IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,	:	
	:	
Plaintiff,	:	
	:	
v.	:	CIVIL ACTION NO.
	:	
MERCK & CO., INC.	:	Filed Electronically
	:	
Defendant	:	

COMPLAINT

The United States of America ("United States"), by the authority of the Attorney General of the United States and through its undersigned counsel, acting at the request and on behalf of the Administrator of the United States Environmental Protection Agency ("EPA"), files this Complaint and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action brought pursuant to the following: (1) Sections 309(b) and (d) and Section 311(b)(7) of the Federal Water Pollution Control Act, as amended by the Clean Water Act of 1977 and the Water Quality Act of 1987 (the "Clean Water Act" or "CWA"), 33 U.S.C. §§ 1319(b) and (d) and 33 U.S.C. § 1321(b)(7); (2) Section 113(b) of the Clean Air Act ("CAA"), 42 U.S.C. § 7413(b); (3) Section 3008(a) of the Solid Waste Disposal Act, as amended by the

Resource Conservation and Recovery Act of 1976 ("RCRA"), 42 U.S.C. § 6928(a); (4) Sections 325(b) and (c) of the Emergency Planning and Community Right-to-Know Act of 1986 ("EPCRA"), 42 U.S.C. §§ 11045(b) and (c); and (5) Section 109(c) of the Comprehensive Environmental Response, Compensation and Liability Act, as Amended by the Superfund Amendment and Reauthorization Act of 1986 ("CERCLA"), 42 U.S.C. § 9609(c). Through this action, the United States is seeking assessment of civil penalties against Merck and Co., Inc. ("Merck" or "Defendant") regarding violations discovered at two of Merck's pharmaceutical research and manufacturing facilities. One facility is located in West Point, Pennsylvania, and the other is located in Riverside, Pennsylvania (collectively, the "Facilities").

2. The United States alleges that Merck violated the following laws: (1) CWA section 301(a), 33 U.S.C. § 1311(a), and the pollutant discharge and oil spill prevention regulations promulgated thereunder that are codified at 40 C.F.R. §§ 112.3, 112.7, 112.20, and 112.21; (2) CAA sections 112(d), 502(a), and 603, 42 U.S.C. §§ 7412(d), 7661a(a),7671b, and the pharmaceutical manufacturing, permit, and ozone protection regulations promulgated thereunder which are codified at 40 C.F.R. §§ 63.1256, 63.1257, 63.1258, 63.1260, 82.156(i), 82.166(k); (3) RCRA sections 3005 and 3008(a), 42 U.S.C. § 6925 and 6928(a), and the emissions control regulations promulgated under section 2002(a) of RCRA, 42 U.S.C. §

6912(a), which are codified at 40 C.F.R. §§ 264.1084, 264.1087, 270.1, 270.30, as well as the federally-enforceable Pennsylvania hazardous waste regulations that are codified at 25 Pa. Code §§ 240a.1, 270a.1, 262a.34, 264a.1, 265a.1; (4) EPCRA sections 304 and 313, 42 U.S.C. §§ 11004 and 11023, and the notification regulations promulgated pursuant to section 328 of EPCRA, 42 U.S.C. § 11048, which are codified at 40 C.F.R. §§ 355.40 and 372.30; and (5) CERCLA section 103, 42 U.S.C. § 9603, and the notification regulations promulgated pursuant to section 102 of CERCLA, 42 U.S.C. § 9602, which are codified at 40 C.F.R. § 302.6.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345, and 1355 and pursuant to Section 309(b) of the CWA, 33 U.S.C. § 1319(b), Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Section 113(b) of CERCLA, 42 U.S.C. § 9613(b), Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), and Sections 325(b) and (c) of EPCRA, 42 U.S.C. §§ 11045(b) and (c).

4. Venue lies in the Middle District of Pennsylvania pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1395(a) and pursuant to Section 309(b) of the CWA, 33 U.S.C. § 1319(b), Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Section 113(b) of CERCLA, 42 U.S.C. § 9613(b), Section 3008(a) of RCRA, 42

U.S.C. § 6928(a), and Sections 325(b) and (c) of EPCRA, 42 U.S.C. §§ 11045(b) and (c), because Merck conducts business in this district and because the violations at the Riverside Facility alleged herein occurred in this judicial district.

AUTHORITY

5. The United States has authority to bring this action on behalf of the Administrator of EPA ("Administrator") in all actions under 28 U.S.C. § 516.

NOTICE

6. Notice of the commencement of this action has been given to the Commonwealth of Pennsylvania (“Pennsylvania”), as required by the following statutes: Section 309(b) of the CWA, 33 U.S.C. § 1319(b); section 113(b) of the CAA, 42 U.S.C. § 7413(b); and section 3008(a) of RCRA, 42 U.S.C. § 6928(a).

DEFENDANT

7. Merck is a New Jersey corporation with its corporate headquarters in Whitehouse Station, New Jersey.

8. At all times pertinent to this action, Merck owned and operated a pharmaceutical manufacturing facility located at 770 Sumneytown Pike in West Point, Montgomery County, Pennsylvania (hereafter referred to as “West Point”).

9. At all times pertinent to this action, Merck owned and operated a pharmaceutical manufacturing facility located at 100 Avenue C in Riverside, Pennsylvania (hereafter referred to as “Riverside”).

10. Merck, a corporation, is a "person" within the meaning of section 502(5) of the CWA, 33 U.S.C. § 1362(5), section 302(e) of the CAA, 42 U.S.C. § 7602(e), section 1004(15) of RCRA, 42 U.S.C. § 6902(15), section 329 of EPCRA, 42 U.S.C. § 11049(7), and section 101(21) of CERCLA, 42 U.S.C. § 9601(21).

STATUTORY AND REGULATORY BACKGROUND

I. CLEAN WATER ACT ("CWA")

A. General Provisions

11. Section 301(a) of the CWA, 33 U.S.C. § 1311(a), prohibits the "discharge of any pollutant" into the waters of the United States by any person except in accordance with certain provisions of the CWA including, but not limited to, Sections 307 and 402, 33 U.S.C. §§ 1317 and 1342.

12. Section 502(12) of the CWA, 33 U.S.C. § 1362(12), defines "discharge of a pollutant" as the addition of any pollutant to navigable waters from a point source.

13. Section 502(6) of the CWA, 33 U.S.C. § 1362(6), defines "pollutant" as, *inter alia*, solid waste, incinerator residue, sewage, garbage, chemical wastes, biological materials, and industrial waste discharged into water.

14. Section 304(a)(4) of the CWA, 33 U.S.C. § 1314(a)(4), identifies biochemical oxygen demand, chemical oxygen demand, and pH as "pollutants."

15. Section 502(14) of the CWA, 33 U.S.C. § 1362(14), defines "point source" as, *inter alia*, any discernable, confined and discrete conveyance, including, *inter alia*, any pipe, ditch, channel, tunnel, conduit, well, or discrete fissure from which pollutants are or may be discharged.

B. National Pollutant Discharge Elimination System ("NPDES")

16. Section 402 of the CWA, 33 U.S.C. § 1342, authorizes EPA and states with EPA-approved programs to issue NPDES permits allowing limited discharges of pollutants under specific conditions.

17. By Memorandum of Agreement dated July 5, 1978, and renewed on May 15, 1991, EPA authorized Pennsylvania to administer an NPDES program pursuant to the CWA statutory and regulatory provisions.

18. EPA retains concurrent enforcement authority pursuant to Section 402(i) of the CWA, 33 U.S.C. § 1342(i).

C. Spill, Prevention, Control, and Countermeasures("SPCC") for Oil

19. Section 311(j)(1)(C) of the CWA, 33 U.S.C. § 1321(j)(1)(C), provides that the President shall issue regulations "establishing procedures, methods, and equipment and other requirements for equipment to prevent discharges of oil…from onshore…facilities, and to contain such discharges…."

20. EPA promulgated the SPCC regulations pursuant to the CWA, 33 U.S.C. §§ 1251 - 1387, which established certain procedures, methods and

requirements upon each owner and operator of a non-transportation-related onshore facility if such facility, due to its location, could reasonably be expected to discharge oil into or upon the navigable waters of the United States or their adjoining shorelines in such quantity as EPA has determined in 40 C.F.R. § 110.3 may be harmful to the public health or welfare or the environment of the United States ("harmful quantity").

21. Pursuant to 40 C.F.R. § 110.3, discharges of harmful quantities include oil discharges that cause either (1) a violation of applicable water quality standards or (2) a film, sheen upon, or discoloration of the surface of the water or adjoining shorelines, or (3) a sludge or emulsion to be deposited beneath the surface of the water or upon adjoining shorelines.

22. Pursuant to 40 C.F.R. §§ 112.1 and 112.2, an SPCC Plan is required for an owner or operator of a non-transportation-related facility that has greater than 1,320 gallons of above ground oil storage, or greater than 42,000 gallons of underground oil storage, and if the person is engaged in, *inter alia*, gathering, storage, usage, or consumption of oil, and if, due to its location, the facility could be reasonably expected to discharge oil to a water of the United States.

23. Under 40 C.F.R. § 112.3(d), the SPCC Plan for a facility must be approved by a registered professional engineer. Under 40 C.F.R. § 112.7(b), the SPCC Plan must include the location of each oil container at a facility, the storage

capacity of each oil container, and an accurate prediction of the potential oil spill direction, rate and amount from each oil container.

D. Facility Response Plan

24. Under 40 C.F.R. § 112.20(a), an owner or operator of an onshore facility must develop a Facility Response Plan ("FRP") for each facility that, due to its oil storage capacity and its proximity to fish and wildlife sensitive environments or public drinking water intakes or other facility-specific characteristics, could reasonably be expected to cause "substantial harm" to the environment by discharging oil to waters of the United States.

25. A facility falling under the FRP requirement must also perform response training and drills, pursuant to 40 C.F.R. § 112.21(a).

26. The criteria for determining whether a facility is a substantial harm facility are found in 40 C.F.R. § 112.20(f). For a facility with an oil storage capacity of equal to or greater than one million gallons, an oil spill can "reasonably be expected to cause substantial harm to the environment" if one of the following is true: (1) the facility lacks adequate secondary containment, (2) the facility is located at a distance such that an oil discharge could cause injury to fish or wildlife sensitive environments, (3) the facility is located at a distance such that an oil discharge would shut down a public drinking water intake, or (4) the facility has had a reportable oil spill of equal to or greater than 10,000 gallons within the last

five years. 40 C.F.R. § 112.20(f)(1)(ii)(A)-(D). These criteria are to be applied in accordance with the flowchart in Attachment C-I to Appendix C of 40 C.F.R. Part 112. 40 C.F.R. § 112.20(f)(1). This flowchart requires a facility owner or operator to use the formula in Attachment C-III to Appendix C of 40 C.F.R. Part 112 to evaluate whether the facility is located at a distance such that an oil spill could cause injury to fish and wildlife sensitive environments or disrupt operations at a public drinking water intake during adverse weather conditions. 40 C.F.R. Part 112, Appendix C, Attachment C-I.

E. Enforcement of the CWA

27. Sections 309(b) and (d) of the CWA, 33 U.S.C. §§ 1319(b) and (d), authorize the United States to commence actions for injunctive relief and/or civil penalties for violations of sections 301, 307, and 402 of the CWA, 33 U.S.C. §§ 1311, 1317, and 1342.

28. Section 311(b)(7)(C) of the CWA, 33 U.S.C. § 1321(b)(7)(C), authorizes civil penalties of up to $25,000 per day of violation of any regulation promulgated under Section 311(j) of the CWA, 33 U.S.C. § 1321(j). The Debt Collection Improvement Act, 31 U.S.C. § 3701 et seq., requires EPA to periodically adjust its civil penalties for inflation. On December 31, 1996, February 13, 2004, and December 11, 2008, EPA adopted and revised regulations entitled “Adjustment of Civil Monetary Penalties for Inflation,” 40 C.F.R. Part 19,

to upwardly adjust the maximum civil penalty under the CWA. For each violation that occurs between March 16, 2004 and January 12, 2009, inclusive, penalties of up to $32,500 per day may be assessed. 69 Fed. Reg. 7121 (Feb. 12, 2004); 73 Fed. Reg. 75340 (Dec. 11, 2008).

II. CLEAN AIR ACT ("CAA")

29. The CAA establishes a regulatory scheme designed to protect and enhance the quality of the nation's air so as to promote the public health and welfare and the productive capacity of its population. 42 U.S.C. § 7401(b)(1).

A. Title V Permit Program

30. Title V of the CAA, 42 U.S.C. §§ 7661-7661f, establishes an operating permit program which requires certain air pollution sources, including "major sources", to obtain a permit under Title V. CAA § 502, 42 U.S.C. § 7611a. The purpose of Title V is to ensure that all "applicable requirements" for compliance with the CAA are collected in one place.

31. Section 501(a) of the CAA, 42 U.S.C. § 7611, defines "major source" as any stationary source or group of stationary sources located within a contiguous area and under common control that, *inter alia*, (1) emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant ("HAP") or 25 tons per year or more of any combination of

HAPs; or (2) any stationary facility or source of air pollutants which directly emits, or has the potential to emit, one hundred tons per year or more of any air pollutant.

32. Pursuant to Section 502(b) of the CAA, 42 U.S.C. § 7661a(b), EPA promulgated regulations implementing the requirements of Title V and establishing the minimum elements of a Title V permit program to be administered by any state or local air pollution control agency. 57 Fed. Reg. 32250 (July 21, 1992). These regulations are codified at 40 C.F.R. Part 70.

33. Section 502(a) of the CAA, 42 U.S.C. § 7661a(a), and 40 C.F.R. § 70.7(b) make it unlawful for any person to violate any requirement of a permit issued under Title V or to operate a "major source" except in compliance with a permit issued by a permitting authority under Title V.

34. EPA approved Pennsylvania's Part 70 (Title V) program, codified at 25 Pa. Code Ch. 127, Subch. G, on July 30, 1996, with an effective date of August 29, 1996. 61 Fed. Reg. 39597 (July 30, 1996).

35. 40 C.F.R. § 70.6(b)(1) specifies that all terms and conditions in a permit issued under a Part 70 program, including any provisions designed to limit a source's potential to emit, are enforceable by the Administrator of EPA under the CAA.

B. National Emission Standards for Hazardous Air Pollutants ("NESHAPs")

1. General Provisions

36. Under Section 112(b) of the CAA, 42 U.S.C. § 7412(b), Congress established a list of 188 HAPs believed to cause adverse health or environmental effects.

37. Under Section 112(c) of the CAA, 42 U.S.C. § 7412(c), EPA published a list of all categories and subcategories of, *inter alia*, major sources of HAPs.

38. "Major source" for HAPs is defined 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 HAP or 25 tons per year or more of any combination of HAPs. CAA § 112(a)(1), 42 U.S.C. § 7412(a)(1).

39. "Stationary source" is defined as any building, structure, facility, or installation which emits or may emit any air pollutant. CAA § 112(a)(3), 42 U.S.C. § 7412(a)(3) (stating that "stationary source" under Section 112(a) has the

same meaning as that term in Section 111(a)(3) of the CAA, 42 U.S.C. § 7411(a)(3)).

