegations set forth in the “Conclusions of Law” section of this Consent Agreement and any right to appeal the attached Final Order.

Jurisdictional Allegations

4. Section 113(d) of the CAA authorizes the EPA Administrator to issue an order assessing civil administrative penalties against any person that has violated or is violating any requirement or prohibition of subchapters I, III, IV-A, V or VI of the Act, or any requirement or prohibition of any rule, order, waiver, permit or plan promulgated pursuant to any of those subchapters, including but not limited to any regulation promulgated pursuant to Section 112 or 114 of the Act.

5. Section 302(e) of the CAA provides that whenever the term “person” is used in the Act, the term includes an individual, corporation, partnership, association, state, municipality, political subdivision of a State, and any agency, department, or instrumentality of the United States and any officer, agent, or employee thereof.

6. Pursuant to EPA Delegation of Authority 7-6-A and EPA Region 2 Delegation of Authority 7-6-A, the Administrator has delegated to the Complainant, the Director of the Caribbean Environmental Protection Division, through the Region 2 Regional Administrator, the authority to (a) make findings of violations, (b) issue CAA Section 113(d) administrative penalty complaints, and (c) agree to settlements and sign consent agreements memorializing those

settlements, for CAA violations that occur in the Commonwealth of Puerto Rico and the Territory of the U.S. Virgin Islands.

7. Pursuant to EPA Delegation of Authority 7-6-C, the Administrator has delegated to the Region 2 Regional Administrator the authority to execute CAA Section 113(d) Final Orders.

8. As contemplated by Section 113(d), the Administrator and the Attorney General, through their respective delegates, have jointly determined that this matter is appropriate for an administrative penalty proceeding. Specifically, on September 24, 2012, and on April 8, 2014, the United States Department of Justice (DOJ) granted EPA's requests for waivers of the CAA Section 113(d) time and penalty limitations on EPA's authority to initiate administrative penalty actions in this matter.

9. Respondent is a "person" within the meaning of Section 302(e) of the Act.

10. Respondent is an "owner or operator" of the Facility, as that term is used in Section 112(a)(9) of the Act and 40 C.F.R. § 63.2.

11. The Facility is a "stationary source," as that term is used Section 112(a)(3) of the Act and 40 C.F.R. § 63.2.

12. The Facility is an "area source" of HAPs, as that term is used in Section 112(a)(2) of the Act and 40 C.F.R. § 63.2.

13. The Facility is subject to the HON MACT.

Legal Background

EPA's Authority to Impose Civil Penalties for CAA Violations

14. Section 302(e) of the CAA provides that whenever the term “person” is used in the Act, the term includes an individual, corporation, partnership, association, state, municipality, political subdivision of a State, and any agency, department, or instrumentality of the United States and any officer, agent, or employee thereof.

15. Section 113(d) of the CAA authorizes the EPA Administrator to assess a civil administrative penalty against any person who has violated the Act or any regulation promulgated pursuant to titles I, III, IV, V and VI of the Act, including but not limited to any regulation promulgated pursuant to Sections 111, 112 and/or 114 of the Act.

CAA Section 112

16. Section 112 of the Act requires the EPA Administrator to: (i) publish a list of hazardous air pollutants (HAPs), (ii) publish a list of categories and subcategories of major and area sources of those HAPs, and (iii) promulgate regulations establishing emission standards for each such category and subcategory.

17. Emissions standards promulgated pursuant to Section 112 are commonly known as National Emissions Standards for Hazardous Air Pollutants, or NESHAPs. NESHAPs promulgated under the CAA as it existed prior to the 1990 CAA amendments are set forth in 40 C.F.R. Part 61. NESHAPs promulgated under the CAA as amended in 1990 are set forth in 40 C.F.R. Part 63. Part 63 NESHAPs are sometimes known as MACT standards, because Section 112(d) of the CAA, as amended in 1990, directs EPA to promulgate emissions standards based on the maximum achievable control technology (MACT).

18. Section 112(a) of the Act contains definitions relevant to Section 112. More specifically:
- a. Section 112(a)(1) of the Act defines “major source” as any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants.
 - b. Section 112(a)(2) of the Act defines “area source” as any stationary source of hazardous air pollutants that is not a major source.”
 - c. Section 112(a)(3) of the Act defines “stationary source” as a any building, structure, facility or installation which emits or may emit any air pollutant.
 - d. Section 112(a)(9) defines “owner or operator” as any person who owns, leases, operates, controls or supervises a stationary source.
19. Section 112(i)(3)(A) of the Act prohibits the operation of a source in violation of any emissions standard, limitation or regulation issued pursuant to Section 112, and directs the Administrator to set a compliance deadline for existing sources that is no more than 3 years after the effective date of the standard.

CAA Section 114

20. Section 114 of the CAA authorizes the EPA Administrator to require testing, monitoring, record-keeping, and reporting of information, to enable him or her to carry out any provision of the Act (except certain provisions in subchapter II) and to assess compliance with, among other requirements, any regulations promulgated under Sections 111 and 112 of the Act.

The Part 63 General Provisions – 40 C.F.R. §§ 63.1-63.16

21. On March 16, 1994, pursuant to Sections 112 and 114 of the Act, EPA promulgated 40 C.F.R. Part 63, Subpart A (the Part 63 General Provisions).
22. The Part 63 General Provisions set forth general definitions, procedures and requirements that apply to every Part 63 NESHAP, unless the individual NESHAP in question

provides differently. More specifically, the owners and operators of sources subject to an individual Part 63 NESHAP are subject to the portions of the general provisions that are expressly included in that individual Part 63 NESHAP. *See* 40 C.F.R. §§ 63.1(a)(4) (“Each relevant standard in this part 63 must identify explicitly whether each provision in this Subpart A is or is not included in such relevant standard.”) and (c)(1) (“If a relevant standard has been established under this Part, the owner or operator of an affected source must comply with the provisions of that standard and this Subpart as provided in paragraph (a)(4) of this Section”).

