UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2

In the Matter of: **Pfizer Pharmaceuticals LLC** PR Road Km. 8.2 Barceloneta, Puerto Rico **Respondent** In a proceeding under Section 113(a) of the Clean Air Act, 42 U.S.C. § 7413(a)	**Complaint** **and** **Notice of Opportunity** **to Request a Hearing** Docket No.: CAA-02-2012-1200

Complaint

The United States Environmental Protection Agency (EPA) issues this Complaint and Notice of Opportunity for Hearing (Complaint) to Pfizer Pharmaceuticals LLC (Respondent) for violations of the Clean Air Act, 42 U.S.C. § 7401 *et seq.* (CAA or the Act), 42 U.S.C. § 7413(d), Section 113(d) of the Act, and proposes the assessment of penalties in accordance with the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, 40 C.F.R. Part 22 (CROP). The Complainant in the matter, the Director of the Caribbean Environmental Protection Division, is duly delegated the authority to issue administrative complaints for violations that occur in the Commonwealth of Puerto Rico.

In this Complaint, EPA alleges that Respondent's facility, located at State Road 2, Km. 58.2, Barceloneta, Puerto Rico, (the Facility), violated requirements or prohibitions of Section 112, 42 U.S.C. § 7671 of the Act, and 40 C.F.R. Part 63, Subpart H, the "HON MACT" regulations.

Section 113(d) of the Act authorizes EPA to bring an administrative penalty action in a matter involving a violation that occurred more than twelve months prior to

the initiation of an action, and to seek an administrative penalty that exceeds the amount provided by Statute, where the Administrator and the Attorney General jointly determine that such an action is appropriate. On September 24, 2012, the Department of Justice (DOJ) granted EPA's request for a waiver of the twelve (12) month period limitation provided in Section 113(d) of the Act.

Statutory Background

1. Section 112(a)(1) of the Act defines a "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 ten (10) tons per year (tpy) or more of any HAP or twenty-five (25) tpy or more of any combination of HAPs.

2. Section 112(a)(2) of the Act defines an "area source" as any stationary source of hazardous air pollutants (HAPs) that is not a major source.

3. Section 112(b)(1) of the Act lists the applicable HAPs and directs the Administrator to periodically review the list, and where appropriate, revise the list to include additional HAPs.

4. Section 112(c) of the Act requires the Administrator to publish a list of categories or subcategories of major and area sources of listed HAPs.

5. Section 112(d) of the Act requires the Administrator to promulgate regulations establishing NESHAPs for each category or subcategory of major and area sources of listed HAPs. Standards promulgated pursuant to Section 112 of the CAA are known as 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.

6. Section 112(d) of the CAA also directs EPA to promulgate emissions standards based on the maximum achievable control technology (MACT) standards. Section 112(i)(3)(A) 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.

7. Section 113(a)(3) of the Act authorizes the Administrator of EPA to issue an administrative penalty order, in accordance with Section 113(d) of the Act, against any person that has violated or is in violation of the Act.

8. Section 114(a)(1) of the Act authorizes the Administrator to require owners or operators of emission sources to submit specific information regarding facilities, establish and maintain records, make reports, sample emission points, and to install, use and maintain such monitoring equipment or methods in order to determine whether any person is in violation of the Act.

9. Section 302(e) of the Act defines the term "person" as an individual, corporation, partnership, association, state municipality, political subdivision of a state, and an agency, department, or instrumentality of the United States and any officer, agent, or employee thereof.

Regulatory Background

10. On March 16, 1994, pursuant to Sections 112 and 114 of the Act, EPA promulgated 40 C.F.R. Part 63, Subpart A, §§ 63.1 - 63.16 (Part 63 NESHAP General Provisions).

11. The Part 63 NESHAP General Provisions set forth definitions and

general requirements applicable to all sources subject to any NESHAP promulgated under Section 112 of the CAA, as amended in 1990.

12. Pursuant to 40 C.F.R. § 63.1(a)(4), each relevant standard in 40 C.F.R. Part 63 must identify explicitly whether each provision in the Part 63 NESHAP General Provisions is or is not included in such relevant standard.

13. 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.

14. Methylene chloride ($MeCl_2$) is listed in Section 112(b) of the Act and 40 C.F.R. Part 63 as a HAP.

15. Pursuant to 40 C.F.R. § 63.1(c), if a relevant standard has been established under Part 63, the owner or operator of an affected source must comply with the provisions of that standard and of the Part 63 NESHAP General Provisions, as provided in 40 C.F.R. § 63.1(a)(4).