40. Pursuant to Section 112(d)(1) of the CAA, 42 U.S.C. § 7412(d)(1), Congress directed EPA to promulgate regulations establishing emission standards for each category or subcategory of, *inter alia*, major sources of HAPs listed under Section 112(c). These emission standards must require the maximum degree of reduction in emissions of HAPs that EPA, 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, pursuant to Section 112(d)(2) of the CAA, 42 U.S.C. § 7412(d)(2).

41. Pursuant to Section 112(d), (f) and (h) of the CAA, 42 U.S.C. § 7412(d), (f) and (h), EPA promulgated regulations that establish national emission standards and/or work practice and equipment standards applicable to major sources of HAPs, which are listed for regulation under Section 112(b) of the CAA, 42 U.S.C. § 7412(b).

42. The emission standards under Section 112 of the CAA, 42 U.S.C. § 7412, are known as the NESHAPs for Source Categories or maximum achievable

control technology ("MACT") standards. These emission standards are found in 40 C.F.R. Part 63.

43. EPA has promulgated regulations that contain general provisions that are applicable to all Part 63 sources listed in 40 C.F.R. Part 63, Subpart A. 40 C.F.R. §§ 63.1 - 63.16.

44. Pursuant to 40 C.F.R. § 63.2, an "affected source" is defined as the stationary source, group of stationary sources, or portion of a stationary source that is regulated by a relevant standard or other requirement established pursuant to Section 112 of the CAA, 42 U.S.C. § 7412.

2. Pharmaceutical MACT ("Pharma MACT")

45. Pursuant to Section 112 of the CAA, EPA promulgated the "National Emission Standards for Hazardous Air Pollutants for Pharmaceutical Production" ("Pharma MACT."), codified at 40 C.F.R. Part 63, Subpart GGG ("Subpart GGG").

46. Pursuant to 40 C.F.R. § 63.1250(a), Subpart GGG applies to all "affected sources," which includes, but is not limited to, existing major sources of HAPs that manufacture pharmaceutical products, as defined in 40 C.F.R. § 63.1251. To control or reduce emissions of HAPs in conformance with Section

112 of the CAA, Subpart GGG establishes standards for several types of emissions points from pharmaceutical manufacturing operations.

47. Section 112(i) of the CAA, 42 U.S.C. § 7412(i), prohibits any person from operating any source in violation of any emission standard, limitation, or regulation promulgated under Section 112 and applicable to such source, and further requires EPA to establish compliance dates for existing sources no later than 3 years after the effective date of such standard, limitation, or regulation.

48. Under 40 C.F.R. § 63.1250(f)(1), Subpart GGG sets forth a compliance date of October 21, 2002, for any owner or operator of an existing source to which Subpart GGG applies.

(a) Wastewater Treatment Process Requirements

49. The Subpart GGG standards for wastewater from a pharmaceutical manufacturing process unit are set forth in 40 C.F.R. § 63.1256.

50. Pursuant to 40 C.F.R. § 60.1256(g)(1), an owner or operator may choose which compliance option under 40 C.F.R. § 60.1256 it wants to use to meet the limits for HAPs concentration in wastewater.

51. Pursuant to 40 C.F.R. §§ 60.1256(g)(7) and 63.1257(e)(2), an owner or operator is required to demonstrate compliance with the applicable HAPs compliance option by conducting either a performance test or a design evaluation.

52. Pursuant to 40 C.F.R. § 63.1257(e)(2)(iii)(A)(2), performance tests must be performed using conditions that are "representative" of the wastewater treatment operating conditions, such as the same inlet flow and pollution concentration.

53. Pursuant to 40 C.F.R. § 63.1256(g)(7), an owner or operator of an affected source may use multiple wastewater treatment processes or control devices to comply with the applicable HAPs control option in 40 C.F.R. § 60.1256.

54. Pursuant to 40 C.F.R. §§ 63.1256(g)(7)(i) or (ii), an owner or operator using a series of wastewater treatment processes ("treatment in series") to reduce or remove HAPs must ensure that either the treatment in series as a whole complies with the applicable HAPs requirements, or that each individual process of the treatment in series independently complies with the applicable HAPs requirements.

55. When using a series of wastewater treatment processes, 40 C.F.R. § 63.1257(e)(2)(iii)(A)(5) requires an owner or operator to conduct a performance

test for the series as a whole—sampling before the first process and after the last process in accordance with 40 C.F.R. § 63.1257(e)(2)(iii)(A(5)(i) — or to conduct a performance test for each individual component of the treatment in series in accordance with 40 C.F.R. § 63.1257(e)(2)(iii)(A(5)(ii).

56. Pursuant to 40 C.F.R. §§ 63.1257(e)(2)(iii)(A), a performance test must account for the HAPs reduction achieved by all components of the treatment in series.

57. Pursuant to 40 C.F.R. § 63.1258(g)(1), to ensure that a wastewater treatment process continues to comply with the HAP emissions limits, an owner or operator must follow the monitoring requirements in Table 7 of Subpart GGG. Pursuant to 40 C.F.R. § 63.1258(g)(3), an owner or operator of a non-biological wastewater treatment process, such as a wastewater stripper, must request approval from EPA to monitor the appropriate parameters which will demonstrate whether or not the treatment process is operating properly.

58. Pursuant to 40 C.F.R. § 63.1260(e), an owner or operator seeking to monitor in a manner different from the approved parameters must request approval from EPA of the alternative monitoring parameters 90 days before the planned change is to be implemented. Pursuant to the general NESHAP provisions in 40 C.F.R. § 63.8(f), an owner or operator must conduct monitoring as set forth in the

relevant standards unless EPA gives permission to use an alternative monitoring procedure.

(b) Condenser Compliance Demonstration Requirements

59. Pursuant to 40 C.F.R. § 63.1257(a), an owner or operator of an affected source must demonstrate compliance with the Pharma MACT standards. Pursuant to 40 C.F.R. § 63.1257(d)(3)(iii)(B), the owner or operator must perform a compliance demonstration on process condensers for all appropriate operating scenarios and document such compliance demonstration in a Notification of Compliance Status report.

(c) Reporting Requirements

60. The Subpart GGG standards for reporting are set forth in 40 C.F.R. § 63.1260.

61. Pursuant to 40 C.F.R. § 63.1260(g), an owner or operator of an affected source must prepare Periodic Reports regarding its HAPs control program. Pursuant to 40 C.F.R. § 63.1260(g)(2)(iv), these reports must contain, *inter alia*, all periods when a vent stream is diverted from a control device through a bypass line.

62. Pursuant to 40 C.F.R. § 63.1260(h), an owner or operator of an affected source must notify EPA of any process changes in its subsequent Periodic Report.

63. Pursuant to 40 C.F.R. § 63.1260(i), an owner or operator must prepare reports of each startup, shutdown, and malfunction of an affected source. Pursuant to 40 C.F.R. § 63.1260(i)(1), these reports are to be submitted on the same schedule as the Periodic Reports.

C. Stratospheric Ozone Protection Regulations

64. EPA promulgated the Stratospheric Ozone Protection Regulations ("Ozone Regulations") in 40 C.F.R. Part 82 for the purpose of controlling the use of substances that deplete the earth's protective stratospheric ozone layer.

65. EPA promulgated the regulations in Subpart F of 40 C.F.R. Part 82 (40 C.F.R. §§ 82.150-82.169 and associated appendices), pursuant to CAA § 608(a)(1), 42 U.S.C. § 7671g(a)(1). Under 40 C.F.R. § 82.150, the purpose of Subpart F of 40 C.F.R. Part 82 is to reduce emissions of ozone-depleting refrigerants and their substitutes by maximizing the recapture and recycling of such refrigerants during the service, maintenance, repair, and disposal of appliances.

66. The ozone-depleting substances addressed by Subpart F of 40 C.F.R. Part 82 are those substances which are listed as Class I or Class II controlled

substances in Appendices A and B of Part 82, Subpart A ("Controlled Substance"). Under 40 C.F.R. § 82.3, the term Controlled Substance includes any Class I or Class II substance, whether existing alone or in a mixture.

67. 40 C.F.R. § 82.152 defines "appliance" as any device containing and using a refrigerant for household or commercial purposes including any air conditioner, refrigerator, chiller or freezer.

68. 40 C.F.R. § 82.152 defines "refrigerant" as any substance consisting "in part or in whole" of a Class I or Class II ozone-depleting substance that is used for heat transfer purposes and provides a cooling effect.

69. 40 C.F.R. §§ 82.156(i)(1) and (2) require owners and operators of commercial and industrial refrigeration appliances containing 50 pounds or more of refrigerant to repair leaks in such equipment within 30 days of discovery if the leaks exceed 35% of the appliance's total refrigerant capacity in a 12-month period.

70. 40 C.F.R. § 82.166(k) requires owners and operators of appliances containing 50 pounds or more of refrigerant to maintain service records documenting the date and type of service, quantity of refrigerant added, and the date when the refrigerant is added.

D. Enforcement of the CAA

71. Section 113(a)(1) of the CAA, 42 U.S.C. 7413(a)(1), authorizes EPA to bring a civil action if the Administrator of EPA finds that any person is in violation of any requirement or prohibition of an applicable permit.

72. Section 113(a)(3) of the CAA, 42 U.S.C. § 7413(a)(3), authorizes EPA to bring a civil action in accordance with CAA § 113(b), 42 U.S.C. § 7413(b), if the Administrator finds that any person is in violation of, *inter alia*, any regulation promulgated or permit issued under Section 112 of the CAA, 42 U.S.C. § 7412, or any regulation promulgated or permit issued under Subchapter V of the CAA (42 U.SC. §§ 7661-7661f) or Subchapter VI of the CAA (42 U.SC. §§ 7671-7671q).

73. Section 113(b) of the CAA, 42 U.S.C. § 7413(b), authorizes EPA to commence a civil action against any person that is an owner or operator of an affected source or a major stationary source who violates, *inter alia*, any regulation promulgated or permit issued under Section 112 of the CAA, 42 U.S.C. § 7412, or any regulation promulgated or permit issued under Subchapter V of the CAA (42 U.SC. §§ 7661-7661f) or Subchapter VI of the CAA (42 U.SC. §§ 7671-7671q).

74. Section 113(b) of the CAA, 42 U.S.C. § 7413(b), authorizes the Court to enjoin a violation, to require compliance, to assess and recover a civil penalty, and to award any other appropriate relief for each violation.

75. Section 113(b) of the CAA, 42 U.S.C. § 7413(b), authorizes civil penalties of up to $25,000 per day for each violation of the CAA. The Debt Collection Improvement Act, 31 U.S.C. § 3701 et seq., requires EPA to periodically adjust its civil penalties for inflation. On December 31, 1996, February 13, 2004, and December 11, 2008, EPA adopted and revised regulations entitled "Adjustment of Civil Monetary Penalties for Inflation," 40 C.F.R. Part 19, to upwardly adjust the maximum civil penalty under the CAA. For each violation that occurs between March 16, 2004 and January 12, 2009, inclusive, penalties of up to $32,500 per day may be assessed. 69 Fed. Reg. 7121 (Feb. 12, 2004); 73 Fed. Reg. 75340 (Dec. 11, 2008).

III. RESOURCE CONSERVATION AND RECOVERY ACT ("RCRA")

A. General Provisions

76. RCRA establishes a comprehensive program to be administered by the Administrator of the EPA for regulating the generation, transportation, treatment, storage, and disposal of hazardous waste under 42 U.S.C. § 6901 – 6992k.

77. Section 1004(5) of RCRA, 42 U.S.C. § 6903(5) defines "hazardous waste" as "a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may: (A) cause, or significantly contribute to an increase in mortality or an increase in

serious irreversible, or incapacitating reversible, illness; or (B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed."

78. Section 1004(34) of RCRA, 42 U.S.C. § 6903(34), defines "treatment" of hazardous waste as "any method, technique, or process, including neutralization, designed to change the physical, chemical, or biological character or composition of any hazardous waste so as to neutralize such waste or so as to render such waste nonhazardous, safer for transport, amenable for recovery, amenable for storage, or reduced in volume. Such term includes any activity or processing designed to change the physical form or chemical composition of hazardous waste so as to render it nonhazardous."

79. Section 1004(33) of RCRA, 42 U.S.C. § 6903(33), defines "storage" of a hazardous waste as "the containment of hazardous waste, either on a temporary basis or for a period of years, in such a manner as not to constitute disposal of such hazardous waste."

80. Section 1004(3) of RCRA, 42 U.S.C. § 6903(3), defines "disposal" as "the discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharged into any waters, including ground waters."

81. Pursuant to its authority under RCRA § 3004(a), 42 U.S.C. § 6924(a), EPA promulgated regulations at 40 C.F.R. Part 260 through 272 which are applicable to owners and operators of hazardous waste treatment, storage, and disposal facilities ("RCRA regulations"). The RCRA regulations generally prohibit treatment, storage, and disposal of hazardous waste without a permit or "interim status." The RCRA regulations prohibit land disposal of certain hazardous wastes and provide detailed requirements to govern the activities of those who are lawfully permitted to store, treat and dispose of hazardous waste.

82. 40 C.F.R. § 260.10 defines "generator" as any person whose act or process produces hazardous waste identified or listed in 40 C.F.R. Part 261 or whose act first causes a hazardous waste to become subject to regulation.

83. 40 C.F.R. § 260.10 defines "owner" as the person who owns a facility or part of a facility.

84. 40 C.F.R. § 260.10 defines "operator" as the person responsible for the overall operation of a facility.

85. 40 C.F.R. § 260.10 defines "person" as, *inter alia*, a firm, joint stock company, corporation, or partnership.

86. 40 C.F.R. § 260.10 defines "hazardous waste" as a hazardous waste as defined in 40 C.F.R. § 261.3.

87. 40 C.F.R. § 260.10 defines "facility" as "all contiguous land, and structures, other appurtenances, and improvements on the land, used for treating, storing, or disposing of hazardous waste" which may consist of several treatment, storage, or disposal operational units.

88. Similar to RCRA, 40 C.F.R. § 260.10 defines "treatment" as "any method, technique, or process, including neutralization, designed to change the physical, chemical, or biological character or composition of any hazardous waste so as to neutralize such waste, or so as to recover energy or material resources from the waste, or so as to render such waste non-hazardous, or less hazardous; safer to transport, store, or dispose of; or amenable for recovery, amenable for storage, or reduced in volume."

89. Similar to RCRA, 40 C.F.R. § 260.10 defines "storage" as "the holding of hazardous waste for a temporary period, at the end of which the hazardous waste is treated, disposed of, or stored elsewhere."

90. 40 C.F.R. § 260.10 adopts RCRA's definition of "disposal" verbatim: "the discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharged into any waters, including ground waters."

91. Pursuant to its authority under RCRA § 3004(n), 42 U.S.C. § 6924(n), EPA promulgated regulations at 40 C.F.R. Part 264 to monitor and control air emissions at hazardous waste treatment, storage, and disposal facilities.

92. Subpart CC of 40 C.F.R. Part 264 (40 C.F.R. §§ 264.1080-264.1091) sets the air emission standards for tanks, surface impoundments, and containers at facilities that treat, store, or dispose of hazardous waste.