23. Pursuant to 40 C.F.R. § 63.1(b), the provisions of 40 C.F.R. Part 63 apply to the owner or operator of any stationary source that (i) emits or has the potential to emit any HAP listed in or pursuant to Section 112(b) of the Act, and (ii) is subject to any standard, limitation, prohibition, or other federally enforceable requirement established pursuant to Part 63.

24. Methylene chloride (MeCl₂) is listed in 40 C.F.R. Part 63 as a HAP.

25. 40 C.F.R. § 63.2 defines “affected source,” as the collection of equipment, activities, or both within a single contiguous area and under common control that is included in a Section 112(c) source category or subcategory for which a Section 112(d) standard or other relevant standard is established pursuant to Section 112 of the Act.

26. 40 C.F.R. § 63.2 defines “existing source” as any affected source that is not a new source.

27. 40 C.F.R. § 63.2 defines “owner or operator” as any person who owns, leases, operates, controls, or supervises a stationary source.

28. 40 C.F.R. § 63.6(c)(1) provides that after the effective date of Part 63 NESHAP, the owners and operators of existing sources subject to that NESHAP must comply with the NESHAP by the compliance date established in the applicable Subpart(s) of 40 C.F.R. Part 63.

Subpart H, the HON MACT - 40 C.F.R. §§ 63.160-63.183

29. On April 22, 1994, pursuant to Sections 112 and 114 of the Act, EPA promulgated 40 C.F.R. Part 63, Subpart H, §§ 63.160 - 63.183, the National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks (HON MACT or Subpart H), 59 Fed. Reg. 19,568 (April 22, 1994).

30. Pursuant to 40 C.F.R. § 63.160(a), the provisions of Subpart H apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, surge control vessels, bottoms receivers, instrumentation systems, and control devices or closed vent systems required by Subpart H that are intended to operate in organic HAP service 300 hours or more during the calendar year within a source subject to the provisions of a specific Subpart in 40 C.F.R. Part 63 that references Subpart H.

31. Pursuant to 40 C.F.R. § 63.160(b)(1), after the compliance date for a process unit to which Subpart H and the provisions of 40 C.F.R. Part 60 apply, the unit will be required to comply only with the provisions of Subpart H.

32. Pursuant to 40 C.F.R. § 63.160(c), if a facility has equipment to which Subpart H does not apply, but which is subject to a standard identified in § 63.160(c)(1), (c)(2), or (c)(3), the owner or operator may elect to apply Subpart H to all such equipment in the process unit. If the owner or operator elects this method of compliance, all VOC in such equipment shall be considered, for purposes of applicability and compliance with Subpart H, as if it were organic HAP. Compliance with the provisions of Subpart H, in the manner described in this paragraph, shall be deemed to constitute compliance with the standards identified in 40 C.F.R. § 63.160(c)(1), (c)(2), or (c)(3).

33. Pursuant to 40 C.F.R. § 63.162(a), compliance with Subpart H will be determined by review of the records required by § 63.181 and the reports required by § 63.182 of Subpart H, review of performance test results, and by inspections.

34. Pursuant to 40 C.F.R. § 63.163(b)(1), the owner or operator of a process unit subject to Subpart H shall monitor each pump monthly to detect leaks by the method specified in § 63.180(b) of Subpart H and shall comply with the requirements of § 63.163(a) through (d), except as provided in § 63.162(b) of Subpart H and § 63.163(e)-(j).

35. Pursuant to 40 C.F.R. § 63.163(c)(1), when a leak at the valves is detected, it shall be repaired as soon as practicable, but not later than 15 calendar days after it is detected, except as provided in § 63.163(c)(3) or § 63.171 of Subpart H.

36. Pursuant to 40 C.F.R. § 63.163(c)(2), a first attempt at repair for valves that are either in gas service or in light liquid service shall be made no later than 5 calendar days after the leak is detected.

37. Pursuant to 40 C.F.R. § 63.167(a)(1), each open-ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve, except as provided in § 63.162(b) of Subpart H and paragraphs (d) and (e) of § 63.167.

38. Pursuant to 40 C.F.R. § 63.167(a)(1), each open-ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve, except as provided in § 63.162(b) and § 63.167(d) and (e) of Subpart H.

39. Pursuant to 40 C.F.R. § 63.167(a)(2), the cap, blind flange, plug, or second valve shall seal the open end at all times except during operations requiring process fluid flow through the open-ended valve or line, or during maintenance or repair.

40. Pursuant to 40 C.F.R § 63.168(b), the owner or operator of a source subject to Subpart H shall monitor all valves, except as provided in § 63.162(b) of Subpart H and paragraphs (h) and (i) of § 63.168, at the intervals specified in § 63.168(c) and (d) and shall comply with all other provisions of § 63.168, except as provided in § 63.171, § 63.177, § 63.178, and § 63.179 of Subpart H.

41. Pursuant to 40 C.F.R § 63.168(c), in Phases I and II, each valve shall be monitored quarterly.

42. Pursuant to 40 C.F.R. § 63.168(f)(1), when a leak at a valve that is in light liquid service is detected, it shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in § 63.171 of Subpart H.