16. 40 C.F.R. § 63.2 defines "affected source," for the purposes of Part 63, 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. This definition of "affected source" applies to each Section 112(d) standard for which the initial proposed rule is signed by the Administrator after June 30, 2002.

17. 40 C.F.R. § 63.2 defines "existing source" as any affected source that is not a new source.

18. 40 C.F.R. § 63.2 defines "owner or operator" as any person who owns, leases, operates, controls, or supervises a stationary source.

19. Pursuant to 40 C.F.R. § 63.6(c), after the effective date of a relevant standard established under 40 C.F.R. Part 63, the owner/operator of an existing source must comply with such standard by the compliance date established by the Administrator in the applicable Subpart(s) of 40 C.F.R. Part 63.

20. On October 18, 1983, EPA promulgated the Standard of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry for which Construction, Reconstruction, or Modification Commenced After January 5, 1981, and On or Before November 7, 2006, 40 C.F.R. §§ 60.480 - 60.489 (Subpart VV).

21. Pursuant to 40 C.F.R. § 60.480(a)(1), the provisions of Subpart VV apply to affected facilities in the synthetic organic chemicals manufacturing industry.

22. Pursuant to 40 C.F.R. § 60.480(a)(2), the group of all equipment (defined in 40 C.F.R. § 60.481) within a process unit is an affected facility.

23. Pursuant to 40 C.F.R. § 60.480(b), any affected facility under 40 C.F.R. § 60.480(a) that commences construction, reconstruction, or modification after January 5, 1981, and on or before November 7, 2006, shall be subject to the requirements of Subpart VV.

24. On April 22, 1994, pursuant to Sections 112 and 114 of the Act, EPA promulgated 40 C.F.R. Part 63, Subpart I, §§ 63.190 – 63.193, the National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes Subject to the

Negotiated Regulation for Equipment Leaks, 59 Fed. Reg. 19587 (Subpart I). Pursuant to 40 CFR § 63.190(b)(5), a pharmaceutical production whose processes use only methylene chloride is subject to Subpart I.

25. 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).

26. 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 for the processes and designated organic HAP's listed in § 63.190(b) of Subpart I.

27. 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.

28. 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.

29. 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 40 C.F.R. § 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 § 63.160(c)(1), (c)(2), or (c)(3). One of the standards identified in § 63.160(c)(1) is 40 C.F.R. Part 60, Subpart VV.

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

31. Pursuant to 40 C.F.R. § 63.168(a)(1)(iii), sources subject to other Subparts of 40 C.F.R. Part 63 that reference the HON must comply on the dates specified in the applicable Subpart, which in this case is Subpart H.

32. Pursuant to 40 C.F.R. § 63.163(a), the provisions of § 63.163 apply to each pump that is in light liquid service. 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 40 C.F.R. § 63.163(e)-(j).

33. 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.

34. 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.

35. 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.

36. 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.

37. 40 C.F.R § 63.168(b) applies to valves that are either in gas service or in light liquid service.

38. 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.

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

40. 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.

41. 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.

42. 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).[1]

43. 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.

44. 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.

45. 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

[1] The response time test is required before placing the instrument into service. If a modification to the sample pumping system or flow configuration is made that would change the response time, a new test is required prior to further use, pursuant to 40 C.F.R. § 60, Appendix A to Part 60, Method 21 - Determination of Volatile Organic Compound Leaks, 3.1.3.c.

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.

46. Pursuant to 40 C.F.R. § 63.182(d), the owner or operator of a source subject to Subpart H shall submit Periodic Reports for each six month period.

47. 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.

Findings of Fact

48. Respondent is a for profit corporation duly incorporated under the laws of Puerto Rico on April 14, 1971.

49. Respondent owns and operates a chemical and pharmaceutical plant that is defined as a synthetic organic manufacturing industry.

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

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

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

53. The Facility's State Operating Permit # PFE-SM-09-1208-0608-I-II-O (State Operating Permit) 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.[2]

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

55. On March 4 and 5, 2010, EPA and PREQB conducted a HON MACT (40 C.F.R. Part 63, Subpart H) Leak Detection and Repair (LDAR) inspection (EPA Inspection) at the Facility.

56. During the EPA Inspection, Mr. Santos (Respondent's Environmental Supervisor), Mr. Arroyo and Ms. Soto (Respondent's LDAR technicians) accompanied EPA.

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

58. During the EPA Inspection, Mr. Santos 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.

59. During the EPA Inspection, Mr. Santos also informed the EPA that he supervises the implementation of the LDAR Program.