93. 40 C.F.R. § 270.1(c) states that RCRA requires a permit for the treatment, storage, and disposal of any hazardous waste as identified or listed in 40 C.F.R. Part 261. Under 40 C.F.R. § 270.30, a RCRA permit holder must comply with all conditions of the issued hazardous waste permit.

94. 40 C.F.R. § 270.1(c)(2)(i) sets forth a 90-day exception to the permit requirement allowing a generator to accumulate hazardous waste on-site in containers or tanks for 90 days or less without a permit so long as such accumulation is in compliance with 40 C.F.R. § 262.34.

95. To be eligible for the 90-day permit exemption, 40 C.F.R. § 262.34 requires a generator to comply with the standards in, *inter alia*, Subparts I, J, and BB of 40 C.F.R. Part 265.

96. Pursuant to 40 C.F.R. § 262.34(b), as incorporated by 25 Pa. Code § 262a.10, a generator who stores hazardous waste for more than 90 days is subject to the permit requirements of 40 C.F.R. Part 270 unless such generator has been

granted an extension to the 90-day period due to unforeseen, temporary, and uncontrollable circumstances.

97. Pursuant to Section 3006 of RCRA, 42 U.S.C. § 6926, EPA may authorize a state to administer a state hazardous waste program in lieu of the federal program when EPA deems the state program to be at least equivalent to the federal RCRA program.

98. In 2000, EPA granted final authorization to Pennsylvania to administer a hazardous waste program. Pennsylvania subsequently promulgated the Pennsylvania Hazardous Waste Regulations ("PaHWR") and, in 2004, EPA re-authorized the hazardous waste program including the PaHWR. The PaHWR which are relevant to this case incorporate the terms of their federal counterparts into the Pennsylvania hazardous waste management program by reference.

B. Enforcement of RCRA

99. Pursuant to Sections 3008(a) and (g) of RCRA, 42 U.S.C. §§ 6928(a) and (g), the United States may enforce the federally-approved Pennsylvania hazardous waste program, as well as the federal regulations that remain effective in Pennsylvania.

100. Section 3008(g) of RCRA, 42 U.S.C. § 6928(g), authorizes civil penalties of up to $25,000 per day of violation of any regulation promulgated under Section 311(j) of the CWA, 33 U.S.C. § 1321(j). The Debt Collection

Improvement Act, 31 U.S.C. § 3701 et seq., requires EPA to periodically adjust its civil penalties for inflation. On December 31, 1996, February 13, 2004, and December 11, 2008, EPA adopted and revised regulations entitled "Adjustment of Civil Monetary Penalties for Inflation," 40 C.F.R. Part 19, to upwardly adjust the maximum civil penalty under RCRA. For each violation that occurs between March 16, 2004 and January 12, 2009, inclusive, penalties of up to $32,500 per day may be assessed. 69 Fed. Reg. 7121 (Feb. 12, 2004); 73 Fed. Reg. 75340 (Dec. 11, 2008).

IV. EMERGENCY PLANNING AND COMMUNITY RIGHT-TO-KNOW ACT ("EPCRA")

A. General Provisions

101. EPCRA was enacted on October 17, 1986, as Title III of the Superfund Amendments and Reauthorization Act of 1986, Pub. L. No. 99-499 (1986) (codified at 42 U.S.C. §§ 11001-11050).

102. The purpose of EPCRA is to provide communities with information on potential chemical hazards within their boundaries and to foster state and local emergency planning efforts to control any accidental releases. Emergency Planning and Community Right-to-Know Programs, Interim Final Rule, 51 Fed. Reg. 41,570 (Nov. 17, 1986).

103. To achieve this end, EPCRA §§ 301 (a) and (c), 42 U.S.C. § 11001(a) and (c), establish a framework of state emergency response commissions ("SERCs") and local emergency planning committees ("LEPCs") to inform the public about the presence of hazardous and toxic chemicals, and to provide for emergency response in the event of a health-threatening release.

104. Sections 304(a) and (b) of EPCRA, 42 U.S.C. §§ 11004(a) and (b), require the owner and operator of a facility at which a hazardous chemical is produced, used, or stored, to immediately notify the SERC and LEPC of releases of reportable quantities of an "extremely hazardous substance" or releases of a " hazardous substance." This notification must be made in accordance with Sections 304(b) and (c) of EPCRA, 42 U.S.C. §§ 11004(b) and (c).

105. Section 329(4) of EPCRA, 42 U.S.C. § 11049(4), and 40 C.F.R. § 355.20 define "facility" to mean, in relevant part, all buildings, equipment, structures, and other stationary items which are located on a single site and that are owned or operated by the same person.

106. Appendices A and B of 40 C.F.R. Part 355 list the minimum amount of reportable quantities of released "extremely hazardous substances" which must be reported to the SERC and LEPC. Table 302.4 of 40 C.F.R. § 302.4 lists the minimum amount of reportable quantities of released "hazardous substances" which must be reported to the SERC and LEPC.

107. 40 C.F.R. Part 355 and 40 C.F.R. § 302.4 identify ammonia as an extremely hazardous substance and hazardous substance, respectively, for which the reportable quantity is 100 pounds.

108. 40 C.F.R. § 302.4 identifies ethylene glycol as a hazardous substance for which the reportable quantity is 5,000 pounds.

109. Section 313 of EPCRA, 42 U.S.C. § 11023, requires the owner or operator of a facility that manufactured, processed, or otherwise used toxic chemicals in excess of certain quantities to complete a toxic chemical release form ("EPA Form R"). Pursuant to EPCRA § 313(c), 42 U.S.C. § 11023(c), the toxic chemicals subject to the release form are those listed in Committee Print Number 99-169 of the Senate Committee on Environment and Public Works, which is titled "Toxic Chemicals Subject to Section 313 of the Emergency Planning and Community Right-To-Know Act of 1986," as well as any of EPA's additions to the list pursuant to EPCRA § 313(d), 42 U.S.C. § 11023(d).

110. The regulations setting forth the requirements for the submission of information pursuant to EPCRA § 313, 42 U.S.C. § 11023, are promulgated in 40 C.F.R. Part 372. These regulations require an owner or operator of a facility that manufactured, processed, or otherwise used a toxic chemical in excess of the quantities established in 40 C.F.R. §§ 372.25, 372.27, or 372.28 in a calendar year to submit the EPA Form R to EPA and to the state in which the facility is located.

40 C.F.R. § 372.30(a). Subpart E of 40 C.F.R. Part 372 requires the reporting facility to certify that the information in the EPA Form R report is "accurate" based on reasonable estimates using information available to the preparer of the report. 40 C.F.R. § 372.85(b)(2).

B. Enforcement of EPCRA

111. Section 325(b)(3) of EPCRA, 42 U.S.C. § 11045(b)(3), provides that any person who violates the notice requirements of Section 304 of EPCRA, 42 U.S.C. § 11004, shall be liable to the United States for civil penalties.

112. Section 325(c)(1) of EPCRA, 42 U.S.C. § 11045(c)(1), provides that any person who violates any requirement of Section 313 of EPCRA, 42 U.S.C. § 11023, shall be liable to the United States for civil penalties.

113. Section 325(b)(3) of EPCRA, 42 U.S.C. § 11045(b)(3), authorizes EPA to assess a civil penalty of up to $25,000 per day of violation of EPCRA Section 304, 42 U.S.C. § 11004, and, in the case of a second or subsequent such violation, $75,000 per day of violation. Section 325(c)(1) of EPCRA, 42 U.S.C. § 11045(c)(1), authorizes EPA to assess a civil penalty of up to $25,000 per day of violation of EPCRA Section 313, 42 U.S.C. § 11023, with each day the violation continues being considered a separate violation for the purpose of penalty assessment. The Debt Collection Improvement Act, 31 U.S.C. § 3701 et seq., requires EPA to periodically adjust its civil penalties for inflation. On December

31, 1996, February 13, 2004, and December 11, 2008, EPA adopted and revised regulations entitled "Adjustment of Civil Monetary Penalties for Inflation," 40 C.F.R. Part 19, to upwardly adjust the maximum civil penalty under EPCRA. For each violation that occurs between March 16, 2004 and January 12, 2009, inclusive, penalties of up to $32,500 per day may be assessed. Additionally, in the case of a second or subsequent violation, for each violation that occurs between March 16, 2004, and January 12, 2009, inclusive, penalties of up to $97,500 per day may be assessed. 69 Fed. Reg. 7121 (Feb. 12, 2004); 73 Fed. Reg. 75340 (Dec. 11, 2008).

V. COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION AND LIABILITY ACT ("CERCLA")

A. General Provisions

114. Section 102(a) of CERCLA, 42 U.S.C. § 9602(a), requires EPA to publish a list of substances designated as hazardous substances which when released into the environment may present substantial danger to public health or welfare or the environment, and to promulgate regulations establishing that quantity of any hazardous substance, the release of which shall be required to be reported under Section 103(a) of CERCLA, 42 U.S.C. § 9603(a) ("Reportable Quantity" or "RQ"). The list of the RQs for hazardous substances is codified at 40 C.F.R. Part 302.

115. 40 C.F.R. § 302.4 identifies ammonia as a hazardous substance for which the reportable quantity is 100 pounds.

116. 40 C.F.R. § 302.4 identifies ethylene glycol as a hazardous substance for which the reportable quantity is 5,000 pounds.

117. Section 103(a) of CERCLA, 42 U.S.C. § 9603(a), as implemented by 40 C.F.R. Part 302, requires, in relevant part, a person in charge of an onshore facility, as soon as he/she has knowledge of a release (other than a federally permitted release) of a hazardous substance from such facility in quantities equal to or greater than the RQ to immediately notify the National Response Center ("NRC") established under Section 311(d)(2)(E) of the CWA, 33 U.S.C. § 1321(d)(2)(E), of such release.

118. Section 101(18) of CERCLA, 42 U.S.C. §9601(18), defines "Onshore facility" as any facility of any kind located in, on, or under, any land or non-navigable waters within the United States.

119. Section 109(c)(1) of CERCLA, 42 U.S.C. § 9609(c)(1), provides that any person who violates the notice requirements of Section 103(a) of CERCLA, 42 U.S.C. § 9603(a), shall be liable to the United States for civil penalties.

B. Enforcement of CERCLA

120. Section 109(c) of CERCLA, 42 U.S.C. § 9609(c), authorizes EPA to assess a civil penalty of up to $25,000 per day of violation, and in the case of a

second or subsequent violation, $75,000 per day of violation of CERCLA Section 103, 42 U.S.C. § 9603. The Debt Collection Improvement Act, 31 U.S.C. § 3701 et seq., requires EPA to periodically adjust its civil penalties for inflation. On December 31, 1996, February 13, 2004, and December 11, 2008, EPA adopted and revised regulations entitled "Adjustment of Civil Monetary Penalties for Inflation," 40 C.F.R. Part 19, to upwardly adjust the maximum civil penalty under CERCLA. For each violation that occurs between March 16, 2004 and January 12, 2009, inclusive, penalties of up to $32,500 per day may be assessed. Additionally, in the case of a second or subsequent violation, for each violation that occurs between March 16, 2004, and January 12, 2009, inclusive, penalties of up to $97,500 per day may be assessed. 69 Fed. Reg. 7121 (Feb. 12, 2004); 73 Fed. Reg. 75340 (Dec. 11, 2008).

FACTUAL ALLEGATIONS

121. Merck is a "person" within the meaning of section 502(5) of the CWA, 33 U.S.C. § 1362(5), section 302(e) of the CAA, 42 U.S.C. § 7602(e), section 1004(15) of RCRA, 42 U.S.C. § 6902(15), section 329 of EPCRA, 42 U.S.C. § 11049(7), and section 101(21) of CERCLA, 42 U.S.C. § 9601(21).

I. RIVERSIDE

122. From 1965 to December 31, 2007, Merck owned and operated the pharmaceutical facility located in Northumberland County, Pennsylvania ("Riverside").

123. In January 2008, Merck sold Riverside to Cherokee Pharmaceuticals and, in September 2010, Merck reacquired Riverside from Cherokee Pharmaceuticals.

124. At all times pertinent to this action, Riverside was a bulk chemical manufacturing site for active pharmaceutical ingredients and other specialty chemicals.

125. At all times pertinent to this action, Merck manufactured pharmaceutical products and other specialty chemicals at Riverside.

126. From February 7, 2006 through February 16, 2006, EPA conducted an on-site inspection of Riverside. At that time, Merck employed approximately 400 people at Riverside.

127. Subsequent to EPA's 2006 inspection of Riverside, EPA sent Merck several information request letters. Merck has provided information to EPA in response to these letters.

Facts Related to CWA Violations

128. Riverside is located on the southern of the North Branch of the Susquehanna River in Pennsylvania.

129. The North Branch of Susquehanna River is a perennial water body that flows into the Susquehanna River which is a traditionally-navigable water body.

130. Pennsylvania has adopted water quality standards designed to protect the beneficial water uses including aquatic life for the North Branch of the Susquehanna River in 25 Pa. Code § 93.9l.

131. The North Branch of the Susquehanna River is a water of the United States.

132. At all times pertinent to this action, Merck was an “industrial user” at Riverside within the meaning of Section 502(18) of the CWA, 33 U.S.C. § 1362(18).

133. Riverside’s NPDES-permitted outfalls are "point sources" which “discharge of pollutants” into "navigable waters" of the United States, all within the respective definitions provided in Section 502(14), (12), and (7) of the Act, 33 U.S.C. § 1362(14), (12), (7).

134. Under the authority of CWA § Section 402(a), 33 U.S.C. § 1342(a), the Pennsylvania Department of Environmental Protection (“PADEP”) issued

NPDES permit No. PA0008419 to Merck for Riverside which expired on September 30, 2009 ("Riverside NPDES Permit") but has been administratively continued. At all times pertinent to this action, the terms of the Riverside NPDES Permit were in full force and effect.

135. At all times pertinent to this action, the Riverside NPDES Permit authorized the discharge of pollutants from Riverside into the Susquehanna River.

136. The Riverside NPDES Permit sets effluent limitations for various pollutants, including Biochemical Oxygen Demand ("BOD"), Chemical Oxygen Demand ("COD"), and pH. The Riverside NPDES Permit also required Merck to monitor for those pollutants at specified frequencies and using specified sampling methodologies.

137. The Riverside NPDES Permit also imposed operation and maintenance requirements upon Merck, namely that Merck at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) which were installed or used to achieve compliance with the terms of the Riverside NPDES Permit. The Riverside NPDES Permit further required Merck to take all reasonable steps to minimize or prevent any discharge, sludge use or disposal in violation of the Permit that has a reasonable likelihood of adversely affecting human health or the environment.

138. At all times pertinent to this action, Merck was required to take samples of treated effluent from the permitted outfalls pursuant to the Riverside NPDES Permit.

139. At all times pertinent to this action, Merck was regulated as a significant industrial user and source of "indirect discharge" of non-domestic wastewater and pollutants from Riverside under Section 307 of the CWA and the implementing regulations covering the Pharmaceutical Manufacturing Point Source Category of the Pharmaceutical Effluent Guidelines and Standards as set forth in Subchapter N of 40 C.F.R. Part 439.

140. At all times pertinent to this action, Merck was the owner and operator of Riverside within the meaning of Section 311(a)(6) of the CWA, 33 U.S.C. § 1321(a)(6), and 40 C.F.R. § 112.2.