43. Pursuant to 40 C.F.R § 63.180(a), each owner or operator subject to the provisions of Subpart H shall comply with the test methods and procedures requirements provided in § 63.180.

44. Pursuant to 40 C.F.R § 63.180(b)(1), monitoring, as required by Subpart H shall comply with Method 21 of 40 C.F.R. Part 60, Appendix A (Method 21).

45. Pursuant to 40 C.F.R § 63.180(b)(2)(i), except as provided for in § 63.180(b)(2)(ii), the detection instrument shall meet the performance criteria of Method 21, except the instrument response factor criteria in Section 3.1.2(a) of Method 21 shall be for the average composition of the process fluid not each individual VOC in the stream. For process streams that contain nitrogen, water, air, or other inerts which are not organic HAPs or VOCs, the average stream response factor may be calculated on an inert-free basis. The response factor may be determined at any concentration for which monitoring for leaks will be conducted.

46. Pursuant to 40 C.F.R. § 63.180(b)(3), the instrument shall be calibrated before use on each day of its use by the procedures specified in Method 21.

47. Pursuant to 40 C.F.R. § 63.181(a), an owner or operator of more than one process unit subject to the provisions of Subpart H may comply with the recordkeeping requirements for these process units in one recordkeeping system if the system identifies each record by process unit and the program being implemented (e.g., quarterly monitoring, quality improvement) for each type of equipment. All records and information required by § 63.181 shall be maintained in a manner that can be readily accessed at the plant site. This could include physically locating the records at the plant site or accessing the records from a central location by computer at the plant site.

48. Pursuant to 40 C.F.R. § 63.182(d), the owner or operator of a source subject to Subpart H shall submit Periodic Reports.

49. Pursuant to 40 C.F.R. § 63.182(d)(xiv), the periodic reports shall contain the results of all monitoring to show compliance with §§ 63.164(i), 63.165(a), and 63.172(f) of Subpart H conducted within the semiannual reporting period.

Subpart I, National Emission Standards for Organic HAPs for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks - 40 C.F.R. §§ 6.190-63.193

50. Pursuant to 40 C.F.R. § 63.192(a)(1), the owner or operator of a source subject to Subpart I shall comply with the requirements of Subpart H of this Part for the processes and designated organic HAP's listed in § 63.190(b) of this Subpart.

51. Pursuant to 40 C.F.R. § 63.192(a)(2), the owner or operator of a pharmaceutical production process subject to Subpart I may define a process unit as a set of operations, within a source, producing a product, as all operations collocated within a building or structure or as all affected operations at the source.

Findings of Fact

52. The factual findings set forth below are the result of an investigation conducted by EPA Region 2 staff pursuant to Section 114 of the CAA.

53. Respondent is a for profit corporation duly formed under the laws of Delaware as a limited liability company on October, 13, 1999.

54. Respondent operates a pharmaceutical manufacturing plant that is defined as a synthetic organic manufacturing industry.

55. Respondent operates a pharmaceutical process that uses methylene chloride as a reactant in its chemical manufacturing processing unit.

56. Methylene chloride is classified as a HAP, as defined by Section 112(b) of the Act.

57. Respondent requested from the Puerto Rico Environmental Quality Board (EQB) a restricted synthetic minor air permit to be reclassified from major source to an area source.

58. The Facility's State Operating Permit # PFE-09-0203-0146-I-II-O indicates that the Facility's total annual HAPs emissions or potential emissions do not exceed 10 tons per year (tpy) of any HAP or 25 tpy of combined HAPs.

59. The State Operating Permit indicates that the Facility must comply with 40 C.F.R. Part 63, Subpart H.

60. On March 4 and 5, 2010, EPA and the EQB conducted a HON MACT Leak Detection and Repair (LDAR) inspection (EPA Inspection) at the Facility.

61. During the EPA Inspection, Pfizer informed EPA that the Facility is subject to the HON MACT due to the use of methylene chloride in several of its manufacturing batch

processes. During the EPA Inspection, Pfizer informed EPA that methylene chloride is the only HAP used at the Facility that is regulated under the HON MACT.

62. During the EPA Inspection, Pfizer informed EPA that the Facility is a synthetic minor source, since it limited its potential to emit HAPs to below 10 tpy of any single HAP or 25 tpy of any combination of HAPs threshold in October 2002.

63. During the EPA Inspection, Pfizer informed EPA that the Facility was having difficulties retrieving its historic LDAR monitoring data. Raw data requested by EPA was not able to be extracted from Respondent's database.

64. During the EPA Inspection, available leak records, work orders and leak repairs from 2005 through 2009 were reviewed.

65. During the EPA Inspection, Respondent confirmed that as a routine instrument calibration at the Facility it has always conducted a Method 21 bump calibration instead of a Method 21 equipment calibration.

66. During the EPA Inspection, Respondent informed that the Facility has 7,088 components.

67. During the EPA Inspection, Respondent informed that its LDAR technicians conduct LDAR evaluations daily on approximately 200 components at the Facility.

68. During the EPA Inspection, EPA also confirmed that Respondent has never conducted a response time test before placing the monitoring instrument into service.

69. During the EPA Inspection, EPA performed side by side monitoring with Pfizer LDAR technicians at 341 components subject to the Facility's HON MACT LDAR Program (EPA Monitoring Review).

70. During the EPA Monitoring Review, EPA found four leaks at certain flanges, plugs and valves components.

71. During EPA Monitoring Review, EPA also found and took pictures of three (3) open-ended lines (OELs). These OELs were not equipped with a cap, blind flange, plug or second valve.

