UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2

In the Matter of:

Schering-Plough Products, L.L.C.
Las Piedras, Puerto Rico

Respondent

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

CONSENT AGREEMENT
AND
FINAL ORDER

CAA-02-2011-1208

PRELIMINARY STATEMENT

The United States Environmental Protection Agency (EPA) issues this Consent Agreement and Final Order (CAFO) under the authority of the Clean Air Act (CAA or Act), 42 U.S.C. § 7401 et seq., Section 113(d), 42 U.S.C. § 7413(d), and pursuant to the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits, 40 C.F.R. Part 22 (Consolidated Rules of Practice). The Complainant in this matter is the Director of the Division of Enforcement and Compliance Assistance (DECA), EPA Region 2. The Complainant is delegated, on behalf of Region 2, the authority to issue CAA administrative complaints and consent agreements for violations that occur in the State of New York, the State of New Jersey, the Commonwealth of Puerto Rico, and the Territory of the U.S. Virgin Islands. The Regional Administrator of EPA Region 2 is duly delegated the authority to execute CAA § 113(d) Final Orders.

On December 13, 2010, the United States Department of Justice (DOJ) granted the EPA Region 2 request for a waiver of the CAA § 113(d) twelve (12) month time limitation on EPA's authority to initiate an administrative action in this matter against Schering-Plough Products, L.L.C. (Schering-Plough or Respondent).

In accordance with §§ 22.13(b), and 22.18(b), EPA and Respondent enter into this Consent Agreement and propose the attached Final Order to resolve the violations alleged in the Conclusions of Law section of this Consent Agreement.

In this action, EPA finds that Schering-Plough, at its Las Piedras facility, located at State Road 183, PRIDCO Industrial Park Las Piedras, Puerto Rico (Facility) violated 40 C.F.R. Part 63, Subpart A, §§ 63.1 - 63.16 (General MACT), 40 C.F.R. Part 63, Subpart H, §§ 63.174 – 63.180 (Equipment Leak MACT) and 40 C.F.R. Part 63, Subpart GGG, §§ 63.1250 – 63.1261 (Pharmaceutical MACT).

For purposes of this proceeding, and to avoid the expense of protracted litigation, Respondent: (1) admits that EPA has jurisdiction over the subject matter as alleged in this Consent Agreement; (2) neither admits nor denies specific factual allegations contained in this Consent Agreement; (3) consents to the terms of agreement set forth in this Consent Agreement; and (4) consents to the issuance of the attached Final Order.

Statutory and Regulatory Background

A. General Provisions

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(b)(1) of the Act provides a list of HAPs.

3. 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.

4. Section 112(d)(1) of the Act directs the Administrator to promulgate regulations establishing emission standards for each category or subcategory of, *inter alia*, major sources of HAPs listed under § 112(c). These emission standards must require the maximum degree of reduction in emissions of hazardous air pollutants that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for the new or existing sources in the category or subcategory to which the emission standard applies.

5. Section 112(h) of the Act authorizes EPA to promulgate "design, equipment, work practice, or operational" standards, or combinations thereof, which are consistent with § 112(d) or (f) of the Act, to the extent that it is not feasible to prescribe or enforce an emission standard for control of a HAP. Pursuant to § 112(d)(2)(D) and (E) of the Act, design, equipment, work practice, or operational standards, or combinations thereof, promulgated under § 112(h) of the Act, are treated as emission standards.

6. The standards EPA promulgated pursuant to § 112(d) and (h) of the Act are known as the National Emission Standards for Hazardous Air Pollutants (NESHAPs). The NESHAPs EPA promulgated pursuant to the Act, as amended November 15, 1990, are known as the "maximum achievable control technology" (MACT) standards.

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

8. Section 113(d)(1)(B) of the Act, authorizes EPA to issue an administrative order against any person whenever, on the basis of any available information, the Administrator finds that such person has or is violating any requirements or prohibitions of titles III, IV-A, V, or VI of the Act including but not limited to a requirement or prohibition of any rule, order, waiver, permit or plan promulgated, issued or approved under the Act.