141. At all times pertinent to this action, Riverside had an oil storage capacity of more than 57,000 gallons.

142. At all times pertinent to this action, Merck engaged in gathering, storing, using, and consuming oil or oil products at Riverside.

143. At all times pertinent to this action, Riverside was an onshore facility within the meaning of Section 311(a)(10) of the CWA, 33 U.S.C. § 1321(a)(10), and 40 CFR § 112.2.

144. At all times pertinent to this action, Riverside was a non-transportation-related facility within the meaning of 40 C.F.R. § 112.2 which, due to its location, could reasonably be expected to discharge oil to a navigable water of the United States or its adjoining shorelines in a harmful quantity ("SPCC-regulated facility").

145. At all times pertinent to this action, pursuant to 40 C.F.R. § 112.1, Merck was subject to the SPCC regulations as the owner and operator of an SPCC-regulated facility.

146. Merck created an SPCC Plan in for Riverside in November 2005 which was certified by Tracy D. Johnson.

147. Tracy D. Johnson's professional engineering registration in North Carolina expired on December 31, 1998. Tracy D. Johnson was not a registered professional engineer in North Carolina in November 2005.

Facts Related to CAA Violations

148. On July 10, 2001, PADEP issued Merck a Title V operating permit for Riverside (Permit No. 49-0007, "Riverside Title V Permit").

149. At all times pertinent to this action, Condition Number 007 of the Riverside Title V Permit required Merck to: (1) operate and maintain air pollution sources in accordance with specifications in operating permit; and (2) not operate

an air pollution source in a manner that is inconsistent with good operating practices.

150. At all times pertinent to this action, Riverside was an "existing source," and a "major source" of HAPs within the meaning of Section 112(a) of the CAA, 42 U.S.C. § 7412(a).

151. At all times pertinent to this action, Merck was an "owner" and an "operator" of Riverside within the meaning of Section 112(a) of the CAA, 42 U.S.C. § 7412(a).

152. At all times pertinent to this action, Riverside was an "affected source" that engaged in pharmaceutical manufacturing operations within the meaning of 40 C.F.R. §§ 63.1250(a) and 63.1251, and thus was subject to the requirements for pharmaceuticals production in 40 C.F.R. Part 63, Subpart GGG.

153. At all times pertinent to this action, Riverside was subject to the Pharma MACT standards for wastewater as set forth in 40 C.F.R. § 63.1256.

154. At all times pertinent to this action, Merck used a wastewater treatment plant at Riverside to treat its wastewater stream.

155. From at least July 1, 2006 through April of 2007, Merck operated a wastewater stripper at Riverside to remove HAPs from the wastewater stream.

156. From at least July 1, 2006 through April of 2007, wastewater passed through the wastewater stripper and into the wastewater treatment plant at Riverside.

157. From at least July 1, 2006 through April of 2007, Merck applied the HAPs reduction compliance standard in 40 C.F.R. 63.1256(g)(11) to the Riverside wastewater treatment plant.

158. From at least March 14, 2003 to at least June 30, 2006, Merck operated process condensers for HAPs removal at Riverside which were subject to the Pharma MACT monitoring standards in 40 C.F.R. § 63.1257, including process condensers identified as CN-1675, CN-1811, CN-3314, CN-3345, and CN-1234.

159. At all times pertinent to this action, Merck prepared Periodic Reports regarding its HAPs control program at Riverside, as required by 40 C.F.R. § 63.1260(g), which it sent to PADEP. Merck's Periodic Reports for Riverside included some periods when a vent stream was diverted from a HAPs control device through a bypass line. Merck also submitted to PADEP reports of some periods of startup, shutdown, and malfunction of its HAPs control device.

160. At all times pertinent to this action, Merck owned and/or operated appliances which held greater than 50 pounds of refrigerant, as defined by 40 C.F.R. § 82.152, at Riverside. These appliances consisted of commercial

refrigeration appliances, industrial process appliances, and/or comfort cooling appliances.

Facts Related to RCRA Violations

161. At all times pertinent to this action, Merck was an "owner" and "operator" that "treated," "stored," and/or "disposed" of "hazardous waste" at Riverside within the meaning of RCRA § 1004, 42 U.S.C. § 6903, and 40 C.F.R. § 260.10, as incorporated by 25 Pa. Code § 260a.1.

162. At all times pertinent to this action, Riverside was a "facility" within the meaning of 40 C.F.R. § 260.10, as incorporated by 25 Pa. Code § 260a.1, and fell within the scope of RCRA, the regulations promulgated thereunder, and the EPA-approved PaHWR.

163. At all times pertinent to this action, Riverside was subject to the air emission standards for tanks, surface impoundments, and containers in Subpart CC of 40 C.F.R. Part 264 as incorporated by 25 Pa. Code § 264a.1.

164. At all times pertinent to this action, Merck possessed a fluidized bed combustor ("FBC") for the purpose of controlling HAPs emissions for Riverside.

165. At all times pertinent to this action, the FBC was designed to control hazardous emissions from hazardous waste tanks at Riverside.

166. Merck did not operate the Riverside FBC from at least October 19, 2004 through December 31, 2004.

167. Merck did not operate the Riverside FBC from January 2005 through June 2005, and again from November 2005 through December 2005.

168. Merck did not operate the Riverside FBC from January 2006 through January 2008.

Facts Related to EPCRA and CERCLA Violations

169. At all times pertinent to this action, Merck owned and operated Riverside where it used and/or stored ammonia, ethylene glycol, and n-hexane.

170. Ammonia and ethylene glycol are "extremely hazardous substances" within the meaning of 40 C.F.R. Part 355.

171. Ammonia and ethylene glycol are "hazardous substances" within the meaning of 40 C.F.R. § 302.4.

172. N-hexane is a toxic chemical pursuant to EPCRA § 313(c), 42 U.S.C. § 11023(c).

173. At all times pertinent to this action, Merck was subject to the notification requirements in EPCRA §§ 304(a)-(c).

174. On November 30, 2004, Merck released approximately 300 pounds of ammonia from Riverside.

175. On or about August 2, 2007, Merck released between approximately 20,293 and 40,726 pounds, of ethylene glycol from Riverside.

176. On August 2, 2007, Merck released between approximately 13,667 and 23,349 pounds of ethylene glycol from Riverside.

177. Merck did not immediately report the November 30, 2004 ammonia release and the August 2, 2007 ethylene glycol releases in accordance with the notification requirements in Section 304 of EPCRA.

178. At all times pertinent to this action, Merck was subject to the toxic release reporting requirements of 40 C.F.R. § 372.30(a).

179. In its 2004 toxic release report (EPA Form R), Merck stated that Riverside's n-hexane stack emissions were approximately 3,912 pounds.

180. Three years later, in its June 28, 2007 letter to EPA, Merck stated that the correct amount of n-hexane stack emissions for 2004 was 6,183 pounds.

181. From 2004 to 2007, Merck was subject to the notification requirements of CERCLA § 103(a), 42 U.S.C. § 9603(a).

182. Merck did not immediately report the November 30, 2004 ammonia release and the August 2, 2007 ethylene glycol releases in accordance with the notification requirements of CERCLA § 103(a), 42 U.S.C. 9603(a).

II. WEST POINT

183. Currently, and at all times pertinent to this action, Merck owns and operates the West Point facility, located in West Point, Montgomery County,

Pennsylvania ("West Point"). Merck manufactures pharmaceutical products and vaccines at West Point.

184. From November 28, 2006 through December 8, 2006, EPA and PADEP conducted an on-site inspection of West Point.

185. West Point is located approximately 1,475 feet from the Wissahickon Creek in Pennsylvania.

186. Subsequent to EPA's 2006 inspection of West Point, EPA sent Merck several information request letters. Merck has provided information to EPA in response to these letters.

Facts Related to CWA Violations

187. The Wissahickon Creek is a perennial water body that flows into the Schuylkill River, a traditionally navigable water of the United States.

188. The Wissahickon Creek supports an aquatic life habitat and recreational uses including seasonal trout fishing. Immediately downstream of the confluence of the Wissahickon and the Schuylkill River, the City of Philadelphia has a major drinking water intake at Queen Lane Station. Pennsylvania has adopted water quality standards designed to protect the beneficial water use including aquatic life for the Wissahickon Creek in Pennsylvania as set forth in 25 Pa. Code § 93.9f.

189. The Wissahickon Creek is a water of the United States within the meaning of CWA § 502, 33 U.S.C. § 1362.

190. Merck is an "industrial user" at West Point within the meaning of Section 502(18) of the CWA, 33 U.S.C. § 1362(18).

191. West Point's storm water outfalls are "point sources" which "discharge […] pollutants" into "navigable waters," all within the respective definitions provided in Section 502(14), (12), and (7) of the CWA, 33 U.S.C. § 1362(14), (12), (7).

192. On May 3, 2004, PADEP issued NPDES permit No. PA0053538 to Merck for West Point ("West Point NPDES Permit") under the authority of CWA Section 402(a), 33 U.S.C. § 1342(a). The terms of the West Point NPDES Permit were in effect from June 1, 2004 through May 31, 2009.

193. On December 29, 2009, PADEP issued Amendment 1 to the West Point NPDES Permit ("Amendment 1") which is effective from January 1, 2010 through August 30, 2014.

194. The West Point NPDES Permit authorized the discharge of pollutants from West Point into the Wissahickon Creek and Towamencin Creek.

195. The Merck NPDES Permit required Merck to develop a Storm Water Pollution Prevention Plan ("SWPPP") that accurately depicts storm water runoff paths at West Point.

196. The West Point NPDES Permit required Merck to sample discharge from its storm water outfalls.

197. Merck is the owner and operator of West Point within the meaning of Section 311(a)(6) of the CWA, 33 U.S.C. § 1321(a)(6), and 40 C.F.R. § 112.2.

198. From approximately September 2000 to December 2008, Merck had an above-ground oil storage capacity of at least 1,400,000 gallons at West Point.

199. At all times pertinent to this action, Merck engaged in gathering, storing, using, or consuming oil or oil products at West Point.

200. At all times pertinent to this action, West Point was a non-transportation-related facility within the meaning of 40 C.F.R. § 112.2 Appendix A, as incorporated by reference within 40 C.F.R. § 112.2.

201. At all times pertinent to this action, West Point was an onshore facility within the meaning of Section 311(a)(10) of the Act, 33 U.S.C. § 1321(a)(10), and 40 C.F.R. § 112.2.

202. At all times pertinent to this action, West Point was a non-transportation facility which, due to its location, could reasonably be expected to discharge oil to a navigable water of the United States or its adjoining shorelines in a harmful quantity ("SPCC-regulated facility").

203. Merck revised its SPCC Plan for West Point on August 2, 2005.

204. At all times pertinent to this action, Merck did not have an FRP for West Point as required by 40 C.F.R. § 112.20.

205. Merck performed a substantial harm determination for West Point. Merck incorporated the holding capacity of West Point's secondary containment structures in the planning distance calculations it performed for West Point.

206. The Fort Washington State Park is approximately 10 miles downstream from West Point along the Wissahickon Creek.

207. Fort Washington State Park meets the definition of a fish and wildlife sensitive environment pursuant to 40 C.F.R. § 112.2.

208. The Queen Lane Station drinking water intake for the city of Philadelphia is approximately 23 miles downstream of West Point.

Facts Related to CAA Violations

209. Merck owns and/or operates appliances at West Point which hold greater than 50 pounds of Class I or Class II ozone-depleting refrigerant, as defined by 40 C.F.R. § 82.152, at West Point. These appliances consist of commercial refrigeration appliances, industrial process appliances, and/or comfort cooling appliances.

Facts Related to RCRA Violations

210. At all times pertinent to this action, Merck was, and continues to be, an "owner" and "operator" that "treated," "stored," and/or "disposed" of

"hazardous waste" at West Point within the meaning of RCRA § 1004, 42 U.S.C. § 6903, and 40 C.F.R. § 260.10, as incorporated by 25 Pa. Code § 260a.1.

211. At all times pertinent to this action, West Point was, and continues to be, a "facility" within the meaning of 40 C.F.R. § 260.10, as incorporated by 25 Pa. Code § 260a.1, and fell within the scope of RCRA and the EPA-approved PaHWR.

212. On September 19, 2002, PADEP issued Merck a hazardous waste permit for West Point which expires on September 19, 2012 (Permit # PAD002387926, "West Point RCRA Permit").

213. The West Point RCRA Permit allows Merck to store hazardous waste at West Point for up to one year in Building 5.

214. Pursuant to 40 C.F.R. §§ 262.34(a)(1)(i) and (ii), as incorporated by 25 Pa Code § 262a.10, Merck may store hazardous waste in a container or tank without a permit for up to 90 days, so long as Merck follows the requirements of, *inter alia*, Subparts I, J, and BB of 40 C.F.R. Part 265.

215. At all times pertinent to this action, Merck stored hazardous waste in containers in the Building 28 sheds at West Point.

216. At all times pertinent to this action, Merck stored hazardous waste in tank TA-213 at West Point.

217. At all times pertinent to this action, Merck stored hazardous waste in tank TA-140 at West Point.

Claims Pertaining to Riverside

FIRST CLAIM FOR RELIEF

(Failure to Adhere to Effluent Limitations in the Riverside NPDES Permit)

218. Paragraphs 1 through 217 are realleged and incorporated by reference.

219. Riverside is subject to the Effluent Limitations Guidelines and Standards for the pharmaceutical manufacturing point source category as set forth in 40 C.F.R. Part 439.

220. At all times relevant to this action, Merck was required to adhere to the conditions of the Riverside NPDES Permit (No. PA0008419) which set forth the following effluent limitations for Riverside: (1) 15,376 pounds of BOD per day; (2) 29,057 pounds per day of COD; and (3) a pH that is not lower than 6.0.

221. Merck exceeded the effluent limitations for BOD in the Riverside NPDES Permit on July 30, 2007 when Merck's daily BOD value was 19,177 pounds per day.

222. Merck exceeded the effluent limitations for COD in the Riverside NPDES Permit on July 30, 2007 when Merck's daily COD value for July 30, 2007 was 48,831 pounds per day.

223. Merck exceeded the effluent limitations for COD in the Riverside NPDES Permit on July 31, 2007 when Merck's daily COD value for July 31, 2007 was 29,913 pounds per day.

224. Merck exceeded the effluent limitations for pH in the Riverside NPDES Permit on September 15, 2005 when Merck's minimum pH value was 4.4.

225. Merck's exceedences of the effluent limitations in the Riverside NPDES Permit on July 30 and 31, 2007 and September 15, 2005 violated the NPDES permit conditions which are enforceable under CWA § 309, 33 U.S.C. § 1319.

226. Merck's exceedences of the effluent limitations in the Riverside NPDES Permit were discharged into the North Branch of the Susquehanna River, a water of the United States, in violation of CWA § 301(a), 33 U.S.C. § 1311(a).

SECOND CLAIM FOR RELIEF

(Failure to Properly Operate or Maintain Equipment Pursuant to the Riverside NPDES Permit)

227. Paragraphs 1 through 226 are realleged and incorporated by reference.

228. At all times relevant to this action, Merck was required to adhere to the conditions of the Riverside NPDES Permit (No. PA0008419) which was issued pursuant to CWA § 402, 33 U.S.C. § 1342.