72. By letter dated March 17, 2010, Respondent informed EPA that: (1) all leaks found during the EPA Inspection were repaired and corrected; (2) OELs were immediately capped during the EPA Inspection; (3) that Respondent implemented the procedures as required in EPA Method 21 to include the response time determination; (4) that Respondent implemented the practice to conduct daily calibrations during all LDAR monitoring activities.

73. On September 30, 2010, EPA filed an Administrative Compliance Order (Compliance Order) against Respondent for violations of 40 C.F.R. Part 63, Subpart H.

74. On January 13, 2011, EPA sent a letter to Respondent in order to assess its compliance with the provisions of Subpart H.

75. On January 21, 2011, Respondent submitted its Response to EPA's January 13, 2011 letter providing the information requested.

76. EPA conducted a review of the information obtained during, and subsequent to, the EPA Inspection, including the information and documents Respondent submitted with its March 17, 2010 and January 21, 2011 letters and concluded that Respondent corrected the violations as stated in the Compliance Order.

Pfizer's disclosure of additional violations

77. On October 28 and November 28, 2011, Pfizer sent letters to EPA's Division of Enforcement and Compliance Assistance (DECA) stating its intention to disclose potential violations at the Facility.

78. On September 29, 2012, EPA filed the Complaint against Pfizer for the violations alleged in the Compliance Order.

79. On November 29, 2012, EPA met with Pfizer to discuss the Complaint. During the meeting, Pfizer referred to the issues raised in the letters sent to DECA on October 28 and November 28, 2011.

80. During the November 29, 2012 meeting, Pfizer stated that it was conducting an internal investigation pertaining to the issues raised in its letters, in order to submit a complete report to EPA.

81. On April 29, 2013, Pfizer representatives met with EPA to discuss the results of its internal investigation.

82. According to Pfizer, an exhaustive internal investigation was conducted in order to further scrutinize the preliminary findings disclosed by Respondent in its letters sent to DECA on October 28 and November 28, 2011.

83. During the April 29, 2013 meeting, EPA requested Pfizer to submit a breakdown of all affected equipment that had been identified as being subject to the HON MACT LDAR program and to submit the revised semiannual reports related to the activities performed since the identification of such equipment.

84. On May 23, 2013, Pfizer submitted the revised semiannual reports for the affected equipment it had identified to cover the period from April 2008 to April 2011, as established by 40 C.F.R. § 63.182(a).

85. EPA conducted an analysis of the revised semiannual reports. The analysis revealed that Pfizer failed to identify 1,274 components (1,040 connectors, 225 valves, 4 agitators and 5 pumps as all the equipment been identified in the new pharmaceutical process) that needed to be included in the Facility's LDAR Program.

86. The analysis also revealed that some of the equipment previously reported as subject to the HON MACT had been removed from the HON MACT components list because they were not using methylene chloride and/or were in service for less than 300 hours as established by 40 C.F.R. § 63.162(c).

87. The analysis also revealed that Respondent had centralized the data required for all affected components subject to Subpart H and had complied with LDAR requirements, as established in 40 C.F.R. § 63.181.

88. The Region has concluded that Pfizer is now in compliance with the HON MACT regulations.

Conclusions of Law

89. Based on the Findings of Fact set forth above, EPA reaches the following Conclusions of Law:

General Conclusions

90. Respondent is a person within the meaning of Section 302(e) of the Act.

91. Respondent is the owner and/or operator of the Facility within the meaning of Section 112(a)(9) of the Act and 40 C.F.R. § 63.2.

92. The Facility is a stationary source as that term is used Section 112(a)(3) of the Act and 40 C.F.R. § 63.2.

93. The Facility is an area source of HAPs within the meaning of Section 112(a)(2) of the Act and 40 C.F.R. § 63.2.

94. The Facility operates in organic HAP service 300 hours or more during the calendar year within a source subject to the provisions of a specific Subpart in 40 CFR Part 63 that references Subpart H, and contains pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, surge control vessels, bottoms receivers, instrumentation systems, and control devices or closed vent systems. Therefore, the Facility is subject to Subpart H.

Specific Violations pertaining to the Administrative Complaint

Count 1

95. During the EPA inspection, EPA observed that the OEL identified as S-HV-14S97 was not equipped with a cap, blind flange, plug, or a second valve.

96. Respondent's failure to equip the OEL identified as S-HV-14S97 with a cap, blind flange, plug, or a second valve is a violation of 40 C.F.R. § 63.167(a)(1).

97. A violation of 40 C.F.R. § 63.167(a)(1) is a violation of Section 112 and 114 of the Act.

Count 2

98. During the EPA Inspection, EPA observed that the OEL identified as G-FL-012S76-003 was not equipped with a cap, blind flange, plug, or a second valve.

99. Respondent's failure to equip the OEL identified as G-FL-012S76-003 with a cap, blind flange, plug, or a second valve is a violation of 40 C.F.R. § 63.167(a)(1).

100. A violation of 40 C.F.R. § 63.167(a)(1) is a violation of Section 112 and 114 of the Act.

Count 3

101. During the EPA Inspection, EPA observed that the OEL identified as TS-HV-111B04 was not equipped with a cap, blind flange, plug, or a second valve.

102. Respondent's failure to equip the OEL identified as TS-HV-111B04 with a cap, blind flange, plug, or a second valve is a violation of 40 C.F.R. § 63.167(a)(1).