9. Section 114(a)(1) of the Act authorizes EPA to require owners or operators of emission sources to submit specific information regarding their 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.

10. 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.

B. General MACT Provisions

11. Pursuant to § 112(d) of the CAA, EPA promulgated the National Emission Standards for Hazardous Air Pollutants for Source Categories at 40 C.F.R. Part 63, Subpart A (General MACT). 40 C.F.R. §§ 63.1 - 63.16.

12. 40 C.F.R. § 63.1(a)(4) provides that each relevant standard in 40 C.F.R. Part 63 must identify explicitly whether each provision in the General MACT is or is not included in such relevant standard.

13. 40 C.F.R. § 63.1(b) provides that the provisions of 40 C.F.R. Part 63 shall 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 § 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. 40 C.F.R. § 63.1(c) provides that 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 General MACT, as provided in 40 C.F.R. § 63.1(a)(4).

15. 40 C.F.R. § 63.2 defines "owner or operator" as any person who owns, leases, operates, controls, or supervises a stationary source.

16. 40 C.F.R. § 63.2 defines "affected source," for the purposes of Part 63 as a stationary source, a group of stationary sources, or a portion of a stationary source that is regulated by a relevant standard or other requirement established pursuant to § 112 of the Act.

17. 40 C.F.R. § 63.6(c) provides that after the effective date of a relevant standard established under 40 C.F.R. Part 63, the owner or 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.

C. Pharmaceutical MACT

18. Pursuant to § 112(c) of the CAA, EPA identified pharmaceutical production as a category of sources of HAPs.

19. Pursuant to §§ 112(d) and 114 of the CAA, EPA promulgated the National Emission Standards for Pharmaceuticals Production at 40 C.F.R. Part 63, Subpart GGG (Pharmaceutical MACT). 40 C.F.R. §§ 63.1250 - 63.1261.

20. 40 C.F.R. § 63.1250(a) provides that the Pharmaceutical MACT applies to pharmaceutical manufacturing operations, as defined in 40 C.F.R. § 63.1251, that, among other things, manufacture a pharmaceutical product, are located at a plant site that is a major source, and process, use, or produce one or more HAPs. Such an operation is an "affected source" under the Pharmaceutical MACT.

21. 40 C.F.R. § 63.1250(a) and (b) provide that all affected sources under the Pharmaceutical MACT that do not meet the new source applicability specifications in 40 C.F.R. § 63.1250(b) are deemed to be existing affected sources.

22. 40 C.F.R. § 62.1250(f)(1) requires existing affected sources to be in compliance with the Pharmaceutical MACT by no later than October 21, 2002 and remain in compliance thereafter.

23. Table 1 of the Pharmaceutical MACT lists the requirements of the General MACT, including 40 C.F.R. §§ 63.1, 63.2 and 63.6, which are applicable to the Pharmaceutical MACT.

24. 40 C.F.R. § 63.1251 defines "equipment" as each pump, compressor, agitator, pressure relief device, sampling connection system, open-ended valve or line, valve, connector, and instrumentation system in organic hazardous air pollutant service; and any control devices or closed-vent systems required by the Pharmaceutical MACT.

25. 40 C.F.R. §§ 63.1252 – 1260 provide specific emission limits, recordkeeping and reporting requirements, test methods and initial compliance requirements for four source categories: Process Vents; Storage Tanks; Equipment Leak; and Wastewater.

26. 40 C.F.R. § 63.1255 provides the Pharmaceutical MACT Equipment Leak Standards, also known as leak detection and repair (LDAR) requirements, which generally require identification and monitoring of equipment, repair of leaks, recordkeeping and reporting. The provisions of § 63.1255 apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems open-ended valves or lines, valves, connectors, storage control vessels, bottoms receivers, instrumentation systems, and control devices or closed-vent systems 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 the Pharmaceutical MACT.