229. Part B, Section I(D) of the Riverside NPDES Permit requires Merck to properly operate and maintain all systems of treatment and control used by Merck to comply with the Riverside NPDES Permit.

230. Nine instances of spills, overflows, and/or leaks from such equipment occurred at Riverside on the following dates: November 4, 2005; December 16, 2006; March 16, 2007; March 18, 2007; April 14, 2007; May 19, 2007; May 31, 2007; July 29, 2007; and August 2, 2007.

231. The spills, overflows, and/or leaks discussed in Paragraph 230 were caused by human error such as leaving valves open that should have been closed or incorrectly setting up equipment.

232. Merck's failure to properly operate equipment in accordance with good operating procedures violated Part B, Section I(D) of the Riverside NPDES Permit, enforceable under CWA § 309, 33 U.S.C. § 1319.

THIRD CLAIM FOR RELIEF

(Failure to Mitigate Discharges Pursuant to Riverside NPDES Permit)

233. Paragraphs 1 through 232 are realleged and incorporated by reference.

234. Part B, Section I(E) of the Riverside NPDES Permit required Merck to take all reasonable steps to minimize or prevent any discharge that has a reasonable likelihood of adversely affecting human health or the environment.

235. Six instances of spills and/or overflows occurred on the following dates: September 27, 2005; May 15, 2006; March 16, 2007; March 18, 2007; May 19, 2007; July 29, 2007.

236. The spills and/or leaks discussed in Paragraph 235 were caused by human error.

237. The spills and/or leaks discussed in Paragraph 235 had a reasonable likelihood of adversely affecting health or the environment and could have been prevented.

238. Merck failed to take reasonable steps to prevent the discharges discussed in Paragraph 235.

239. Accordingly, Merck's failure to mitigate the discharges discussed in Paragraph 235 which had a reasonable likelihood of adversely affecting health or the environment was a violation of Part B, Section I(E) of the Riverside NPDES Permit, enforceable under CWA § 309, 33 U.S.C. § 1319.

FOURTH CLAIM FOR RELIEF

(Failure to Properly Certify Riverside SPCC Plan)

240. Paragraphs 1 through 239 are realleged and incorporated by reference.

241. At the time of the violations, Merck owned Riverside which is an SPCC-regulated facility.

242. 40 CFR § 112.3(d) requires that the owner or operator of an SPCC-regulated facility have a licensed Professional Engineer ("PE") who is familiar with the SPCC regulations and through a visit and personal examination or through a visit and examination by his agent is also familiar with the facility review and certify the SPCC plan as having been prepared in accordance with good engineering practice, including consideration of applicable industry standards, and in accordance with the requirements of the SPCC regulations.

243. On November 10, 2005, Tracey D. Johnson certified the Riverside SPCC Plan as a "Registered Professional Engineer" who was licensed as a PE in North Carolina (license number 22075).

244. Tracey D. Johnson's North Carolina PE license expired on December 31, 1998 and has not yet been renewed.

245. Accordingly, Merck's failure to have a licensed PE certify that Riverside's SPCC Plan had been prepared in accordance with good engineering practice, including consideration of applicable industry standards, and in accordance with the requirements of the SPCC regulations, violated 40 C.F.R. § 112.3(d).

FIFTH CLAIM FOR RELIEF

(Inaccurate Prediction of Oil Flow and Path in SPCC Plan for Riverside)

246. Paragraphs 1 through 245 are realleged and incorporated by reference.

247. 40 C.F.R. § 112.3 requires that the owner or operator of an SPCC-regulated facility prepare a written SPCC plan in accordance with 40 C.F.R. § 112.7.

248. Pursuant to 40 C.F.R. § 112.7(b), an SPCC plan must contain a prediction of oil flow, direction, rate, and amount that could be discharged from oil-containing equipment that has a reasonable potential for equipment failure.

249. At all times relevant to this action, Merck owned Riverside which is an SPCC-regulated facility.

250. At all times relevant to this action, there were oil-containing transformers at Riverside.

251. Oil-containing transformers have a reasonable potential for equipment failure.

252. Merck failed to include in the Riverside SPCC plan the prediction of oil flow, direction, rate, and amount from the oil-containing transformers at the following Riverside locations: 69 KV Yard; Substation A; Substation B; Substation C; Substation E; Substation H, Substation J; and Praxair Station in accordance with 40 C.F.R. § 112.7(b) and, therefore, violated 40 C.F.R. § 112.3.

SIXTH CLAIM FOR RELIEF

(Violation of Riverside CAA Title V Permit Condition No. 007)

253. Paragraphs 1 through 252 are realleged and incorporated by reference.

254. At all times pertinent to this action, Riverside was a "major source" as defined within the meaning of CAA § 502(a), 42 U.S.C. § 7661a(a).

255. At all times pertinent to this action, Riverside had multiple pharmaceutical manufacturing process units that were affected sources within the meaning of 40 C.F.R. § 63.1250.

256. Pursuant to CAA § 502(a), 42 U.S.C. § 7661a(a), Merck is required to adhere to the conditions of the Riverside Title V Permit (No. 49-0007).

257. Condition No. 007 of the Riverside Title V Permit requires Merck to maintain the sources of HAPs and "air cleaning devices" in accordance with the specifications in the permit application and the conditions in the plan approval and operating permit. Condition No. 007 of the Riverside Title V Permit also prohibits Merck from operating an air contamination source in a manner inconsistent with good operating practices.

258. Merck failed to properly maintain and/or operate the thermal oxidizer unit ("TOU") and scrubber, both of which are HAPs control devices, on 17 occasions at Riverside between January 6, 2005 and December 19, 2007, including on: January 6, 2005; March 17, 2005; May 18, 2005; May 19, 2005; June 28, 2005; July 26, 2005; October 13, 2005; November 1, 2006; March 4, 2007; March 26, 2007; March 31, 2007; August 16, 2007; October 29, 2007; October 30, 2007; November 29, 2007; December 16, 2007; and December 19, 2007.

259. Merck's improper operation and/or maintenance of the TOU and scrubber discussed in Paragraph 258 resulted in four main types of TOU problems during this time: (1) five incidents of low instrument pressure; (2) four instances of problems resulting from maintenance; (3) four incidents of scrubber pump failure; and (4) four incidents of blower problems.

260. Merck's failure to properly maintain/operate the TOU and scrubber violated Condition 007 of the Riverside Title V Permit and is, therefore, a violation of CAA § 502(a), 42 U.S.C. § 7661a(a).

SEVENTH CLAIM FOR RELIEF

(Failure to Keep Proper Service Records for Riverside Appliances Containing Refrigerant)

261. Paragraphs 1 through 260 are repeated and re-alleged as if set forth fully herein.

262. At all times pertinent to this action, Merck owned and operated the following appliances at Riverside that contained at least 50 pounds of a refrigerant listed as a Controlled Substance Appendices A and B of 40 C.F.R. Part 82, Subpart A: HVAC-AHU1 (B214); CH202 N/S (B229); CU262 A (B262); CH301-12 (B301); CH403 (B303); CH419 (B303); and CH420 (B303).

263. At all times pertinent to this action, under 40 C.F.R. § 82.166(k), Merck was required to maintain servicing records documenting the date and type

of service, quantity of refrigerant added, and the date when the refrigerant is added for appliances containing 50 pounds or more of refrigerants listed as Controlled Substances.

264. In at least 14 instances between December 2, 2004 and December 27, 2005, Merck failed to document in its service records the date and type of service, quantity of refrigerant added, or the date when the refrigerant was added for the appliances identified in Paragraph 262.

265. Merck's failure to maintain adequate service records for the appliances covered by the Ozone Regulations, as identified in Paragraph 262, is a violation of 40 C.F.R. § 82.166(k).

EIGHTH CLAIM FOR RELIEF

(Failure to Conduct Performance Test on Riverside Wastewater Treatment in Series)

266. Paragraphs 1 through 265 are realleged and incorporated by reference.

267. At all times pertinent to this action, Riverside was subject to the Pharma MACT standards for wastewater from a pharmaceutical manufacturing process unit as set forth in 40 C.F.R. § 63.1256.

268. The performance standards for treatment processes managing wastewater and/or residuals removed from wastewater are set forth in 40 C.F.R. § 63.1256(g). In particular, 40 C.F.R. § 63.1256(g)(7) sets forth standards specific to

an owner or operator using a "series" of HAPs treatment processes for a wastewater stream and includes an option to measure compliance across all treatment units in the series.

269. When using a series of wastewater treatment processes, 40 C.F.R. § 63.1257(e)(2)(iii)(A)(5) requires an owner or operator to conduct a performance test for the series as a whole.

270. From at least July 1, 2006 through April of 2007, Merck sent Riverside's wastewater stream through the wastewater stripper and into the wastewater treatment plant.

271. From at least July 1, 2006 through April of 2007, Merck operated the wastewater stripper to remove HAPs from the wastewater stream flowing through it. The wastewater from the wastewater stripper then flowed to the wastewater treatment plant.

272. From at least July 1, 2006 through April of 2007, Merck operated the wastewater treatment plant at Riverside on a continual basis to treat the HAPs it received in the wastewater stream coming from the wastewater stripper.

273. From at least July 1, 2006 through April of 2007, Merck operated the wastewater stripper and wastewater treatment plant at Riverside as a HAPs treatment in series.

274. From at least July 1, 2006 through April of 2007, Merck applied the wastewater treatment standard found in 40 C.F.R. § 63.1256(g)(11) to the wastewater treatment plant.

275. In or around early 2006, Merck conducted a performance test on the wastewater treatment plant.

276. Merck did not operate the wastewater stripper during the 2006 performance test.

277. Merck did not conduct a performance test on the wastewater stripper.

278. Merck violated 40 C.F.R. § 63.1256(g)(7) when it did not conduct a performance test across the entire treatment in series, either in whole or across each treatment unit comprising the series, as required by 40 C.F.R. §§ 63.1256(g)(7)(i) and (ii) and 40 C.F.R. § 63.1257(e)(2)(iii)(A)(5).

279. Merck's failure to conduct the performance test accounting for the wastewater stripper resulted in violations of three additional regulations: (1) Merck violated 40 C.F.R. § 63.1257(e)(2)(iii)(A)(2) because it did not operate the wastewater stripper during the performance test of the treatment in series, thereby failing to utilize the "representative treatment process operating conditions" (i.e. having wastewater go through the stripper and then to the treatment plant); (2) Merck violated 40 C.F.R. § 63.1257(e)(2)(iii)(A)(5) because it failed to execute the performance test as required for a treatment in series; and (3) Merck violated 40

C.F.R. § 63.1258(g)(3) when it failed to obtain EPA approval of its monitoring parameters for the wastewater stripper as a treatment in series.

NINTH CLAIM FOR RELIEF

(Failure to Perform Initial Compliance Demonstration Based on Actual Operating Scenario of Condensers)

280. Paragraphs 1 through 279 are realleged and incorporated by reference.

281. 40 C.F.R. § 63.1257(d)(3)(iii)(B) requires an owner or operator subject to the Pharma MACT standards to perform a compliance demonstration on process condensers for all appropriate operating scenarios and documented in the Notification of Compliance Status report.

282. On or about July 26, 2001, Merck performed compliance demonstrations for CN-780 and CN-785 using water instead of the HAPs used in its operating process.

283. On March 14, 2003, Merck reported to EPA that the operating scenario for condensers CN-780 and CN-785 involves HAPs.

284. On June 8, 2007, Merck performed another compliance demonstration for CN-780 and CN-785 using the actual operating scenario conditions.

285. Because water is not the primary operating scenario for CN-780 and CN-785, Merck failed to perform the initial compliance demonstrations for CN-

780 and CN-785 based on the actual HAPs operating scenario from at least October 19, 2004 to June 8, 2007 in violation of 40 C.F.R. § 63.1257.

TENTH CLAIM FOR RELIEF

(Failure to Report All Incidents of HAPs Stream Bypass for Riverside)

286. Paragraphs 1 through 285 are realleged and incorporated by reference.

287. 40 C.F.R. § 63.1260(g)(2)(iv) requires an owner or operator subject to the Pharma MACT, to report in its Pharma MACT Periodic Reports all incidents where a HAPs stream was diverted from a HAPs control device to the atmosphere.

288. In 2005, Merck did not include in its Periodic Reports to PADEP at least one instance of HAPs bypassing the TOU, a HAPs control device, and being diverted directly to the atmosphere. This incident is identified in Merck incident report number TN8523.

289. Merck violated 40 C.F.R. § 63.1260(g)(2)(iv) when it failed to include in its Periodic Reports the incident in which a HAPs stream was diverted from the TOU, a HAPs control device, to the atmosphere as discussed in Paragraph 288.

ELEVENTH CLAIM FOR RELIEF

(Failure to Report Incidents of Startup, Shutdown, and Malfunction of HAPs Control Devices)

290. Paragraphs 1 through 289 are realleged and incorporated by reference.

291. 40 C.F.R. §§ 63.1260(i)(1) and (2) require an owner or operator subject to the Pharma MACT to report all incidents of startup, shutdown, and malfunction of its HAPs control program.

292. Between 2005 and 2007, Merck did not include at least two incidents of shutdown and/or malfunction in its Periodic Reports regarding the Riverside HAPs control program.

293. Merck violated 40 C.F.R. §§ 63.1260(i)(1) and (2) when it failed to report the two incidents of shutdown and/or malfunction identified in the following Merck incident reports: TN8425 and TN8523.

TWELFTH CLAIM FOR RELIEF

(Failure to Correct Malfunction of Hazardous Waste Control Device at Riverside)

294. Paragraphs 1 through 293 are realleged and incorporated by reference.

295. Pursuant to 40 C.F.R. § 264.1087(c)(2)(v), as incorporated by 25 Pa. Code § 264a.1, if a HAPs emissions control device malfunctions, an owner or operator must fix the malfunction as soon as practicable to minimize the release of pollutants.

296. Merck's FBC, a HAPs emissions control device, was not operational for at least two months in 2004 (October 19, 2004 to December 31, 2004) and at least six months in 2005 (January 1, 2005 to June 30, 2005).

297. Upon information and belief, the FBC was not functioning properly due to an extended malfunction.

298. Merck violated 40 C.F.R. § 264.1087(c)(2)(v), as incorporated by 25 Pa. Code § 264a.1, when it failed to fix the FBC malfunction as soon as practicable during the eight-and-a-half months that the FBC was not operational.

THIRTEENTH CLAIM FOR RELIEF

(Failure to Operate the Riverside Control Device while the Level 1 Tanks Associated with It Were Managing Hazardous Waste)

299. Paragraphs 1 through 298 are realleged and incorporated by reference.

300. The emissions standards for tanks managing hazardous waste are set forth in 40 C.F.R. § 264.1084, as incorporated by 25 Pa. Code § 264a.1. These regulations create two tank categories with differing emissions requirements: Level 1 tanks and Level 2 tanks.

301. The emissions standards for a Level 1 tank managing hazardous waste are set forth in 40 C.F.R. §§ 264.1084(c)(1)-(4), as incorporated by 25 Pa. Code § 264a.1. These standards include a requirement that each Level 1 tank have a fixed roof with no open spaces, 40 C.F.R. § 264.1084(c)(2)(ii), and a requirement that each opening in the roof be equipped with a closure device or be vented to a closed-vent system that is vented to an emissions control device, 40 C.F.R. § 264.1084(c)(2) (iii).