103. A violation of Subpart H at 40 C.F.R. § 63.167(a)(1) is a violation of Section 112 and 114 of the Act.

Count 4

104. During the EPA Inspection, Respondent stated that it had never conducted a response time test on the Total Volatile Analyzer, model TVA 1000s monitoring instrument.

105. By letter dated March 17, 2010, Respondent advised EPA that it had implemented at the Facility procedures to include the response time determination as required in Method 21.

106. Respondent's failure to conduct a response time test on the Total Volatile Analyzer, model TVA 1000s monitoring instrument is a violation of 40 C.F.R. § 63.180(b)(1).

107. A violation of 40 C.F.R. § 63.180(b)(2) is a violation of Section 112 and 114 of the Act.

Count 5

108. During the EPA Inspection, EPA observed a routine instrument calibration of the Total Volatile Analyzer, model TVA 1000s, performed by a Respondent technician and confirmed that the technician performed a bump calibration or calibration drift test.

109. By letter dated March 17, 2010, Respondent advised EPA that it had adopted the procedures to conduct the proper instrument calibration at the facility as required by Subpart H at 40 C.F.R. § 63.180(b)(3).

110. 40 C.F.R § 63.180(b)(3) requires that the instrument shall be calibrated before use on each day of its use by the procedures specified in Method 21 of 40 C.F.R. Part 60, Appendix A.

111. Respondent's failure to calibrate the monitoring instrument before use, following the procedures specified in Method 21 of 40 C.F.R. Part 60, Appendix A, is a violation of 40 C.F.R. § 63.180(b)(3) and the procedures specified in Method 21.

112. A violation of 40 C.F.R. § 63.180(b)(3) is a violation of Sections 112 and 114 of the Act.

Specific Violations pertaining to the information disclosed by Pfizer

Count 6

113. EPA was able to confirm from Pfizer's revised semiannual reports that Respondent had previously reported as equipment subject to HON MACT components that were not using methylene chloride and/or were in service for less than 300 hours.

114. Respondent's failure to identify each piece of equipment in a process unit to which Subpart H applies such that it can be distinguished readily from equipment that is not subject to Subpart H is a violation of 40 C.F.R. § 63.162(c).

115. A violation of 40 C.F.R. § 63.162(c) is a violation of Sections 112 and 114 of the Act.

Count 7

116. EPA was able to conclude from Pfizer's revised semiannual reports that Respondent failed to maintain one centralized recordkeeping system with the data required for all affected components subject to Subpart H.

117. Respondent's failure to comply with the recordkeeping requirements for the process units in one recordkeeping system that can be readily accessed at the plant site is a violation of 40 C.F.R. § 63.181.

118. A violation of 40 C.F.R. § 63.180(b)(3) is a violation of Sections 112 and 114 of the Act.

Count 8

119. On May 23, 2013, Respondent submitted Pfizer's revised semiannual reports for the affected equipment it had identified to cover the period from April 2008 to April 2011.

120. Respondent's failure to timely submit the reports listed in 40 C.F.R. §§ 63.182(a)(1)-(5) is a violation of 40 C.F.R. § 63.182 (a).

121. A violation of 40 C.F.R. § 63.180(b)(3) is a violation of Sections 112 and 114 of the Act.

Settlement

122. Pursuant to Section 113(d) of the Act, Respondent shall pay a civil penalty of \$317,992.00. Respondent shall have the option of paying the \$317,992.00 either by corporate, cashiers' or certified check within thirty (30) days from the effective date of the attached Final Order (the date of filing with the regional Hearing clerk). Respondent shall: (1) clearly type or write the docket numbers CAA-02-2012-1220 on the check to ensure proper payment; (2) make the check payable to the order of "Treasurer, United States of America;" and (3) send the check to:

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

Respondent shall send notice of payment to the following:

Nancy Rodríguez, Acting Chief
Multi-Media Permit and Compliance Branch
U.S. Environmental Protection Agency - Region 2
City View Plaza II - Suite 7000
48 Rd. 165 Km. 1.2
Guaynabo, PR 00968-8069

and

Carolina Jordán-García
Office of Regional Counsel-CT
U.S. Environmental Protection Agency - Region 2
City View Plaza II - Suite 7000
48 Rd. 165 Km. 1.2
Guaynabo, PR 00968-8069
jordan-garcia.carolina@epa.gov

123. If Respondent fails to make full, complete and timely payment of the \$317,992.00 penalty that is required 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 make partial payment, any unpaid portion of the assessed penalty shall bear interest 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 monthly handling charge of fifteen dollars (\$15.00) shall be paid if any portion of the assessed penalty is more than thirty (30) days past 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 42 U.S.C. § 413(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 nonpayment penalty for each quarter during which such a failure to pay persists. Such nonpayment penalty shall be ten percent of the aggregate amount of Respondent's outstanding penalties and nonpayment penalties accrued from the beginning of such quarter.

Supplemental Environmental Project

124. Respondent shall complete the supplemental environmental project (SEP) described in Appendix A to this Consent Agreement, which the parties agree is intended to secure significant environmental and/or public health benefits.

125. Within thirty (30) days from the effective date of the approval of the SEP and the CAFO, Respondent shall deposit \$410,440.00 in an Escrow Account, subject to conditions to assure that the money is used to acquire equipment equal or similar to the equipment listed in the Recycling Plan of the Municipality of Barceloneta described in Appendix A to this Consent Agreement

126. Respondent shall complete the SEP by no later than November 30, 2014.

127. By executing this Consent Agreement, Respondent certifies that it has prepared a good faith estimate of the cost of implementing the SEP and that it has concluded, in good faith, that it will cost \$410,440.00 to complete the SEP.