60. During the EPA Inspection, Mr. Santos and Mr. Arroyo informed EPA that all first attempts at repair for all affected components are made by Mr. Arroyo.

61. During the EPA Inspection, Mr. Santos informed EPA that the Facility

[2] On February 18, 2011, the PREQB issued a renewal for the 2004 State Operating Permit # PFE-09-0203-0146-I-II-O to Respondent.

was having difficulties retrieving its historic LDAR monitoring data. Raw data requested by EPA was not able to be extracted from Respondent's database.

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

63. During the EPA Inspection, Mr. Santos and Mr. Arroyo informed EPA that Respondent owns and maintains 3 Total Volatile Analyzers, model TVA 1000s, which are the instruments used by Respondent to conduct leak detection monitoring at the Facility.

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

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

66. During the EPA Inspection, Mr. Santos explained that Mr. Arroyo conducts LDAR evaluations daily on 200 components. Mr. Santos further informed that the Facility has 7,088 components.

67. However, 40 C.F.R § 63.180(b)(3) and the procedures specified in Method 21, require the Facility to make a daily calibration of the Total Volatile Analyzer, model TVA 1000s instead of a bump calibration or a calibration drift test before use every time it is used .

68. During the EPA Inspection, EPA also confirmed with Mr. Santos and Mr.

Arroyo that Respondent has never conducted a response time test before placing the instrument into service.

69. During the EPA Inspection, Mr. Arroyo informed EPA that the Facility uses the following calibration gases: zero air, 550 parts per million (ppm) methane (CH_4), 1,000 ppm CH_4, and 9,500 ppm CH_4.

70. During the EPA Inspection, EPA performed side by side monitoring with Mr. Arroyo and Ms. Soto, at 341 components subject to the Facility's HON MACT LDAR Program (EPA Monitoring Review).

71. During the EPA Monitoring Review, EPA found four leaks located at flange TS-HV-111B04-001, plug NT-001, plug TS-HV-100AB04-003 and flange SR-P-01C01-002 and 2 visual leaks at flange G-XV-02S85-001 and valve G-HV-04S86-000.

72. During EPA Monitoring Review, EPA also found and took pictures of three (3) open-ended lines (OELs) identified by EPA as S-HV-14S97, G-FL-012S76-003 and TS-HV-111B04.

73. The OELs were not equipped with a cap, blind flange, plug or second valve as required by 40 C.F.R. § 63.167(a)(1).

74. By a 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 has implemented the procedures as required in EPA Method 21 to include the response time determination; (4) that Respondent has implemented the practice to conduct daily calibrations during all LDAR monitoring activities.

75. In order to assess compliance with the provisions of 40 C.F.R. Part 63, Subpart H, on January 13, 2011, Complainant sent a letter to Respondent requesting the following:

a. Each and every document, if any, showing proof of a first attempt to repair pumps, as required by Section 63.163(c)(2). Pursuant to 40 C.F.R. § 63.163(c)(2), a first attempt at repair for pumps 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.

b. Each and every document, if any, showing proof of a first attempt to repair valves, as required by 40 C.F.R. § 63.168(f)(2). Pursuant to 40 C.F.R. § 63.168(f)(2), a first attempt at repair for valves in gas/vapor, shall be made no later than 5 calendar days after each leak is detected.

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

77. 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.

CONCLUSIONS OF LAW

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

General Conclusions

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

79. Respondent is the owner and/or operator of the Facility.

80. 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 the HON MACT (Subpart H).

Counts

81. Respondent violated the Part 63 NESHAP General Provisions and the HON MACT as follows:

Count 1

82. Paragraphs 1-81 are incorporated herein by reference.

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

84. 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).

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

Count 2

86. Paragraphs 1-81 are incorporated herein by reference.

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

88. 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).

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

Count 3

90. Paragraphs 1-81 are incorporated herein by reference.

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

92. Respondent's failure to equip cap 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).

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

Count 4

94. Paragraphs 1-81 are incorporated herein by reference.

95. During the EPA Inspection, on March 4 and 5, 2010, the EPA inspectors were told by Mr. Santos and Mr. Arroyo that Respondent has never conducted a response time test on the Total Volatile Analyzer, model TVA 1000s monitoring instrument.

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

97. 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).

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

Count 5

99. Paragraphs 1-81 are incorporated herein by reference.

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

101. By letter dated March 17, 2010, Respondent advised EPA that the Facility adopted the procedures to conduct the proper instrument calibration as required by 40 C.F.R. § 63.180(b)(3).