27. The LDAR requirements in the Pharmaceutical MACT refer to and incorporate many of the requirements of the National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leak found at 40 C.F.R. Part 63, Subpart H (Equipment Leak MACT). 40 C.F.R. §§ 63.160 - 63.183.

28. 40 C.F.R. § 63.1255(b)(4) provides that the owner or operator must comply with § 63.174, the National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leak (Equipment Leak MACT), except as specified in paragraphs (b)(4)(i) through (iv) of § 63.1255(b)(4).

29. 40 C.F.R. § 63.1255(d)(1)(i) provides that each open-ended valve or line must be equipped with a cap, blind flange, plug, or a second valve.

30. 40 C.F.R. § 63.1255(e) provides the standards for valves in gas/vapor service and in light liquid service.

31. 40 C.F.R. § 63.1255(e)(3) provides that the owner or operator of a source subject to § 63.1255 must monitor all valves at the intervals specified in paragraph (e)(4) of § 63.1255 and must comply with all other provisions of § 63.1255.

32. 40 C.F.R. § 63.1255(e)(4) provides that after conducting the initial survey required in paragraph (e)(2) of § 63.1255, the owner or operator must monitor valves for leaks at the intervals specified in (e)(4)(i)-(v).

33. 40 C.F.R. § 63.1255(h) provides the reporting requirements for each owner or operator of a source subject to § 63.1255.

34. 40 C.F.R. § 63.1255(h)(3) provides that the owner or operator of a source subject to § 63.1255 must submit Periodic Reports containing information specified in (h)(3)(i) – (iv) of § 63.1255(h) on a semi-annual basis.

35. 40 C.F.R. § 63.1260(j) provides that the owner or operator of any affected source implementing the LDAR program specified in § 63.1255 must implement the reporting requirements in § 63.1255 and copies of all reports must be retained as records for a period of 5 years.

D. Equipment Leak MACT

36. 40 C.F.R. § 63.174 provides the standards for connectors in gas/vapor service and in light liquid service.

37. 40 C.F.R. § 63.174(a) provides that the owner or operator of a process unit subject to § 63.174 shall monitor all connectors in gas/vapor and light liquid service at the intervals specified in paragraph (b) of § 63.174.

38. 40 C.F.R. § 63.174(b)(1) specifies that for each group of existing process units within an existing source, the owner or operator shall monitor all connectors by no later than 12 months after the compliance date.

E. Title V of the Act

39. Section 501(2)(A) of the Act provides that the term "major source" means any stationary source (or group of stationary sources located within a contiguous area and under common control) that is a major source as defined in § 112 of the Act, § 302 of the Act or Part D of Subchapter I of the Act.

40. Section 502(a) of the Act provides that after the effective date of any permit program approved or promulgated pursuant to title V of the Act, it

shall be unlawful for any person to violate any requirement of a permit issued under title V of the Act or to operate a title V affected source, including a major source or any other source (including an area source) subject to standards or regulations under § 111 or 112 of the Act, except in compliance with a permit issued by a permitting authority under title V of the Act.

41. Section 502(d) of the Act requires each State to develop and submit to the Administrator a permit program meeting the requirements of title V of the Act.

42. Section 503(a) of the Act provides that any source specified in § 502(a) of the Act shall become subject to a permit program and shall be required to have a permit to operate.

43. Section 503(b)(2) of the Act provides that the regulations promulgated pursuant to § 502(b) of the Act must include requirements that the permittee periodically (but no less frequently than annually) certify that the facility is in compliance with any applicable requirements of the title V operating permit, and promptly report any deviations from permit requirements to the permitting authority.

44. Section 504(a) of the Act directs that each title V operating permit include enforceable emission limitations and standards, a schedule of compliance, a requirement that the permittee submit to the permitting authority, no less often than every six (6) months, the results of any required monitoring, and any such conditions as are necessary to assure compliance with applicable

requirements of the Act, including the requirements of the applicable implementation plan.