302. Under 40 C.F.R. § 264.1084(c)(2)(iii)(B), for Level 1 tanks that are connected by a closed-vent system to a control device, the control device must remove or destroy air pollutants in the vent stream and the control device must be operating whenever the Level 1 tanks are managing hazardous wastes.

303. Tanks TA-931, 932, 934, and 935 are Level 1 tanks that manage hazardous waste.

304. Upon information and belief, tank TA-900 is a Level 1 tank that manages hazardous waste.

305. Tanks TA-900, 931, 932, 934, and 935 have fixed roofs which are connected to a closed vent system that vents to the FBC.

306. The FBC is the air emissions control device associated with tanks TA-900, 931, 932, 934, and 935.

307. Merck shut down its FBC, an air emissions control device, for at least two months in 2004 (October 19, 2004 to December 31, 2004) and at least eight months in 2005 (January 1, 2005 to June 30, 2005 and from November 3, 2005 to December 31, 2005); and Merck shut down the FBC indefinitely from January 2006 until it sold Riverside in January 2008.

308. The FBC was not operating while it was shut down from 2004 through 2007.

309. Tank TA-900 managed hazardous waste from at least October 19, 2004 through October 22, 2005.

310. Tank TA-931 managed hazardous waste from at least October 19, 2004 through October 2, 2006.

311. Tank TA-932 managed hazardous waste from at least October 19, 2004 through May 19, 2006.

312. Tank TA-934 managed hazardous waste from at least October 19, 2004 through November 4, 2005.

313. Tank TA-935 managed hazardous waste from at least October 19, 2004 through November 10, 2005.

314. Merck vented hazardous fumes, vapors, and/or gases from tank TA-900, TA-931, TA-932, TA-934, and/or TA-935 to the atmosphere through Conservation Vent CV-101 ("CV-101") for approximately 2,799 minutes from October 19, 2004 through December 31, 2007.

315. Merck violated 40 C.F.R. § 264.1084(c)(2)(iii)(B), as incorporated by 25 Pa. Code § 264a.1, when it failed to operate the FBC while tanks TA-900, 931, 932, 934, and 935 managed hazardous waste periodically from October 19, 2004 through December 31, 2007.

FOURTEENTH CLAIM FOR RELIEF

(Failure to Notify Emergency Responders of Ammonia Leak above RQ from Riverside)

316. Paragraphs 1 through 315 are realleged and incorporated by reference.

317. At all times pertinent to this action, Merck owned and operated Riverside where it used and/or stored ammonia.

318. Ammonia is an "extremely hazardous substance" pursuant to 40 C.F.R. Part 355, Appendix A.

319. At all times pertinent to this action, Merck was subject to the notification requirements in EPCRA §§ 304(a)-(c), 42 U.S.C. §§ 11004(a)-(c).

320. On November 30, 2004, Merck released approximately 300 pounds of ammonia from Riverside, which was above the 100-pound RQ.

321. Merck contacted the Northumberland Emergency Management Agency ("NCEMA") about the ammonia spill 125 minutes after Merck was aware of the spill.

322. Merck did not contact the Pennsylvania Emergency Management Agency ("PEMA") about the ammonia spill.

323. Merck did not send a written follow-up to NCEMA or PEMA about the ammonia release until 2007.

324. Merck violated EPCRA §§ 304(a)-(c), 42 U.S.C. §§ 11004(a)-(c), when it failed to immediately contact NEMA and PEMA about the ammonia spill above the RQ and when it failed to send written notice to NEMA and PEMA in a timely manner.

FIFTEENTH CLAIM FOR RELIEF

(Failure to Notify Emergency Bodies of Ethylene Glycol Leaks above RQ from Riverside)

325. Paragraphs 1 through 324 are realleged and incorporated by reference.

326. At all times pertinent to this action, Merck owned and operated Riverside where it used and/or stored ammonia, ethylene glycol, and n-hexane.

327. Ethylene glycol is a "hazardous substance" pursuant to 40 C.F.R. § 302.4 that requires notification of a release under CERCLA § 103(a), 42 U.S.C. § 9603(a).

328. At all times pertinent to this action, Merck was subject to the notification requirements in EPCRA §§ 304(a)-(c), 42 U.S.C. §§ 11004(a)-(c).

329. On or about August 2, 2007, Merck released between approximately 20,293 and 40,726 pounds of ethylene glycol from Riverside and into the North Branch of the Susquehanna River, over the 5,000-pound RQ.

330. Merck contacted NCEMA and PEMA about 2 hours after Merck was aware of the spill.

331. On August 2, 2007, Merck had an additional release of between approximately 13,667 and 23,349 pounds of ethylene glycol from Riverside, over the 5,000-pound RQ. Merck did not report this spill to NCEMA and/or PEMA.

332. Merck violated EPCRA §§ 304(a)-(c), 42 U.S.C. §§ 11004(a)-(c), when it failed to immediately contact NEMA and/or PEMA about the ethylene spills above the RQ on August 2, 2007.

SIXTEENTH CLAIM FOR RELIEF

(Failure to Accurately Report Toxic Chemical Use for n-Hexane at Riverside)

333. Paragraphs 1 through 332 are realleged and incorporated by reference.

334. At all times pertinent to this action, Merck owned and operated Riverside where it used and/or stored n-hexane.

335. 40 C.F.R. § 372.30(a) requires an owner or operator of a facility that manufactured, processed, or otherwise used a toxic chemical in excess of the quantities established in 40 C.F.R. §§ 372.25, 372.27, or 372.28 in a calendar year to submit a toxic chemical release form, known as "EPA Form R," to EPA and to the state in which the facility is located.

336. 40 C.F.R. § 372.85(b)(2) requires the reporting facility to certify that the information in the Form R report is "accurate" based on reasonable estimates using information available to the preparer of the report.

337. N-hexane is a toxic chemical pursuant to EPCRA § 313(c), 42 U.S.C. § 11023(c).

338. At all times pertinent to this action, Merck was subject to the toxic release reporting requirements of 40 C.F.R. § 372.30(a).

339. In its 2004 EPA Form R report, Merck stated that Riverside's n-hexane stack emissions were approximately 3,912 pounds.

340. On June 28, 2007, Merck stated that the correct amount of n-hexane stack emissions for 2004 was 6,183 pounds.

341. Merck violated EPCRA § 313, 42 U.S.C. § 11023, and 40 C.F.R. § 372.30(a) when it failed to accurately report Riverside's n-hexane emissions in its 2004 Form R report.

SEVENTEENTH CLAIM FOR RELIEF

(Failure to Notify the NRC of Ammonia Leak above RQ from Riverside)

342. Paragraphs 1 through 341 are realleged and incorporated by reference.

343. At all times pertinent to this action, Merck owned and operated Riverside where it used and/or stored ammonia.

344. Ammonia is a "hazardous substance" pursuant to 40 C.F.R. § 302.4.

345. At all times pertinent to this action, Merck was subject to the notification requirements of CERCLA § 103(a), 42 U.S.C. § 9603(a).

346. On November 30, 2004, Merck released approximately 300 pounds of ammonia from Riverside which was over the 100-pound RQ for ammonia.

347. Merck contacted the NRC 52 minutes after Merck was aware of the spill.

348. Merck violated CERCLA § 103(a), 42 U.S.C. § 9603(a), when it failed to immediately contact the NRC about the ammonia spill above the RQ on November 30, 2004.

EIGHTEENTH CLAIM FOR RELIEF

(Failure to Properly Notify the NRC of Ethylene Glycol Spills from Riverside)

349. Paragraphs 1 through 348 are realleged and incorporated by reference.

350. At all times pertinent to this action, Merck owned and operated Riverside where it used and/or stored ethylene glycol.

351. Ethylene glycol is a "hazardous substance" pursuant to 40 C.F.R. § 302.4.

352. At all times pertinent to this action, Merck was subject to the notification requirements of CERCLA § 103(a), 42 U.S.C. § 9603(a).

353. On or about August 2, 2007, Merck released between approximately 20,293 and 40,726 pounds of ethylene glycol from Riverside and into the North Branch of the Susquehanna River, over the 5,000-pound RQ. Merck contacted the NRC about two hours after Merck was aware of the spill.

354. On August 2, 2007, Merck had an additional release of approximately 23,349 pounds of ethylene glycol from Riverside, over the 5,000-pound RQ. Merck did not report this spill to the NRC.

355. Merck violated CERCLA § 103(a), 42 U.S.C. § 9603(a), when it failed to immediately contact the NRC about the ethylene glycol spills above the RQ on August 2, 2007.

Claims Pertaining to West Point

NINETEENTH CLAIM FOR RELIEF

(Inaccurate Storm Water Flow in SWPPP for West Point)

356. Paragraphs 1 through 355 are realleged and incorporated by reference.

357. Pursuant to 40 C.F.R. § 122.26(a) and Title 25, Chapter 91 of the Pennsylvania Clean Streams Law, dischargers of storm water associated with industrial activity are required to seek coverage under a NPDES permit.

358. Pursuant to 40 C.F.R. § 122.26(b)(14), industrial activity requiring a permit for storm water discharges includes, *inter alia*, material handling activities such as storage, loading and unloading, transportation, or conveyance of any raw material, intermediate product, final product, by-product, or waste product.

359. 40 C.F.R. § 122.26(c)(1)(i)(A) requires dischargers of storm water associated with industrial activity to submit an NPDES permit application including a topographic map of the site or, if a topographic map is unavailable, a

map showing, *inter alia*, the outline of drainage areas served by the outfalls covered in the NPDES permit application and, more specifically, the drainage area of each storm water outfall.

360. Part C, Section 6(d)(1) of NPDES Permit No. PA0053538 requires Merck to create a SWPPP that identifies potential sources of pollution that may reasonably be expected to affect the quality of storm water discharges from West Point.

361. Merck engages in industrial activity at West Point that requires a storm water permit.

362. PADEP issued Merck the West Point NPDES Permit (No. PA0053538) pursuant to CWA § 402, 33 U.S.C. § 1342 which was effective from June 1, 2004 through May 31, 2009.

363. Industrial activities occur in and around West Point Building 68 that could reasonably be expected to affect the quality of storm water discharges from West Point.

364. From at least October 19, 2004 to January 1, 2010, Merck's SWPPP incorporated a map entitled "West Point PA Site Plan Stormwater Runoff Areas and Storm Sewer System" ("Drainage Map").

365. From at least October 19, 2004 to January 1, 2010, the Drainage Map incorporated into Merck's SWPPP, as referenced in Paragraph 364, depicted storm

water drainage from the Building 68 area flowing to Detention Basin 4, which drains to the storm water compliance monitoring point known as Outfall 001.

366. In 2006, EPA observed that storm water drainage from and around Building 68 did not flow to Outfall 001 but instead flowed to a discharge point downstream of Outfall 001.

367. From at least November of 2006 to present, storm water drainage from and around Building 68 has flowed to a separate discharge point that is downstream of Outfall 001.

368. From at least October 19, 2004 to January 1, 2010, Merck's SWPPP inaccurately described the storm water path from Building 68.

369. Merck's failure to accurately describe the storm water drainage path from Building 68 in the West Point SWPPP is a violation of Part C, Section 6(d)(1) of the West Point NPDES Permit which is enforceable under CWA § 309, 33 U.S.C. § 1319.

TWENTIETH CLAIM FOR RELIEF

(Unpermitted Discharging of Storm Water)

370. Paragraphs 1 through 369 are realleged and incorporated by reference.

371. Pursuant to 40 C.F.R. § 122.26(a) and Title 25, Chapter 91 of the Pennsylvania Clean Streams Law, dischargers of storm water associated with industrial activity are required to seek coverage under an NPDES permit.

372. Industrial activities occur in and around West Point Building 68 that could reasonably be expected to affect the quality of storm water discharges from West Point.

373. From at least November of 2006 to January 1, 2010, Merck represented to PADEP that its storm water sampling at Outfall 001 included storm water drainage associated with Building 68.

374. From at least November of 2006 to present, storm water drainage from and around Building 68 has flowed to a separate discharge point that is downstream of Outfall 001.

375. From at least November of 2006 to present, Merck has not performed storm water sampling of the outfall associated with the storm water drainage from the Building 68 area.

376. From at least November 2006 to January 1, 2010, Merck's storm water discharge from the outfall associated with Building 68 was not covered by NPDES permit No. PA0053538.

377. From at least November 2006 to January 1, 2010, Merck violated 40 C.F.R. § 122.26(a) when it discharged storm water from the outfall associated with the Building 68 area without authorization from an NPDES permit.

TWENTY-FIRST CLAIM FOR RELIEF

(Violation of Storm Water Outfall Sampling Requirements in the West Point NPDES Permit)

378. Paragraphs 1 through 377 are realleged and incorporated by reference.

379. PADEP issued NPDES permit No. PA0053538 to Merck for West Point pursuant to CWA Section 402(a), 33 U.S.C. § 1342(a).

380. The West Point NPDES Permit requires Merck to sample discharge from storm water outfalls 001, 002, and 003 for phosphorous using a composite sample.

381. Part A(II) of the West Point NPDES Permit requires all "composite" storm water samples to consist of a combination of individual samples consisting of at least 100 milliliters and taken at regular intervals over either an eight- or 24-hour period.

382. Part A(III)(A)(4) of the West Point NPDES Permit requires storm water samples to be tested using methods approved under 40 C.F.R. Part 136.

383. Table IB of 40 C.F.R. § 136.3 sets forth the approved test methods for testing samples for phosphorous. The appropriate test methods for phosphorous are identified as EPA methods 365.3, 365.1, or 365.4.

384. During its storm water phosphorous sampling from at least October of 2004 to June of 2006, Merck used 50 milliliter samples for its phosphorous

sampling of outfalls 001 and 002. Merck failed to pull a composite sample comprised of 100 milliliter-individual samples as required by Part A(II) of the West Point NPDES Permit.

385. During its storm water phosphorous sampling from at least October of 2004 to September of 2006, Merck used nitric acid (HNO_3) to preserve its phosphorous sampling of outfalls 001 and 002. During its storm water phosphorous sampling from at least October of 2006 to December of 2006, Merck used nitric acid (HNO_3) to preserve its phosphorous sampling of outfall 003.

386. Merck used test method 200.7 for its phosphorous sampling of outfall 001 and outfall 002 from at least October of 2004 to September of 2006 and for its phosphorous sampling of outfall 003 from at least October of 2006 to December of 2006.

387. Because Merck used nitric acid (HNO_3) instead of sulfuric acid (H_2SO_4) to preserve its phosphorous samples, Merck failed to preserve the samples discussed in Paragraphs 384 and 385 according to Table II of 40 C.F.R. § 136.3.

388. Merck did not use EPA test methods 365.3, 365.1, or 365.4, as required by Table IB of 40 C.F.R. § 136.3, for the sampling events discussed in Paragraphs 398 through 400.

389. Merck's failure to follow the requirements set forth in Part A(II) and Part A(III)(A)(4) of the West Point NPDES Permit regarding volume, type,

temperature, and test method for its storm water sampling at outfalls 001, 002, and 003, as discussed in Paragraphs 384 through 386, is a violation of its NPDES permit, which is enforceable under CWA § 309, 33 U.S.C. § 1319.