102. 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.

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

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

Proposed Civil Penalty

Section 113(d) of the Act provides that the Administrator may assess a civil administrative penalty of up to $25,000 per day for each violation of the Act. The Debt Collection Improvement Act of 1996 (DCIA), 31 U.S.C. §§ 3701 *et seq.*, requires EPA to periodically adjust its civil monetary penalties for inflation. Pursuant to the DCIA, on December 31, 1996, February 13, 2004, and January 7, 2009, EPA adopted regulations entitled Civil Monetary Penalties Inflation Adjustment Rule, 40 C.F.R. Part 19 (Part 19). Part 19 provides that the maximum civil penalty per day should be adjusted up to $27,500 for violations that occurred from January 30, 1997 through March 15, 2004, up to $32,500 for violations that occurred after March 15, 2004 through January 12, 2009, and up to $37,500 for violations that occurred after January 12, 2009. Consistent with Part 19, EPA has amended its civil penalty policies, for example, its CAA Stationary Source Civil Penalty Policy, to increase the initial gravity component of the penalty calculation by 10% for violations which occurred on or after January 30, 1997, increase the gravity component by an additional 17.23% for violations which occurred March 15, 2004 through January 12, 2009, for a total increase of 28.95%, and further increase it by an additional 9.83% for violations that occurred after January 12, 2009.

In determining the amount of penalty to be assessed, Section 113(e) of the Act requires that the Administrator consider the size of the business, the economic impact of the penalty on the business, the violator's full compliance history and good faith efforts to comply, the duration of the violation as established by any credible evidence, the payment by the violator of penalties previously assessed for the same violation, the

economic benefit of noncompliance, the seriousness of the violation and other factors as justice may require.

Respondent's violations alleged in Counts 1 through 5 resulted in Respondent being subject to the assessment of administrative penalties pursuant to Section 113(d) of the Act. The proposed penalty has been prepared in accordance with the criteria in Section 113(e) of the Act, and in accordance with the guidelines set forth in EPA's "Clean Air Act Stationary Source Civil Penalty Policy" (CAA Penalty Policy), Appendix VI- Volatile Hazardous Air Pollutant Penalty Policy.

EPA proposes a total penalty of $216,555 for all Counts alleged in this Complaint. Below are brief narratives explaining the reasoning behind the penalty proposed, along with the reasoning behind various general penalty factors and adjustments that were used in the calculation of the total penalty amount.

Preliminary Deterrence Component of Proposed Penalty

The CAA Penalty Policy indicates that the preliminary deterrence amount is determined by combining the gravity component and the economic benefit component of the penalty calculated. The gravity component includes, as applicable, penalties for actual harm, importance to the regulatory scheme, size of violator and adjustments to the gravity component for degree of willfulness or negligence, degree of cooperation, prompt reporting, correction, history of non-compliance and environmental damage. Actual harm is calculated, where applicable, in accordance with the level of the violation, the toxicity of pollutant, the sensitivity of the environment, and the length of time of violation.

Gravity Component

Count 1: Violation of 40 C.F.R. § 63.167(a)(1)

EPA has determined that Count 1 is an equipment standard violation. The CAA Penalty Policy-Appendix VI directs that the proposed initial gravity component of Count 1 be $15,000 for the importance to the regulatory scheme element.

In addition, the DCIA and Part 19 direct EPA to adjust the gravity component 41.63% for violations occurring after January 12, 2009. Therefore, EPA proposes a $6,245 inflationary adjustment, which reflects the 41.63% inflation adjustment for violations that occurred during this period of time.

The total proposed penalty for Count 1 is $21,245.

Count 2: Violation of 40 C.F.R. § 63.167(a)(1)

EPA has determined that Count 2 is an equipment standard violation. The CAA Penalty Policy-Appendix VI directs that the proposed initial gravity component of Count 2 be $15,000 for the importance to the regulatory scheme element.

In addition, the DCIA and Part 19 direct EPA to adjust the gravity component 41.63% for violations occurring after January 12, 2009. Therefore, EPA proposes a $6,245 inflationary adjustment, which reflects the 41.63% inflation adjustment for violations that occurred during this period of time.

Therefore, the total proposed penalty for Count 2 is $21,245.

Count 3: Violation of 40 C.F.R. § 63.167(a)(1)

EPA has determined that Count 3 is an equipment standard violation. The CAA

Penalty Policy directs that the proposed initial gravity component of Count 3 be $15,000 for the importance to the regulatory scheme element.