45. In accordance with § 502(d)(1) of the Act and 40 C.F.R. Part 70, Puerto Rico developed and submitted Part VI of the Regulation for the Control of Atmospheric Pollution (PRRCAP), the Operating Permits Program, to meet the requirements of title V of the Act.

46. Section 502(e) of the Act provides that EPA maintains its authority to enforce title V operating permits issued by a State.

47. Section 504(a) of the Act provides that a title V permit issued to a source must include all regulations applicable to the source.

48. Section 504(c) of the Act provides that a title V compliance certification submitted at the time of application and annually thereafter, shall include a certification regarding compliance with all applicable regulations and requirements applicable to the source.

49. EPA approved the Puerto Rico Environmental Quality Board (PREQB) CAA § 112(l) delegation request on February 26, 1996 and granted final full approval of the Puerto Rico Title V Operating Permit Program, with an effective date of March 27, 1996. *See* 40 C.F.R. Part 70, Appendix A.

50. EPA approved delegation to PREQB of all CAA § 112 MACTs, pursuant to Subpart E of 40 C.F.R. Part 63 (Approval of State Programs and Delegation of Federal Authorities). 61 Fed. Reg. 7073.

F. Title V Operating Permit

51. On August 24, 2004, Puerto Rico issued Respondent a Title V Operating Permit Number: PFE-TV-2834-44-0197-002, (Facility's Title V Operating Permit) for the Facility.

52. Section III, Part 7 of the Facility's Title V Operating Permit includes, as an applicable requirement, reporting of non-compliance in Title V Annual Compliance Certifications.

53. The Facility's Title V Operating Permit requires that the owner or operator must submit to PREQB semi-annual deviation reports in accordance with Section III, Part 18 of the Title V Operating Permit. The six-month reports must clearly identify all deviations from operating permit requirements applicable to process vents, equipment leaks, storage tanks, and wastewater streams that are included in the Pharmaceutical MACT, the probable cause of such deviations, and any corrective actions and preventive measures taken. In the event that no deviations occurred, the report must state so.

54. The Facility's Title V Operating Permit requires that the owner or operator must submit to PREQB and EPA an annual compliance certification for each applicable requirement, pursuant to Section III, Part 7 of the Title V Operating Permit on November 24, 2005 and thereafter, within 90 days after the end of each calendar year during which the permit was in effect.

55. The Facility's Title V Operating Permit Section VIII includes specific applicable requirements of the General MACT, Equipment Leak MACT and the Pharmaceutical MACT.

56. Section VIII-D.2 of the Facility's Title V Operating Permit includes 40 C.F.R. § 63.174 as an applicable requirement.

57. Section VIII-D.4.a of the Facility's Title V Operating Permit includes 40 C.F.R. § 63.1255(d)(1)(i) as an applicable requirement.

58. Section VIII-D.5.c of the Facility's Title V Operating Permit includes 40 C.F.R. § 63.1255(e)(3) as an applicable requirement.

59. Section VIII-D.5.e.iii of the Facility's Title V Operating Permit includes 40 C.F.R. § 63.1255(e)(4) as an applicable requirement.

Findings of Fact

60. Respondent is the owner and/or operator of a pharmaceutical manufacturing plant located at State Road 183, PRIDCO Industrial Park, Las Piedras, Puerto Rico (Facility).

61. The Facility manufactures one or more "pharmaceutical products" within the meaning of 40 C.F.R. § 63.1251, such as Zetia, Potassium Chloride, Clarinex, Rebetol, Temodar, and Claritin.

62. The Facility used methanol and methylene chloride, both of which are listed as HAPs under § 112(b)(1) of the Act, in its pharmaceutical manufacturing processes.

63. EPA conducted an inspection of the Facility (Inspection) on July 14 - 16, 2008.

64. During the Inspection, EPA inspectors observed that the Facility failed to cap two (2) open-ended valves or lines at tag number 904-TNK-037 and at a distillation column at the solvent recovery system.

