UNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND

UNITED STATES OF AMERICA, Plaintiff, v. COSMED GROUP, INC., Defendant.	CIVIL ACTION NO. **COMPLAINT**

Plaintiff, United States of America, by authority of the Attorney General of the United States and on behalf of the Administrator of the United States Environmental Protection Agency, alleges as follows:

NATURE OF ACTION

1. This is a civil action brought against Cosmed Group, Inc. ("Cosmed"), to obtain injunctive relief and civil penalties for violations of the Clean Air Act (the "Act" or "CAA"), 42 U.S.C. § 7401 et seq., and the federal and state regulations promulgated with respect thereto.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345, and 1355 and Section 113(b) of the Act, 42 U.S.C. § 7413(b).

3. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395 and Section 113(b) of the Act, 42 U.S.C. § 7413(b), because Cosmed's principal place of business and corporate headquarters are in this District in Jamestown, Rhode Island and the alleged violations occurred and/or are occurring at Cosmed's former Rhode Island facility as well as at five other current

or former Cosmed facilities in five separate states, namely, California, Illinois, Maryland, New Jersey, and Texas.

NOTICE TO STATES

4. Notice of the commencement of this action has been given to the States of California, Illinois, Maryland, New Jersey, Rhode Island, and Texas pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b).

DEFENDANT

5. Cosmed is a business organized under the laws of the State of Maryland with its headquarters located in the State of Rhode Island. At all times relevant to the violations alleged in this complaint, Cosmed provided contract sterilization services for diverse products including medical devices, pharmaceuticals, packaging, cosmetics, seeds, and spices. Cosmed is a "person," as defined in Section 302(e) of the CAA, 42 U.S.C. § 7602(e).

6. At all times relevant to the violations alleged in this complaint, Cosmed owned or operated at least eight sterilization plants located in the following states: California, Illinois, Maryland, New Jersey (2 facilities), Nevada, Rhode Island, and Texas. Six of those current or former Cosmed facilities are alleged herein to have operated in violation of the CAA and federally-enforceable regulations promulgated thereunder. The six sterilization facilities are sources that are alleged to have violated the Act and its implementing regulations include the current or former Cosmed facilities located in San Diego, CA, Waukegan, IL, Baltimore, MD, South Plainfield, NJ, Coventry, RI, and Grand Prairie, TX (those six facilities hereinafter referred to, collectively, as the "Violating Facilities").

7. At all times relevant to the violations alleged in this complaint, at each of the

Violating Facilities, Cosmed used ethylene oxide ("EtO") in sterilization processes from which EtO is emitted to the outside air. EtO is a volatile organic compound ("VOC") which is designated as a hazardous air pollutant ("HAP") under Section 112 of the Act, 42 U.S.C. § 7412.

STATUTORY AND REGULATORY BACKGROUND

Statutory Background (Hazardous Air Pollutants)

8. The CAA establishes a statutory 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 the population. 42 U.S.C. § 7401(b)(1).

9. In 1990, Congress amended the Act, requiring the United States Environmental Protection Agency ("EPA") to establish national emissions standards for certain hazardous air pollutants under Section 112. 42 U.S.C. § 7412. These National Emissions Standards for Hazardous Air Pollutants ("NESHAPs") are required for designated HAPs.

10. Under Section 112(b) of the Act, 42 U.S.C. § 7412(b), EtO is designated as a HAP. EtO is a probable carcinogen. EtO also is associated with serious reproductive harm, can irritate the lungs, and may cause damage to the liver and kidneys.

11. Pursuant to Section 112 of the Act, NESHAPs promulgated by EPA are intended to control HAP emissions by requiring the maximum achievable control technology ("MACT") to provide maximum emissions reduction for new or existing sources. 42 U.S.C. § 7412. Under Section 112, EPA promulgated MACT standards entitled *Ethylene Oxide Emissions Standards for Sterilization Facilities*, codified at 40 C.F.R. Part 63, Subpart O ("Subpart O" or "EtO MACT"). EPA also promulgated general MACT provisions under Section 112 (entitled *General Provisions*), codified at 40 C.F.R. Part 63, Subpart A ("Subpart A"), that are applicable to sources regulated by the EtO

MACT, pursuant to 40 C.F.R. § 63.360 of Subpart O.

Statutory Background (State Implementation Plans)

12. Section 109(a) of the CAA, 42 U.S.C. § 7409(a), requires the Administrator of EPA to promulgate national ambient air quality standards ("NAAQS") for certain air pollutants. EPA has designated ground-level ozone, commonly known as "smog," as an ambient air pollutant and has developed a national ambient air quality standard for ozone, pursuant to 40 C.F.R. § 50.9. Ozone is a primary ingredient in smog which irritates the respiratory system. Ground-level ozone forms on still, hot summer days when VOCs react with oxides of nitrogen in sunlight. The CAA requires the control of VOCs and NOx emissions in order to limit smog formation.