In addition, the DCIA and Part 19 direct EPA to adjust the gravity component 41.63% for violations occurring after January 12, 2009. Therefore, EPA proposes a $6,245 inflationary adjustment, which reflects the 41.63% inflation adjustment for violations that occurred during this period of time.

Therefore, the total proposed penalty for Count 3 is $21,245.

Count 4: Violation of 40 C.F.R. § 63.180(b)(1)

EPA has determined that Count 4 is a monitoring violation. The CAA Penalty Policy-Appendix VI directs that the proposed initial gravity component of Count 4 be determined based on the 82 days missed to conduct the calibration requirement. Appendix VI states that for the first 10 days, a penalty of $100 per day be collected and for the remaining 95 days, a penalty of $500 per day shall be collected. The total penalty was estimated in $ 37,000.[3]

In addition, the DCIA and Part 19 direct EPA to adjust the gravity component 27.23% for violations occurring between March 15, 2004 and January 12, 2009.

[3] The Region determined that Count 4 and 5 are monitoring violations. The policy directs that $100 per day of violation be assigned for the first ten (10) days, and $500 per day for each violation thereafter. Respondent has identified as components in the Facility: 30 pumps and 13 agitators (which are monitored monthly), 827 valves (monitored quarterly) and 3, 264 connectors (monitored annually) are been monitored at the frequency established by the HON Rule. Respondent also informed EPA that it takes its LDAR technician 8 hours to complete 200 components. The Region has calculated that Respondent has a total of 7,088 components and that the technician invests at least 36 days per year to complete the annual monitoring of all affected components. Additionally, for the three (3) months in 2007 and three (3) months in 2010, EPA estimated an additional 10 days. In summary, the period of violation started on October 2007 until March 2010, or 82 days of monitoring period. The Region has determined a penalty of $1,000 for the first 10 days and $15,500 for the remaining 31 days for a total of $16,500 per year. For these violations, an amount of $37,000 was estimated for each type of violation. Therefore, the proposed penalty for Counts 4 and 5 is $ 74,000.

Accordingly, EPA adjusted the penalty by $7,141 for violations occurring within this period of time. Following the DCIA and Part 19, EPA further adjusted the gravity component 41.63% for violations occurring after January 12, 2009. EPA proposes a $5,134 inflationary adjustment, which reflects the 41.63% inflation adjustment. The total inflationary adjustment for this violation is $12,275.

The total proposed penalty for Count 4 is $49,275.

Count 5: Violation of 40 C.F.R. § 63.180(b)(3)

EPA has determined that Count 5 is a monitoring violation. The CAA Penalty Policy-Appendix VI directs that the proposed initial gravity component of Count 5 be determined based on the 82 days missed to conduct the calibration requirement. Appendix VI states that for the first 10 days, a penalty of $100 per day be collected and for the remaining 95 days, a penalty of $500 per day shall be collected. The total penalty was estimated in $37,000.

In addition, the DCIA and Part 19 direct EPA to adjust the gravity component 27.23% for violations occurring between March 15, 2004 and January 12, 2009. Accordingly, EPA adjusted the penalty by $7,141 for violations occurring within this period of time. Following the DCIA and Part 19 EPA further adjusted the gravity component 41.63% for violations occurring after January 12, 2009. EPA proposes a $5,134 inflationary adjustment, which reflects the 41.63% inflation adjustment for the violations that occurred after January 12, 2009. The total inflationary adjustment for this violation is $12,275.

The total proposed penalty for Count 5 is $49,275.

Size of Violator

The CAA Penalty Policy directs that a penalty be proposed that takes into account the size of the violator, determined by the violator's net worth. Based on the Independent Audit Report of 2007, submitted by Respondent to the PR State Department, Respondent's net worth is estimated at $100,000,000. In accordance with the Policy, the size of violator, before the inflation adjustment, is $70,000. After adjustment for inflation the proposed size of violator component is $92,484.

Economic Benefit

In addition to the gravity component of the proposed penalties, the CAA Penalty Policy directs that EPA determine the economic benefit derived from noncompliance. The CAA Penalty Policy explains that the economic benefit component of the penalty should be derived by calculating the amount the violator benefited from delayed and/or avoided costs. EPA calculates the economic benefit using a computer program that is called the BEN Model.

The CAA Penalty Policy, Appendix X, states that although the CAA Penalty Policy indicates that it is EPA's goal to collect the violator's economic benefit, EPA may elect not to assess an economic benefit component in enforcement actions where the violator's economic benefit is less than $5,000. EPA determined that in this case, the economic benefit of noncompliance is less than $5,000 and has determined not to add an economic benefit penalty.