65. Following the Inspection, EPA inspectors conducted a file review (EPA File Review) and reviewed *inter alia* the following documents:

a. the Facility's semi-annual Pharmaceutical MACT Periodic Reports for years 2005 - 2008;
b. the Facility's leak repair history database documented in the leak data acquisition system (LeakDAS);
c. the Facility's available Leak Detecting and Tracking forms for years 2005 - 2008;
d. the Facility's Title V Operating Permit Annual Compliance Certification for years 2006 - 2008; and
e. the Facility's NOCs for the Pharmaceutical MACT.

66. During the EPA File Review EPA found instances when the Facility's LeakDAS database indicated that several valves and connectors were not monitored within the required monitoring frequency from 2004 – 2007.

67. During the EPA File Review, EPA found that Schering-Plough did not identify, in the Facility's semi-annual Pharmaceutical MACT Periodic Reports for years 2005, 2006 and 2007, noncompliance with the Pharmaceutical MACT and with the condition in the Title V Operating Permit which includes the Pharmaceutical MACT as applicable requirements.

68. During the EPA File Review, EPA found that Schering-Plough did not identify, in the Facility's Title V Annual Certification for the years 2006 and 2007, noncompliance with the General MACT, Pharmaceutical MACT and Equipment Leak MACT and of the conditions in the Title V Operating Permit which includes the Equipment Leak MACT regulations as applicable requirements.

69. On January 27, 2010, pursuant to § 114 of the Act, EPA issued a request for information (114 Request) to Schering-Plough, seeking further information concerning the operations of the Facility.

70. On February 10, 2010, Schering-Plough provided responses to the 114 Request (114 Response).

71. EPA and Schering-Plough met on several occasions from May 2009 to April 2010 to discuss settlement and exchange information regarding operations at the Facility.

72. From May 2009 to September 2010, EPA requested and received further information from Schering-Plough.

73. On or about April 23, 2010, the Puerto Rico Environmental Quality Board (PREQB) signed a confidentiality agreement with the United States on behalf of EPA to allow PREQB to participate in settlement negotiations.

74. EPA, Schering-Plough, PREQB and the Department of Justice (DOJ) met on several occasions from April 2010 to September 2010 to discuss settlement and exchange information regarding operations at the Facility.

75. Schering-Plough neither admits nor denies specific factual allegations stated above.

76. On March 24, 2011, PREQB issued a letter to EPA and Schering-Plough stating that it "commits itself not to commence an administrative procedure against Schering for these infractions [contained in paragraphs 87-90 of the CAFO], nor will address them in any other manner."

Conclusions of Law

77. Paragraphs 1- 71 are re-alleged and incorporated herein by reference.

78. From the Findings of Fact set forth above, EPA finds that Schering-Plough is a person within the meaning of § 302(e) of the Act.

79. From the Findings of Fact set forth above, EPA finds that Schering-Plough is the owner and/or operator of the Facility within the meaning of § 112(a)(9) of the Act.

80. From the Findings of Fact set forth above, EPA finds that the Facility is a "stationary source," within the meaning of §§ 112(a)(3) and 302(z) of the Act, and a "major source" of HAPs within the meaning of § 112(a)(1) of the Act.

81. From the Findings of Fact set forth above, EPA finds the pharmaceutical manufacturing operations at the Facility are subject to the Pharmaceutical MACT, including the equipment leak standards at 40 C.F.R. § 63.1255.

82. From the Findings of Fact set forth above, EPA finds that the Facility is an existing "affected source" within the meaning of the Pharmaceutical MACT, 40 C.F.R. § 63.1250(a), and during all relevant times to this Consent Agreement and Final Order, the Facility operated as an affected source.

83. From the Findings of Fact set forth above, EPA finds that the Facility was required to be in compliance with the Pharmaceutical MACT by no

later than October 21, 2002 and is required to comply with the Pharmaceutical MACT thereafter.