128. By executing this Consent Agreement, Respondent certifies that it is not a party to any open federal financial assistance transaction that is funding or could be used to fund the same activity as the SEP. Respondent further certifies that, to the best of its knowledge and belief after reasonable inquiry, there is no such open federal financial transaction that is funding or could be used to fund the same activity as the SEP, nor has the same activity been described in an unsuccessful federal financial assistance transaction proposal submitted to EPA within two years of the date of this settlement (unless the project was barred from funding as statutorily ineligible). For the purposes of this certification, the term "open federal financial assistance transaction" refers to a grant, cooperative agreement, loan, federally-guaranteed loan guarantee or other mechanism for providing federal financial assistance whose performance period has not yet expired.

129. By executing this Consent Agreement, Respondent certifies that, as of the date of its signature, Respondent is not required to perform or develop the SEP by any federal, state or local law or regulation; nor is Respondent required to perform or develop the SEP by any other agreement, grant or as injunctive relief in this or any other case. Respondent further certifies that it has not received, and is not presently negotiating to receive, credit in any other enforcement action for the SEP.

130. Respondent shall submit a SEP Report to EPA by no later than two months after November 30, 2014, containing the following information: a detailed description of the SEP as implemented; a description of any operating problems encountered and the solutions thereto;

itemized costs (Respondent shall clearly identify and provide acceptable documentation for all eligible SEP costs such as invoices, purchase orders, or other documentation that specifically identifies and itemizes the individual costs of the goods and/or services for which payment is being made); certification that the SEP has been fully implemented consistent with this Consent Agreement; and a description of the environmental and/or public health benefits resulting from implementation of the SEP (with a quantification of the benefits and pollutant reductions, if feasible).

131. EPA, in its sole discretion, shall determine whether the SEP has been satisfactorily completed in a manner consistent with this Consent Agreement.

132. Respondent shall submit all notices and reports required by this Consent Agreement, by first class mail to:

Nancy Rodríguez, Acting Chief
Multi-Media Permit and Compliance Branch
U.S. Environmental Protection Agency - Region 2
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and

Carolina Jordán-García
Office of Regional Counsel-CT
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133. Any public statement, oral or written, in print, film or other media, made by Respondent making reference to the SEP shall include the following language: “This project was undertaken in connection with the settlement of an enforcement action taken by the U.S. Environmental Protection Agency for alleged violations of the Clean Air Act.” “Este proyecto

fue realizado como parte de un acuerdo legal con relación a una acción de cumplimiento por violaciones a la Ley Federal de Aire Limpio presentada por la Agencia Federal de Protección Ambiental de los Estados Unidos.”

Stipulated Penalties for Failure to Complete the SEP

134. Except as provided in paragraph 135 below, in the event that Respondent fails to complete the SEP by November 30, 2014, Respondent shall pay a stipulated penalty to the United States in the amount of \$411,440.00.

135. If the SEP is not completed satisfactorily, but Respondent: (a) made good faith and timely efforts to complete the project; and (b) certifies, with supporting documentation, that at least seventy five percent of the amount of money which was required to be spent was expended on the SEP, Respondent shall pay a stipulated penalty in the amount of the remaining funds existing in the Escrow Account described in Appendix A.

136. Respondent's payment of the stipulated penalty required by paragraph 134 or 135, as the case may be, will discharge Respondent's obligations to perform the SEP.

137. In the event Respondent fails to submit a timely SEP Report to EPA, Respondent shall pay a stipulated penalty to the United States in the amount of \$200 per day the report is late.

138. Stipulated penalties under this Consent Agreement shall begin to accrue on the day after performance is due, and shall continue to accrue through the final day of the completion of the activity.

139. Respondent shall pay stipulated penalties not more than fifteen days after receipt of written demand by EPA for such penalties. Method of payment shall be in accordance with the provisions of Paragraph 123 above. Interest and late charges shall be paid as stated in Paragraph 140 below.

140. The Director of CEPD, Region 2 may, in his sole discretion, reduce or eliminate any stipulated penalty due if Respondent has, in writing, demonstrated to EPA's satisfaction good cause for such action by EPA. If, after review of Respondent's submission, Complainant determines that Respondent has failed to comply with the provisions of this Consent Agreement, and Complainant does not, in its sole discretion, eliminate the stipulated penalties demanded by EPA, Complainant will notify Respondent, in writing, that either the full stipulated penalty or a reduced stipulated penalty must be paid by Respondent. Respondent shall pay the stipulated penalty amount indicated in EPA's notice within twenty (20) calendar days of their receipt of such written notice from EPA.

141. Pursuant to 31 U.S.C. § 3717, EPA is entitled to assess interest and penalties on debts owed to the United States and a charge to cover the cost of processing and handling a delinquent claim. Interest will therefore begin to accrue on a civil or stipulated penalty if it is not paid by the last date required. Interest will be assessed at the rate of the United States Treasury tax and loan rate in accordance with 4 C.F.R. § 102.13(c). A charge will be assessed to cover the costs of debt collection, including processing and handling costs and attorney's fees. In addition, a non-payment penalty charge of six (6) percent per year compounded annually will be assessed on any portion of the debt which remains delinquent more than ninety (90) days after payment is due. Any such non-payment penalty charge on the debt will accrue from the date the penalty payment becomes due and is not paid in accordance with 4 C.F.R. §§ 102.13(d) and (e).