Finally, a 15% downward adjustment for degree of cooperation was factored in, resulting in a total reduction of $38,216. Pfizer is entitled to the 15% downward adjustment because it was cooperative during the pre-filling investigation and performed

prompt and diligent actions to correct the problems identified by EPA. The total penalty of $254,770 was modified by the degree of cooperation factor and resulted in a final total penalty of $216,555.

Total Proposed Penalty for All Counts

In summary, EPA proposes a total penalty of $216,555 for the violations alleged in this Complaint.

Notice of Opportunity to Request a Hearing

The hearing in this matter is subject to the Administrative Procedure Act, 5 U.S.C. §§ 552 *et seq*. The procedures for this matter are found in the CROP, a copy of which can be found at http://www.epa.gov/oalj/rules/crop.pdf. References to specific procedures in this Complaint are intended to inform you of your right to contest the allegations of the Complaint and the proposed penalty and do not supersede any requirement of the CROP.

You have a right to request a hearing: (1) to contest any material facts set forth in the Complaint; (2) to contend that the amount of the penalty proposed in the Complaint is inappropriate; or (3) to seek a judgment with respect to the law applicable to this matter. In order to request a hearing you must file a written Answer to this Complaint along with the request for a hearing with the EPA Regional Hearing Clerk within thirty (30) days of your receipt of this Complaint. The Answer and request for a hearing must be filed at the following address:

Karen Maples
Regional Hearing Clerk
U.S. Environmental Protection Agency - Region 2
290 Broadway - 16th Floor
New York, New York 10007-1866

papers filed in this matter, are to be served on EPA to the attention of EPA counsel at the following address:

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
Tel.: (787) 977-5834

Your Answer should, clearly and directly, admit, deny, or explain each factual allegation contained in this Complaint with regard to which you have any knowledge. If you have no knowledge of a particular factual allegation of the Complaint, you must so state and the allegation will be deemed to be denied. The Answer shall also state: (1) the circumstances or arguments which you allege constitute the grounds of a defense; (2) whether a hearing is requested; and (3) a concise statement of the facts which you intend to place at issue in the hearing.

If you fail to serve and file an Answer to this Complaint within thirty (30) days of its receipt, Complainant may file a motion for default. A finding of default constitutes an admission of the facts alleged in the Complaint and a waiver of your right to a hearing. The total proposed penalty becomes due and payable without further proceedings thirty (30) days after the issue date of a Default Order.

Settlement Conference

EPA encourages all parties against whom the assessment of civil penalties is proposed to pursue the possibility of settlement by informal conferences. However, conferring informally with EPA in pursuit of settlement does not extend the time allowed

to answer the Complaint and to request a hearing. Whether or not you intend to request a hearing, you may confer informally with the EPA concerning the alleged violations or the amount of the proposed penalty. If settlement is reached, it will be in the form of a written Consent Agreement which will be forwarded to the Regional Administrator with a proposed Final Order. You may contact EPA counsel, Carolina Jordán-García, at (787) 977-5834, jordan-garcia.carolina@epa.gov, or at the address listed above, to discuss settlement. If Respondent is represented by legal counsel in this matter, Respondent's counsel should contact EPA.

Payment of Penalty in lieu of Answer, Hearing and/or Settlement

Instead of filing an Answer, requesting a hearing, and/or requesting an informal settlement conference, you may choose to pay the full amount of the penalty proposed in the Complaint. Such payment should be made by a cashier's or certified check payable to the Treasurer, United States of America, marked with the docket number and the name of the Respondent which appear on the first page of this Complaint. The check must be mailed to:

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

A copy of your letter transmitting the check and a copy of the check must be sent simultaneously to EPA counsel assigned to this case at the address provided under the section of this Complaint entitled Notice of Opportunity to Request a Hearing. Payment of the proposed penalty in this fashion does not relieve one of responsibility to comply with any and all requirements of the Clean Air Act.

Dated: Sept 28, 2012

José C. Font, Acting Director
Caribbean Environmental Protection Division
U.S. Environmental Protection Agency - Region 2

To:

Pfizer
Eduardo Cordero
Pfizer Pharmaceuticals, LLC
PO Box 628
Barceloneta PR 00617

cc: Pedro J. Nieves, Chairman
Puerto Rico Environmental Quality Board
PO Box 11488
San Juan, PR 00910