TWENTY-SECOND CLAIM FOR RELIEF

(Failure to Identify Location of Oil-Containing 55-Gallon Drums in West Point SPCC Plan)

390. Paragraphs 1 through 389 are realleged and incorporated by reference.

391. Merck did not identify in its SPCC Plan the location of several 55-gallon drums of oil that were observed by EPA during the 2006 inspection.

392. Merck's 2006 SPCC Plan for West Point was not prepared in accordance with 40 C.F.R. § 112.7(b) because it did not include the location of each oil container.

393. Merck's failure to adequately prepare an SPCC Plan for West Point in accordance with 40 C.F.R. § 112.7(b) as discussed in Paragraph 391 violated 40 C.F.R. § 112.3.

TWENTY-THIRD CLAIM FOR RELIEF

(Failure to Identify Storage Capacity of Each Oil Container at West Point in the SPCC Plan)

394. Paragraphs 1 through 393 are realleged and incorporated by reference.

395. At all times pertinent to this action, Merck's SPCC Plan for West Point identified the storage capacity of Tank B-2 as 600 gallons.

396. Tank B-2 has an oil storage capacity of approximately 1,260 gallons.

397. Merck did not accurately identify the storage capacity of Tank B-2 in its SPCC plan for West Point as required by 40 C.F.R. § 112.7(b).

398. Merck's failure to adequately prepare an SPCC Plan for West Point in accordance with 40 C.F.R. § 112.7(b) is a violation 40 C.F.R. § 112.3.

TWENTY-FOURTH CLAIM FOR RELIEF

(Failure to have an FRP for West Point)

399. Paragraphs 1 through 398 are realleged and incorporated by reference.

400. 40 C.F.R. § 112.20(a) sets forth the requirements for determining whether a facility is a substantial harm facility and therefore needs an FRP.

401. Pursuant to Section 5.0 of Attachment C-III to Appendix C of 40 C.F.R. Part 112, the planning distance that applies to West Point when determining whether it is a substantial harm facility is 29 miles downstream along the Wissahickon Creek.

402. From approximately September 2000 to December 2008, West Point had an oil storage capacity of at least 1,400,000 gallons.

403. West Point is less than ¼ mile away from the Wissahickon Creek.

404. West Point is approximately 10 miles upstream from Washington Crossing State Park, a New Jersey state park along the banks of the Wissahickon Creek.

405. Approximately 23 miles downstream from West Point is the City of Philadelphia drinking water intake at Queen Lane Station.

406. At all times that West Point had an oil storage capacity of more than 1,000,000 gallons, it was a substantial harm facility because its proximity to the fish and wildlife sensitive environments and a public drinking water intake makes it so that an oil spill could reasonably have been expected to cause "substantial harm" to the environment by discharging oil to the Wissahickon Creek pursuant to 40 C.F.R. § 112.20(a).

407. At all times that West Point had an oil storage capacity of more than 1,000,000 gallons, West Point was a substantial harm facility that required an FRP.

408. At all times pertinent to this action, Merck did not have an FRP for West Point.

409. Merck violated 40 C.F.R. § 112.20(a) because it did not have an FRP for West Point when it was a substantial harm facility.

TWENTY-FIFTH CLAIM FOR RELIEF

(Failure to Implement FRP Training Drills and Exercise Program at West Point)

410. Paragraphs 1 through 409 are realleged and incorporated by reference.

411. At all times that West Point had an oil storage capacity of more than 1,000,000 gallons, West Point was a substantial harm facility that required an FRP pursuant to 40 C.F.R. § 112.20(a).

412. A facility falling under the FRP requirement must also perform response training and drills, pursuant to 40 C.F.R. § 112.21(a).

413. Merck did not perform FRP training drills and exercise programs while it had an oil storage capacity of more than 1,000,000 gallons.

414. Merck violated 40 C.F.R. § 112.21(a) when Merck failed to implement the FRP training drills and exercise programs while it was a substantial harm facility requiring an FRP.

TWENTY-SIXTH CLAIM FOR RELIEF

(Failure to Repair West Point Refrigerant Leak in a Timely Manner)

415. Paragraphs 1 through 414 are realleged and incorporated by reference.

416. At all times pertinent to this action, Merck owned and operated appliances at West Point that contained at least 50 pounds of a refrigerant listed as a Controlled Substance Appendices A and B of 40 C.F.R. Part 82, Subpart A.

417. Under 40 C.F.R. § 82.156(i)(1), Merck was required to repair leaks in the commercial refrigerant appliances containing refrigerants listed as Controlled Substances within 30 days of discovery if the leaks exceed 35% of the appliance's total refrigerant capacity in a 12-month period.

418. Cold Vault 147 #2 in Building 1 is a commercial refrigeration system that contains at least 55 pounds of HCFC 401A which is a Controlled Substance pursuant to 40 C.F.R. § 82.3.

419. On January 20, 2006, Merck discovered that the Cold Vault 147 #2 unit was leaking more than 35% of its full charge of refrigerant.

420. Merck did not fix the refrigerant leak in Cold Vault 147 #2 until March of 2006, more than 30 days after discovering it.

421. In 2006, Cold Vault 147 #2 leaked at least 20 pounds of HCFC 401A, a Controlled Substance, and Merck did not repair the leak within 30 days of its discovery.

422. Merck's failure to repair the refrigerant leak from Cold Vault 147 #2 in 2006 within 30 days, as discussed in Paragraphs 419-421, was a violation of 40 C.F.R. § 82.156(i)(1).

TWENTY-SEVENTH CLAIM FOR RELIEF

(Failure to Keep Proper Service Records for Refrigerant-Containing Appliances at West Point)

423. Paragraphs 1 through 422 are realleged and incorporated by reference.

424. At all times pertinent to this action, Merck owned and operated the following appliances at West Point that contain at least 50 pounds of a refrigerant listed as a Controlled Substance Appendices A and B of 40 C.F.R. Part 82, Subpart A: Cold Vault 147 #2 (B1); Chiller #2 (B29); Chiller #1 (B60); AC (B62); ACCH2 SYS2 (B69); and ACCH1 SYS1 (B69).

425. At all times pertinent to this action, under 40 C.F.R. § 82.166(k), Merck was required to maintain servicing records documenting the date and type of service, quantity of refrigerant added, and the date when the refrigerant is added for appliances containing 50 pounds or more of refrigerants listed as Controlled Substances.

426. In at least six instances between November 10, 2004 and August 10, 2006, Merck failed to document in its service records the date and type of service, quantity of refrigerant added, or the date when the refrigerant was added for the appliances identified in Paragraph 424.

427. Merck's failure to maintain adequate service records for the appliances covered by the Ozone Regulations, as identified in Paragraph 424, is a violation of 40 C.F.R. § 82.166(k).

TWENTY-EIGHTH CLAIM FOR RELIEF

(Violation of One-Year Storage Condition of the West Point RCRA Permit)

428. Paragraphs 1 through 428 are realleged and incorporated by reference.

429. At all times pertinent to this action, Merck was a generator that treated, stored, and/or disposed of hazardous waste at West Point within the meaning of RCRA § 1004, 42 U.S.C. § 6903, and 40 C.F.R. § 260.10, as incorporated by 25 Pa Code § 260a.1.

430. 40 C.F.R. § 270.1(c), as incorporated by 25 Pa. Code § 270a.1, prevents owners and operators of a facility from treating, storing, and/or disposing of any hazardous waste without a permit.

431. On September 19, 2002, PADEP issued Merck a hazardous waste permit for West Point (Permit # PAD00238792) allowing Merck to store hazardous waste at West Point for up to one year in Building 5. This permit expires on September 19, 2012.

432. Under 40 C.F.R. § 270.30, as incorporated by 25 Pa. Code § 270a.1, Merck must comply with all conditions of the West Point hazardous waste permit.

433. From at least 2005 through November 2006, Merck used faulty re-labeling practices for consolidated drums of hazardous waste at West Point. Merck consolidated various smaller containers of hazardous waste into large containers for storage in Building 5. Merck placed an accumulation start date on the smaller containers of waste when they were generated. When Merck moved the small containers to Building 5, it consolidated the small containers into larger containers of hazardous waste and placed a new accumulation start date on the larger drum which reflected the later date on which the small containers were consolidated into one large container.

434. Merck tracked the dates that containers of hazardous waste were received in Building 5 from other areas of West Point.

435. Merck tracked the dates that the containers of hazardous waste in Building 5 were shipped off-site from West Point.

436. At least six shipments of hazardous waste from West Point in 2005 consisted of multiple containers of hazardous waste that Merck stored in Building 5 for more than one year.

437. Merck violated 40 C.F.R. §270.30(a), as incorporated by 25 Pa. Code § 270a.1, because it failed to comply with the storage limit in its permit when it stored containers of hazardous waste in Building 5 for more than one year.

TWENTY-NINTH CLAIM FOR RELIEF

(Storage of Hazardous Waste in Building 28 Sheds without a Permit—Failure to Inspect West Point as Required for RCRA Permit Exemption)

438. Paragraphs 1 through 437 are realleged and incorporated by reference.

439. Pursuant to 40 C.F.R. § 262.34(a)(1)(i), as incorporated by 25 Pa. Code § 262a.10, a generator may store hazardous waste in a container without a permit for up to 90 days, so long as the generator follows the requirements of, *inter alia*, Subpart I of 40 C.F.R. Part 265.

440. Subpart I of Part 265, specifically 40 C.F.R. § 265.174, requires an owner or operator to inspect areas where hazardous waste containers are stored at least weekly.

441. At all times relevant to this action, Merck stored hazardous waste at West Point in containers in four Building 28 sheds, which Merck identified as a less-than-90-day storage area that is exempt from the RCRA permit requirement.

442. From December 29, 2005 to December 6, 2006, Merck failed to inspect two of the Building 28 sheds weekly, pursuant to Subpart I of Part 265—specifically, 40 C.F.R. § 265.174, as incorporated by 25 Pa. Code § 265a.1—as required for the permit exemption in 40 C.F.R. § 262.34(a)(1)(i).

443. Merck violated 40 C.F.R. § 270.1(c), as incorporated by 25 Pa. Code § 270a.1, because it stored hazardous waste in containers in the Building 28 sheds without a permit and failed to meet the requirements for the permit exemption under 40 C.F.R. § 262.34(a)(1)(i), as incorporated by 25 Pa. Code § 262a.10.

THIRTIETH CLAIM FOR RELIEF

(Failure to Monitor Pumps and Valves of TA-140 and TA-213 at West Point Building as Required for RCRA Permit Exemption)

444. Paragraphs 1 through 443 are realleged and incorporated by reference.

445. Pursuant to 40 C.F.R. § 262.34(a)(1)(ii), a generator may store hazardous waste in a tank without a permit for up to 90 days, so long as the generator follows the requirements of, *inter alia*, Subpart BB of 40 C.F.R. Part 265.

446. Subpart BB of Part 265, specifically 40 C.F.R. § 265.1052(a), requires an owner or operator to inspect hazardous waste pumps in light liquid service monthly.

447. Subpart BB of Part 265, specifically 40 C.F.R. § 265.1057(a), requires an owner or operator to inspect hazardous waste valves in light liquid service monthly.

448. TA-140 and TA-213 are not identified in Merck's hazardous waste permit as permitted hazardous waste storage tanks.

449. Merck identifies tanks TA-140 and TA-213 as less-than-90-day hazardous waste storage tanks.

450. The pumps and valves associated with TA-140 and TA-213 are in "light liquid service" as defined in 40 C.F.R. § 265.1031.

451. Tanks TA-140 and TA-213 came into hazardous waste service before 2002.

452. Merck did not identify two pumps and 17 valves on TA-140 as requiring monitoring in its November 2, 2002 Subpart BB manual.

453. Merck did not identify 11 valves on TA-213 as requiring monitoring in its November 2, 2002 Subpart BB manual.

454. In its May 18, 2006 Subpart BB manual, Merck did identify the valves and pumps discussed in Paragraphs 452 and 453 as requiring monitoring.

455. From at least October 19, 2004 to May 18, 2006, Merck failed to monitor two pumps and 17 valves on TA-140 pursuant to Subpart BB of Part 265—specifically 40 C.F.R. § 265.1052(a) for pumps and 40 C.F.R. § 265.1057(a) for valves, as incorporated by 25 Pa. Code § 265a.1—as required for the permit exemption in 40 C.F.R. § 262.34(a)(1)(ii).

456. From at least October 19, 2004 to May 18, 2006, Merck failed to monitor 11 valves on TA-213 pursuant to Subpart BB of Part 265—specifically 40 C.F.R. § 265.1052(a) for pumps and 40 C.F.R. § 265.1057(a) for valves, as incorporated by 25 Pa. Code § 265a.1—as required for the permit exemption in 40 C.F.R. § 262.34(a)(1)(ii).

457. Merck violated 40 C.F.R. § 270.1(c), as incorporated by 25 Pa. Code § 270a.1, because it stored hazardous waste in tanks TA-140 and TA-213 without a permit and failed to meet the monitoring requirements for a permit exemption under 40 C.F.R. § 262.34(a)(1)(ii).

THIRTY-FIRST CLAIM FOR RELIEF

(Storage of Hazardous Waste in West Point Tank TA-140 without a Permit—Failure to Monitor West Point Tank TA-140 as Required for RCRA Permit Exemption)

458. Paragraphs 1 through 457 are realleged and incorporated by reference.

459. Pursuant to 40 C.F.R. § 262.34(b), as incorporated by 25 Pa. Code § 262a.10, a generator who stores hazardous waste for more than 90 days is subject

to the permit requirements of 40 C.F.R. Part 270 and must obtain a permit for such storage unless the generator has been granted an extension to the 90-day period due to unforeseen, temporary, and uncontrollable circumstances.

460. Another exemption from the permit requirement falls under 40 C.F.R. § 262.34(a)(1)(ii), as incorporated by 25 Pa. Code § 262a.10, which states that a generator may store hazardous waste in a tank without a permit for up to 90 days, so long as the generator follows the requirements of, *inter alia*, Subpart J of 40 C.F.R. Part 265.

461. Subpart J of Part 265, specifically 40 C.F.R. § 265.195, requires an owner or operator to inspect hazardous waste tanks at least daily or weekly, depending upon whether the tank system has leak detection equipment.

462. Merck identifies TA-140 as a less-than-90-day hazardous waste storage tank.

463. TA-140 is not identified in Merck's hazardous waste permit as a permitted hazardous waste storage tank.

464. Tank TA-140 came into hazardous waste service before 2002.

465. TA-140 collects waste before sending it to TA-213. TA-140's automatic pump begins pumping hazardous waste out of TA-140 once TA-140 is more than 25% full.

466. TA-140 consistently has about 33 gallons (25% capacity) of hazardous waste in it.

467. From at least mid-May 2007 to mid-December 2007, TA-140 contained hazardous waste.

468. Merck did not receive an extension to the 90-day storage period for TA-140 between mid-May 2007 and mid-December 2007.

469. Merck stored hazardous waste in TA-140 for more than 90 days in 2007 without an extension and was, therefore, subject to the permit requirements in 40 C.F.R. Part 270.