142. Nothing in this Consent Agreement shall be construed as prohibiting, altering or in any way limiting the ability of EPA to seek any other remedies or sanctions available by virtue of Respondent's violation(s) of this Consent Agreement, the statutes and regulations upon which

this Consent Agreement is based, or for Respondent's violation(s) of any applicable provision of law.

143. This Consent Agreement is being entered into voluntarily and knowingly by the parties in full settlement of Respondent's alleged violations of the Act set forth herein and as disclosed by Respondent to EPA on October 28 and November 28, 2011 and April 29, 2013, and in the revised semiannual reports submitted by Respondent on May 23, 2013.

144. Nothing in this Consent Agreement and attached Final Order shall relieve Respondent of the duty to comply with all applicable provisions of the Clean Air Act and other environmental laws and it is the responsibility of the Respondent to comply with such laws and regulations.

145. This Consent Agreement and attached Final Order 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.

146. This Consent Agreement, attached Final Order, 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.

147. Respondent explicitly waives its right to request a hearing and/or contest allegations in this Consent Agreement and explicitly waives its right to appeal the attached Final Order.

148. Respondent waives any right it may have pursuant to 40 C.F.R. § 22.08 to be present during discussions with, or to be served with and to reply to any memorandum or communication addressed to, the Regional Administrator or the Deputy Regional Administrator

where the purpose of such discussion, memorandum, or communication is to recommend that such official accept this Consent Agreement and issue the attached Final Order.

149. Each party to this Consent Agreement shall bear its own costs and attorneys' fees in this action resolved by this Consent Agreement and attached Final Order.

150. The Consent Agreement and attached Final Order shall be binding on Respondent and its successors and assignees.


151. Each of the undersigned representative(s) to this Consent Agreement certifies that he or she is duly authorized by the party whom he or she represents to enter into the terms and conditions of this Consent Agreement and bind that party to it.

In the Matter of Pfizer Pharmaceuticals LLC
CAA-02-2012-1220

Signatures

For Complainant:

Date:

A handwritten signature in black ink, appearing to read "José C. Font", written over a horizontal line.

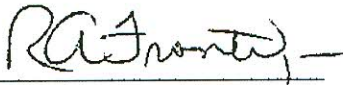
José C. Font
Director, Caribbean Environmental Protection Division

May 8, 2014

In the Matter of Pfizer Pharmaceuticals LLC
CAA-02-2012-1220

For Respondent:

Date:

Handwritten signature of Ramón Frontanes in black ink, written over a horizontal line.

Ramón Frontanes
President

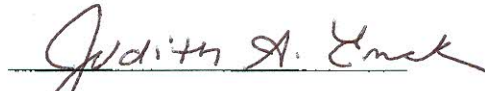
09. MAY. 2014

In the Matter of Pfizer Pharmaceuticals LLC
CAA-02-2012-1220

FINAL ORDER

The Regional Administrator of EPA, Region 2, concurs in the foregoing Consent Agreement, in the matter of Pfizer Pharmaceuticals LLC, CAA-02-2012-1220 and CAA-02-2012-1220. The Consent Agreement, entered into by the parties, is hereby approved and issued, as a Final Order. Pursuant to EPA's Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, this Final Order becomes effective at the time it is filed by Complainant's representatives with the Region 2 Regional Hearing Clerk.

DATE: 5/9/14



Judith A. Enck
Regional Administrator
United States Environmental
Protection Agency, Region 2

SEP Proposal
Pfizer Pharmaceuticals, LLC
Consent Agreement and Final Order
Docket No. CAA-02-2012-1220

I. EPA SEP Policy

To further EPA's goals to protect and enhance public health and the environment, in certain instances an environmentally beneficial project or Supplemental Environmental Project ("SEP") may be part of a settlement. The primary purpose of this policy is to encourage and obtain environmental and public health protection and improvements that may not otherwise have occurred without the settlement incentives provided by this Policy.

The EPA encourages the use of SEPs which are consistent with this Policy. SEPs can play an additional role in securing significant environmental or public health protection and improvements. SEPs may be particularly appropriate to further the objectives in the statutes EPA administers and to achieve other policy goals, including promoting pollution prevention and environmental justice.

The project to be implemented by Respondent meets the definition of a SEP. The SEP proposed satisfies all legal guidelines and is not required by any federal, state or local law or regulation. The project will not be inconsistent with any provision of the Clean Air Act and, in fact, will advance the objectives of the statute. The EPA will perform oversight, but will not retain authority, manage or administer the SEP. The project will not be used to satisfy EPA's statutory obligations or another federal agencies' obligation to perform a particular activity. Further, Respondent is not otherwise legally required to perform this SEP.

II. Description of SEP

Respondent will make available to the Municipality of Barceloneta the sum of \$410,440.00 to be used to acquire equipment equal or similar to the equipment listed in the Municipality's Recycling Plan as described in Attachment A to this SEP. The Municipality has represented that it proposes a five month action plan as described in Attachment B to this SEP. Respondent's SEP responsibility will be to make available the sum of \$410,440.00. The implementation of the action plan is the responsibility of the Municipality.

The funds to be provided by Pfizer will allow the Municipality of Barceloneta to acquire equipment necessary to significantly expand the scope and reach of the Recycling Plan to cover most of the Municipality.

The purpose of this environmental protection project is to provide the equipment to increase the collection, segregation, processing, transportation and use of recyclable materials, which will reduce the amount of solid waste to be disposed in landfill; thus, providing environmental and public health protection and ensure future environmental benefits and environmental justice to the people of the Municipality of Barceloneta.