84. From the Findings of Fact set forth above, EPA finds that during all times relevant to this CAFO, pharmaceutical manufacturing process units ("PMPUs") and any other equipment not associated with an individual PMPU, but that are located at a facility for the purpose of manufacturing pharmaceutical products and are under common control, within the meaning of 40 C.F.R. § 63.1251, were located at the Facility.

85. From the Findings of Fact set forth above, EPA finds that the Facility is subject to applicable requirements the Equipment Leak MACT, which the Pharmaceutical MACT incorporates by reference. 40 C.F.R. § 63.1255(b).

86. From the Findings of Fact set forth above, EPA finds that the Facility is subject to a Title V Operating Permit that was issued to Schering-Plough pursuant to Part VI PRRCAP, 40 C.F.R. Part 70, and title V of the Act.

87. From the Findings of Fact set forth above, EPA finds that Schering-Plough's failures to cap two (2) open-ended valves or lines at tag number 904-TNK-037 and at a distillation column at the solvent recovery system are violations of 40 C.F.R. § 63.1255(d)(1)(i), and violations of § 112 of the Act. Each failure is also a violation of Section VIII.D.4.a of the Facility's Title V Operating Permit, which includes 40 C.F.R. 63.1255(d)(1)(i) as an applicable requirement.

88. From the Findings of Fact set forth above, EPA finds that each of Schering-Plough's failures to monitor several valves and connectors within the

required monitoring frequency is a violation of 40 C.F.R. §§ 63.174(b)(3)(i), 63.1255(e)(3), and §§ 112 and 114 of the Act. Each failure is also a violation of Sections VIII.D.5.c and VIII.D.2 of the Facility's Title V Operating Permit, which includes §§ 63.174(b)(3)(i) and 63.1255(e)(3) as applicable requirements.

89. From the Findings of Fact set forth above, EPA finds that Schering-Plough's failures to identify noncompliance with Pharmaceutical MACT LDAR standards in semi-annual Pharmaceutical MACT Periodic Reports, is a violation of § 63.1260(j) and a violations of § 112 of the Act. Each failure is also a violation of Section VIII.A.10 of the Facility's Title V Operating Permit, which includes § 63.1260(j) as applicable requirements.

90. From the Findings of Fact set forth above, EPA finds that Schering-Plough's failures to identify noncompliance in the Title V Annual Certifications, is a violation of Section III.7 of the Facility's Title V Operating Permit.

91. Schering-Plough neither admits nor denies the Conclusions of Law set forth above.

Consent Agreement

Based on the foregoing, and in accordance with federal laws and regulations, it is agreed that:

92. Respondent has ceased manufacturing of the pharmaceutical manufacturing product(s) that use or produce one or more HAPs at the Facility.

93. Respondent represents that it is no longer capable of using the pharmaceutical manufacturing process that requires use or produces one or more HAPs because it has completed the following:

a. Draining and empting any HAPs from any process equipment including, but not limited to, piping and associated ancillary equipment, including but not limited to, storage tanks, distillation columns, and pumps;

b. Removing all residual HAPs remaining after draining and emptying as directed in (a) above, by cleaning the process equipment and associated ancillary equipment and legally disposing of the generated waste;

c. Removing related manufacturing vessels from the manufacturing area and blocking off the inlet to the air pollution control train that includes the cooler, carbon absorption, and solvent recovery systems; and

d. Disconnecting any power supply to any pumps and/or controls associated with the manufacturing of any pharmaceutical product that uses or produces one or more HAPs.

94. Pursuant to § 113(d) of the Act Respondent shall pay a civil penalty of **$260,000** within thirty (30) days from the date of issuance of the attached Final Order (Due Date). Respondent shall have the option of paying the entire **$260,000**, either by corporate, cashiers,' or certified check, or wire transfer. If paying by corporate, cashiers', or certified check Respondent shall: (1) clearly type or write the docket number (CAA-02-2011-1208) 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

If paying by wire transfer Respondent shall: (1) clearly type or write the docket number (CAA-02-2011-1208) on the wire transfer to ensure proper payment; and (2) direct the wire transfer to the Federal Reserve Bank of New York as follows:

Federal Reserve Bank of New York
ABA = 021030004
Account = 68010727
SWIFT address = FRNYUS33
33 Liberty Street
New York, New York 10045
Note: The Field Tag 4200 of the Fedwire message should read:
"D 68010727 Environmental Protection Agency"

Respondent shall send notice of payment to the following individuals:

Kenneth Eng, Air Compliance Branch Chief
Division of Enforcement and Compliance Assistance
U.S. Environmental Protection Agency – Region 2
290 Broadway – 21st Floor
New York, New York 10007

and

Flaire Hope Mills, Air Branch Chief
Office of Regional Counsel
U.S. Environmental Protection Agency – Region 2
290 Broadway – 16th Floor
New York, New York 10007

95. If Respondent fails to make full and complete payment of the **$260,000** 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 § 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.

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.

96. 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.

97. Respondent has read the Consent Agreement and consents to the terms and issuance as a Final Order.

98. This Consent Agreement and attached Final Order constitute a settlement by EPA of all claims for civil penalties, appropriate injunctive or other equitable relief pursuant to the Clean Air Act for findings of violations alleged in this Consent Agreement and for any Pharmaceutical MACT violations that EPA may have identified prior to the activities detailed in paragraph 93.

99. 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.

100. 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.

101. 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 if its terms and conditions.

102. 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.

103. 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.

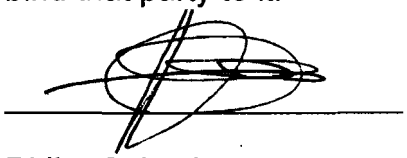
104. Each party to this Consent Agreement shall bear its own costs and attorneys' fees in this action resolved by this Consent Agreement and attached Final Order.

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

106. This Consent Agreement and attached Final Order will terminate after Respondent has paid the civil penalty required by paragraphs 91-92.

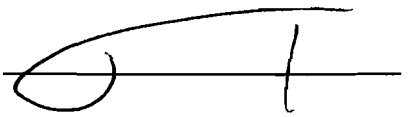
107. Each of the undersigned representative(s) to this Consent Agreement certifies that he or she is duly authorized by the party whom he or she represents to enter into the terms and conditions of this Consent Agreement and

bind that party to it.



Didier Colombeen
Senior Vice President
North America Ops &
Consumer Health
Merck, Sharp & Dohme Corp.

Date May 20- 2011



Dore LaPosta, Director
Division of Enforcement and
Compliance Assistance
United States Environmental
Protection Agency, Region 2

Date MAY 24, 2011

In the Matter of Schering-Plough Products, L.L.C.
CAA-02-2011-1208

FINAL ORDER

The Regional Administrator of EPA, Region 2, concurs in the foregoing Consent Agreement, in the matter of Schering-Plough Products, L.L.C. CAA-02-2011-1208. The Consent Agreement, entered into by the parties, is hereby approved and issued, as a Final Order, effective immediately.

DATE: May 31, 2011

Judith A. Enck
Regional Administrator
U.S. Environmental Protection
Agency – Region 2

In the Matter of Schering-Plough Products, L.L.C.
Docket No. CAA-02-2011-1208

CERTIFICATE OF SERVICE

I, Marie Quintin, certify that the foregoing fully executed Consent Agreement and Final Order was sent this day in the following manner to the addressees listed below:

Original and One Copy by
Hand to:

Office of Regional Hearing Clerk
U.S. Environmental Protection
Agency - Region 2
290 Broadway, 16th floor
New York, NY 10007-1866

Copy by
Regular Mail to:

R. Juge Gregg, Esquire
Sidley Austin, LLP
1501 K Street N.W.
Washington, DC 20005

Copy by
Hand to:

Marie Quintin, Esquire
Assistant Regional Counsel
U.S. Environmental Protection
Agency - Region 2
290 Broadway, 16th floor
New York, NY 10007-1866

Dated: June 1, 2011
New York, New York

Marie Quintin