470. Merck did not identify tank TA-140 as requiring monitoring in its November 2, 2002 Subpart BB manual.

471. Merck did identify tank TA-140 as requiring monitoring in its May 18, 2006 Subpart BB manual.

472. From at least May 2007 to December 2007, Merck failed to monitor TA-140 daily or weekly pursuant to 40 C.F.R. § 265.195, as incorporated by 25 Pa. Code § 265a.1, as required for the permit exemption in 40 C.F.R. § 262.34(a)(1)(ii).

473. Merck violated 40 C.F.R. § 270.1(c), as incorporated by 25 Pa. Code § 270a.1, because it stored hazardous waste in TA-140 for more than 90 days without a permit and without being granted an extension to the 90-day period, and

because Merck failed to meet the requirements for the permit exemption under 40 C.F.R. § 262.34(a)(1)(ii).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the United States of America, respectfully prays that this Court:

1. Assess civil penalties against Merck of up to $37,500 per day for each violation at Riverside and West Point under the CWA, CAA, RCRA, EPCRA, and CERCLA, and 40 C.F.R. Part 19, as described in this Complaint.

2. Award the United States its costs for this action.

3. Grant such other and further relief as the Court may deem appropriate.

Respectfully submitted,

DATE: 9/22/11

ROBERT G. DREHER
Acting Assistant Attorney General
Environment and Natural Resources Division
United States Department of Justice

DATE: 9/26/11

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JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

United States of America

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Leigh P. Rende, United States Department of Justice (ENRD)
Ben Franklin Station, P.O. Box 7611, Washington, DC 20044-7611
Telephone: 202-514-1461

DEFENDANTS

Merck & Co., Inc.

County of Residence of First Listed Defendant Northumberland
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)
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II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☒ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

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- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☒ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
33 USC 1311; 42 USC 7412, 7661a, and 7671b; 42 USC 6925 and 6928; 42 USC 11004; and 42 USC 9603

Brief description of cause:
Violations of multiple federal environmental laws at two of Merck & Co., Inc.'s facilities in Pennsylvania

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☑ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
09/28/2011

SIGNATURE OF ATTORNEY OF RECORD
[redacted]

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,	:	
	:	
Plaintiff,	:	
	:	
v.	:	CIVIL ACTION NO.
	:	
MERCK & CO., INC.	:	Filed Electronically
	:	
Defendant.	:	
	:	

_____

NOTICE OF FILING OF COMPLAINT AND SETTLING STIPULATION AND ORDER

Plaintiff files this Notice of Filing of Complaint and Settling Stipulation and Order, together with the attached Complaint and Stipulation and Order, for the Court's review, signature (on Page 8 of the Stipulation and Order), and entry onto the Docket of the above-captioned matter. The attached Stipulation and Order memorializes the settlement of the violations alleged in the accompanying Complaint.

Respectfully submitted,

ROBERT G. DREHER
Acting Assistant Attorney General
Environment and Natural Resources Division
United States Department of Justice

September 28, 2011
Date

s/ Leigh P. Rendé
LEIGH P. RENDÉ
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Environmental Enforcement Section
Environment and Natural Resources Division
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OF COUNSEL:

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(410) 305-3016 (telephone)

CAROLINE B.C. HERMANN
Special Litigation & Projects Division
Office of Civil Enforcement (2248-A)
United States Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460
(202) 564-2876 (telephone)

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,	:	
	:	
Plaintiff,	:	
	:	
v.	:	CIVIL ACTION NO.
	:	
MERCK & CO., INC.	:	Filed Electronically
	:	
Defendant.	:	
	:	

_____

STIPULATION AND ORDER BETWEEN PLAINTIFF UNITED STATES OF AMERICA AND DEFENDANT MERCK & CO., INC.

WHEREAS, Plaintiff United States of America, on behalf of the United States Environmental Protection Agency ("EPA"), has filed a complaint in this action ("Complaint") pursuant to Sections 309(b) and (d) and Section 311(b)(7) of the Federal Water Pollution Control Act, as amended by the Clean Water Act of 1977 and the Water Quality Act of 1987 (the "Clean Water Act" or "CWA"), 33 U.S.C. §§ 1319(b) and (d) and 33 U.S.C. § 1321(b)(7); Section 113(b) of the Clean Air Act ("CAA"), 42 U.S.C. § 7413(b); Section 3008(a) of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976 ("RCRA"), 42 U.S.C. § 6928(a); Sections 325(b) and (c) of the Emergency Planning and Community Right-to-Know Act of 1986 ("EPCRA"), 42 U.S.C. §§ 11045(b) and (c); and Section 109(c) of the Comprehensive Environmental

Response, Compensation and Liability Act, as Amended by the Superfund Amendment and Reauthorization Act of 1986 ("CERCLA"), 42 U.S.C. § 9609(c), alleging that, *inter alia*, Defendant Merck & Co., Inc. ("Merck"), violated sections of the CWA, CAA, RCRA, EPCRA, CERCLA, and their implementing regulations, in connection with two of Merck's pharmaceutical research and manufacturing facilities, one of which is located in West Point, Pennsylvania, and the other of which is located in Riverside, Pennsylvania.

WHEREAS, Merck denies the violations alleged in the Complaint and does not admit liability to the United States arising out of the transactions or occurrences alleged in the Complaint.

WHEREAS, Merck has cooperated with the United States to investigate the violations alleged in the Complaint and has undertaken numerous corrective actions.

WHEREAS, Merck has requested to discuss the following areas with the United States and the United States has so agreed: current recordkeeping procedure for refrigerant-containing appliances at Merck's West Point facility, the existing Clean Air Act Title V permit at Merck's Riverside facility, and the existing National Pollutant Discharge Elimination System permit at Merck's Riverside facility.

WHEREAS, the United States and Merck (the "Parties") agree that settlement of the United States' claims against Merck, without further litigation, is in the public interest.

WHEREAS, the Parties further agree that the Court's approval of this Stipulation and Order ("Stipulation") is an appropriate means of resolving the claims in this action.

NOW THEREFORE, before the taking of any testimony, without adjudication or admission of any issue of fact or law, except as provided in Paragraph 1, below, and with the consent of the Parties, IT IS HEREBY ADJUDGED, ORDERED AND DECREED as follows:

1. This Court has jurisdiction over the parties to, and the subject matter of, this action pursuant to 28 U.S.C. §§ 1331, 1345 and 1355, Sections 309(b) and 311(b)(7)(e) of the CWA, 42 U.S.C. §§ 1319(b) and 1321(b)(7)(e), Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Section 113(b) of CERCLA, 42 U.S.C. § 9613(b), and Section 325 of EPCRA, 42 U.S.C. § 11045. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1395(a), Sections 309(b) and 311(b)(7)(E) of the CWA, 33 U.S.C. §§ 1319(b) and 1321(b)(7)(E), Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Section 113(b) of CERCLA, 42 U.S.C. § 9613(b), and Section 325 of EPCRA, 42 U.S.C. § 11045,

because Merck owns and operates facilities in this District and because a portion of the violations alleged in the Complaint occurred in this District. Merck waives service of process in accordance with the requirements set forth in the Federal Rules of Civil Procedure. Merck shall not be required to respond to the Complaint filed in conjunction with this Stipulation and Order.

2. Merck shall, within thirty (30) days of the date this Stipulation is entered by the Court, pay to the United States a civil penalty in the amount of one million five-hundred thousand dollars ($1,500,000.00), plus an additional sum for interest as discussed in this paragraph. No interest shall accrue if payment in the full amount is made within the first fifteen (15) days from date of entry of this Stipulation. For any amount of the civil penalty that is not paid within fifteen (15) days of the date this Stipulation is entered by the Court, interest shall be assessed in the amount calculated on such sum beginning the sixteenth day following the date this Stipulation is entered and through the date of the full civil penalty payment. "Interest" shall mean interest at the statutory judgment rate established by 28 U.S.C. § 1961. The applicable rate of interest shall be the rate in effect at the time the interest accrues.

3. The payment shall be made by FedWire Electronic Funds Transfer ("EFT") in accordance with current electronic funds transfer procedures, referencing USAO File No. 2011V00485, EPA Docket No. 03-2007-0344,

and DOJ Case No. 90-5-1-1-09322. The payment shall be made in accordance with instructions provided to Merck by the Financial Litigation Unit of the U.S. Attorney's Office for the Middle District of Pennsylvania. Any EFTs received at the DOJ lockbox bank after 4:00 p.m. Eastern Time will be credited on the next business day. Within five (5) business days of payment, Merck shall provide written notice of payment and a copy of any transmittal documentation to DOJ, EPA, and the U.S. Attorney's Office at the addresses below.

As to DOJ:	Chief, Environmental Enforcement Section Environment and Natural Resources Division U.S. Department of Justice P.O. Box 7611 Washington, D.C. 20044-7611 Re: DOJ No. 90-5-1-1-09322
As to EPA:	Susan Janowiak Office of Regional Comptroller (3PM30) U.S. Environmental Protection Agency Region III 1650 Arch Street Philadelphia, PA 19103-2029
As to EPA:	Daniel L. Isales (3RC60) Environmental Science Center U.S. Environmental Protection Agency 701 Mapes Road Fort Meade, MD 20755-5350

As to the U.S. Attorney's Office: J. Justin Blewitt, Jr.
Assistant United States Attorney
Middle District of Pennsylvania
William J. Nealon Federal Building & Courthouse
235 N. Washington Ave., Suite 311
Scranton, PA 18503
Re: USAO No. 2011V00485

4. If the civil penalty is not fully paid within thirty (30) days of the date this Stipulation is entered by the Court, Merck shall pay a stipulated penalty of $500 per day for each day that the payment is delayed beyond the due date except that no stipulated penalty shall accrue until ten (10) days following issuance of payment instructions by the FLU in accordance with Paragraph 3. Interest shall continue to accrue on the unpaid balance. Stipulated penalties are due and payable within 30 days of the date of the demand for payment of the penalties by the United States. Penalties shall accrue as provided in this Paragraph regardless of whether the United States has notified Merck of the violation or made a demand for payment, but need only be paid upon demand. All penalties shall begin to accrue on the day after payment is due and shall continue to accrue through the date of payment.

5. All payments required by this Stipulation are penalties within the meaning of Section 162(f) of the Internal Revenue Code, 26 U.S.C. § 162(f), and are not a tax deductible expenditure for purposes of federal law.

6. The payment by Merck under this Stipulation shall resolve the civil claims of the United States for the violations alleged in the Complaint.

7. The United States reserves, and this Stipulation is without prejudice to, all rights against Merck with respect to all other matters not asserted by the United States in the Complaint, including, but not limited to, any criminal liability.

8. Nothing in this Stipulation shall be construed to release Merck or its agents, successors, or assigns from their respective obligations to comply with any applicable Federal, State, or local law, regulation, or permit. Nothing contained herein shall be construed to prevent or limit the United States' rights to seek penalties or injunctive relief for any violations of the CWA, RCRA, CAA, CERCLA or EPCRA other than those expressly alleged in the complaint.

9. This Stipulation shall constitute an enforceable judgment for purposes of post-judgment collection in accordance with Rule 69 of the Federal Rules of Civil Procedure, the Federal Debt Collection Procedure Act, 28 U.S.C. §§ 3001-3308, and other applicable authority. The United States shall be deemed a judgment creditor for purposes of collection of any unpaid amounts of the civil and stipulated penalties and interest. Further, Merck shall be liable for attorneys' fees and costs incurred by the United States in any litigation to collect any amounts due under this Stipulation.

10. After receipt of the full settlement amount to be paid by Merck, the United States and Merck shall promptly execute and file with the Court a stipulation of dismissal with prejudice with respect to Plaintiff's claims against Merck. The United States' Complaint in this action shall be dismissed only upon payment of the entire settlement amount and any other monies due in accordance with this Stipulation, as indicated by the filing of a stipulation of dismissal.

11. Each party shall bear its own costs and attorneys' fees in this matter, except as provided in Paragraph 9, above.

12. The undersigned representatives of Merck and the Assistant Attorney General of the Environment and Natural Resources Division or his or her designee each certify that he or she is fully authorized to enter into the terms and conditions of this Stipulation and to execute and legally bind Merck and the United States, respectively, to it.

SO ORDERED this _____ day of _____, 20__.

_____
United States District Judge
Middle District of Pennsylvania

FOR PLAINTIFF THE UNITED STATES OF AMERICA:

Date 9/22/11

[redacted]

ROBERT G. DREHER
Acting Assistant Attorney General
Environment and Natural Resources Division
U.S. Department of Justice
Washington, D.C. 20530

[redacted]

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(570) 348-2800 (telephone)

FOR PLAINTIFF THE UNITED STATES OF AMERICA CONTINUED:

SEP 19 2011

Date

[redacted]

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Regional Administrator
U.S. EPA Region III
1650 Arch Street
Philadelphia, PA 19103-2029

[redacted]

MARCIA E. MULKEY
Regional Counsel
U.S. EPA Region III
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DANIEL L. ISALES
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U.S. EPA Region III
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FOR PLAINTIFF THE UNITED STATES OF AMERICA CONTINUED:

9/24/11
Date

[redacted]

CYNTHIA GILES
Assistant Administrator
Office of Enforcement & Compliance Assurance
U.S. Environmental Protection Agency

[redacted]

ADAM M. KUSHNER
Office Director
Office of Civil Enforcement
Office of Enforcement & Compliance Assurance
U.S. Environmental Protection Agency

[redacted]

BERNADETTE M. RAPPOLD
Division Director
Special Litigation and Projects Division
Office of Civil Enforcement
Office of Enforcement & Compliance Assurance
U.S. Environmental Protection Agency

[redacted]

CAROLINE B.C. HERMANN
Attorney Advisor
Special Litigation and Projects Division
Office of Civil Enforcement
Office of Enforcement & Compliance Assurance
U.S. Environmental Protection Agency

FOR MERCK & CO. INC.:

9-7-2011
Date

[redacted]
NAME: [redacted]
TITLE: [redacted]
ADDRESS: [redacted]

AS COUNSEL:

9-8-2011
Date

[redacted]
NAME: Kenneth J. Warren
TITLE: Counsel for Merck & Co., Inc.
ADDRESS: Hangley Aronchick Segal & Pudlin
One Logan Square - 27th Floor
Philadelphia, PA 19103

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,	:	
	:	
Plaintiff,	:	
	:	
v.	:	CIVIL ACTION NO.
	:	
MERCK & CO., INC.	:	Filed Electronically
	:	
Defendant.	:	
	:	

_____

CERTIFICATE OF SERVICE

I hereby certify that, on September 28, 2011, pursuant to Local Rule 4.1, I caused copies of the foregoing Complaint, Stipulation and Order Between Plaintiff United States of America and Defendant Merck & Co., Inc., and the accompanying Notice of Filing, to be mailed to Defendant via electronic mail and overnight mail at the following addresses:

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e-mail: kwarren@hangley.com

Stephen E. Tarnowski
Merck and Co., Inc.
1 Merck Drive
Whitehouse Station, NJ 08889
e-mail: stephen_tarnowski@merck.com

s/ Leigh P. Rendé
LEIGH P. RENDÉ
Trial Attorney
Environmental Enforcement Section
Environment and Natural Resources Division
United States Department of Justice