III. Implementation

Within thirty (30) days from the effective date of the approval of the SEP and the CAFO, Respondent shall deposit \$410,440.00 in an Escrow Account, subject to conditions to assure that the money is used for the designated purpose, such as, for example, that: the money shall be used to acquire equipment equal or similar to the equipment listed in Attachment A to this SEP; the Escrow Account shall be administered by an escrow agent to be assigned by Respondent; the Escrow Agent shall be directed to pay the vendor for the equipment from the SEP funds by the Mayor of Barceloneta, with copy of such request to Respondent; all equipment purchases shall have been made no later than four months from the date the sum of \$410,440.00 is deposited in the Escrow Account. If the equipment purchases are not completed by the municipality within those four months, Respondent will have no more responsibility with the municipality, and unless the remainder of the funds are to be paid to EPA as part of the civil penalty, Respondent is free to dispose the remainder of the funds.

IV. Site Description

The SEP will be implemented in the Municipality of Barceloneta, which is located in the north coastal region of Puerto Rico. It borders the Atlantic Ocean and is adjacent to the Municipalities of Arecibo, Florida and Manatí. It has a surface area of 36.4 square miles (94.24 km²). It is located in the karst region, primarily limestone with highly permeable aquifers, and features hills, "mogotes", and caves. It also features the Rio Grande de Manatí and the Caño Tiburones, the largest swamp on the island.

Barceloneta has a population of approximately 24,816. The Municipality comprises industrial, infrastructure, commercial, educational, agricultural and residential areas spread through six wards, including the town.

V. Environmental Benefits

This supplemental environmental protection project will provide the funding to acquire the equipment necessary to increase the scope and reach of recycling in the Municipality. In 2012, the Municipality reported that it had disposed 9,474 tons of solid wastes in landfill and had recycled 252 tons of solid wastes which amounts to a rate of recycling of 3%. With the additional new equipment, the Municipality expects to increase the recycling rate to 10% or 20%.

The alleged violations contained in the CAFO are related to the control of hazardous air pollutants under the Clean Air Act. Helping the municipality purchase equipment to enhance its recycling efforts will help to enhance air quality in the local community and environment. Increasing the rate of recycling has many environmental benefits including reducing the volume of solid wastes disposed in the area landfills, thereby extending the life of the landfill and helping to mitigate the need to develop additional land as a landfill; reducing the potential of landfill greenhouse gas and other pollutant emissions in the air basin, which directly benefits the residents of Barceloneta, adjacent municipalities, as well as the environment in general.

Recycling newspapers, paper and other recyclable materials reduces the use virgin materials to produce new products (for example, recycling paper reduced the need to cut trees), which in turn helps to avoid carbon emissions. Producing products using recovered products rather than raw materials uses significantly less virgin raw material and uses less energy which results in reduced burning of fossil fuels and, therefore, reduced emissions of air pollutants (e.g. HAPs, SOx, NOx, GHGs, PM).

In addition to the benefits connected to the Clean Air Act issues, the SEP helps extend landfill life as well as the conservation of resources.

In summary, the SEP reduces the adverse impact and overall risk to public health and the environment potentially affected by the Clean Air Act issues.

RECYCLING PLAN MUNICIPALITY OF BARCELONETA

**Estimate Costs and Equipment Proposed to be Acquired
by the Municipality of Barceloneta**

Equipment	Quantity	Use	Comment	Estimate Cost
Residential Containers	4,200	Collection of recyclable residential materials	A written contract per residence (in stages).	\$96,600
Exterior Containers Uptown	20	Collection of recyclable materials in public areas	To be placed in strategic places in the municipality.	\$23,320
Conveyor 50' with receiver 18'	1	Management of recyclable materials for segregation	To process materials received in the center.	\$37,875
Truck Gancho 16 yards	1	Collection of recyclables and vegetative material	Commercial and domestic collection; processing and management of compost and/or chip/shaving.	\$62,995
Bobcat	2 \$42,550 each	Movement of materials to compost center, tree planting	To be used in the collection center and in the management of compost and/or chip/shaving.	\$85,100
Bobcats Accesories	1	Movement of materials	42" Pallet Forks 15H Bobcat Auger Combination bucket	\$9,900
Shredder	1	Shredding of vegetative material	Chip/shaving and compost	\$59,450
Siever & Conveyor	1	Separation of shredded material	Compost	\$25,000
Mixer and carts	1 2	Mixture and transportation	Compost	\$10,200
TOTAL				\$410,440

CERTIFICATE OF SERVICE

2014 MAY 13 PM 2: 02

I hereby certify that on May 13, 2014 I caused to be mailed a copy of the
Consent Agreement and Final Order entered In the Matter of: Pfizer Pharmaceuticals LLC
Docket No.: CAA-02-2012-1220 to be sent to the following persons in the manner indicated:

REGIONAL HEARING
CLERK

Copy by Email and UPS:

Hon. Lisa Buschmann
Office of Administrative Law Judges
U.S. Environmental Protection Agency
1099 14th Street, N.W., Suite 350
Washington, D.C. 20005
Fax (202) 565-0044

By Hand Delivery:

Karen Maples
Regional Hearing Clerk
U.S. EPA – Region 2
290 Broadway, 16th Floor
New York, New York 10007

**Copy by Certified Mail /
Return Receipt Requested:**

Eduardo Negrón Navas, Esq.
Oriental Center
254 Muñoz Rivera Avenue
6th Floor
Hato Rey, Puerto Rico 00918

Date: May 13, 2014

Lynne Chauvy