13. Section 110(a)(1) of the CAA, 42 U.S.C. § 7410(a)(1), requires each state to adopt and submit to EPA for approval a State Implementation Plan ("SIP") that provides for the attainment and maintenance of the NAAQS. A state must submit its SIP, and any subsequent revisions, to EPA for approval. 42 U.S.C. §§ 7410(a)(2) and (3). The federal government may enforce the regulations in a SIP once EPA has approved it. 42 U.S.C. §§ 7413(a) and (b).

Statutory Background (Enforcement)

14. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), the United States, on behalf of the Administrator of EPA, may commence a civil action for injunctive relief and civil penalties not to exceed $25,000 per day for each violation of the CAA which takes place on or before January 30, 1997 and not to exceed $27,500 per day for each violation which takes place between January 30, 1997, and March 14, 2004, and not to exceed $32,500 for violations occurring after March 15, 2004, in accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. § 2461 note; Pub. L. 101- 410, enacted October 5, 1990; 104 Stat. 890), as amended by the Debt

Collection Improvement Act of 1996 (31 U.S.C. § 3701 note; Public Law 104-134, enacted April 26, 1996; 110 Stat. 1321).

15. Section 113(a)(3) of the CAA, 42 U.S.C. § 7413(a)(3), provides, in part, that whenever the Administrator of EPA finds a violation of any requirement or prohibition of, among other things, NESHAPs promulgated under Section 112, the Administrator of EPA may issue an order as described in Section 113(a)(4) of the Act, 42 U.S.C. § 7413(a)(4), requiring compliance with such requirement or prohibition. Section 113(a)(3) of the Act also provides, in part, that whenever the Administrator of EPA finds a violation of any requirement or prohibition of, among other things, NESHAPs promulgated under Section 112, the Administrator of EPA may commence a civil action in accordance with 113(b) of the Act, 42 U.S.C. § 7413(b), or may issue an administrative penalty order in accordance with Section 113(d) of the Act, 42 U.S.C. § 7413(d).

16. Section 113(a)(1) of the Act, 42 U.S.C. § 7413(a)(1), provides, in part, that whenever the Administrator of EPA finds a violation of an applicable SIP, the Administrator of EPA shall notify the person violating and the State in which the SIP applies. Section 113(a)(1) of the Act also provides, in part, that at any time after the expiration of 30 days following the date on which the notice of violation ("NOV") is issued, the Administrator of EPA may bring a civil action in accordance with 113(b) of the Act, 42 U.S.C. § 7413(b), issue an order requiring compliance with such SIP, or issue an administrative penalty order in accordance with Section 113(d), 42 U.S.C. § 7413(d).

17. Pursuant to Section 114(a) of the Act, 42 U.S.C. § 7414(a), for the purpose of determining whether any person is in violation of any emission standard under Section 112 or of carrying out any provision of Subchapter I the CAA, the Administrator of EPA may require any owner or operator of an emission source to establish and maintain records, make reports, install monitoring

equipment, sample emissions, keep records, and provide such other information as EPA may reasonably require. Section 114(a)(2) of the Act, 42 U.S.C. § 7414(a)(2), also authorizes the Administrator of EPA or his authorized representative, among other things, to inspect such emission sources and to copy any records required under Section 114(a)(1), inspect any monitoring equipment required under Section 114(a)(1), and sample any emissions required to be sampled under Section 114(a)(1).

Regulatory Background (EtO MACT)

18. Subpart O defines "*source(s) using 10 tons*," at 40 C.F.R. § 63.361, to mean sterilization sources using 10 tons (9,070 kilograms (kg)) or more of EtO in any consecutive 12-month period after December 6, 1996 ("Ten Ton Sources"). A Ten Ton Source is the largest sterilization source category regulated under Subpart O and is an "*affected source*," as defined at 40 C.F.R. § 63.2. A Ten Ton Source, by definition, also falls within the meaning of "*source(s) using 1 ton*," defined at 40 C.F.R. § 63.361 as sterilization sources using 1 ton (907 kg) or more of EtO within any consecutive 12-month period after December 6, 1996 ("One Ton Sources").

19. Pursuant to 40 C.F.R. § 63.360, the owner or operator of any Ten Ton Source using EtO in sterilization or fumigation operations is subject to the emissions standards of 40 C.F.R. § 63.362, except as specified in 40 C.F.R. §§ 63.360(b) through (e), and also must comply with the requirements of 40 C.F.R. Part 63, Subpart A, according to the applicability of Subpart A to such sources, as set forth in Table 1 of 40 C.F.R. § 63.360(a) and in 40 C.F.R. § 63.1(a)(4).

20. Pursuant to 40 C.F.R. §§ 63.362(a) and (b), on and after the compliance dates specified at 40 C.F.R. § 63.360(g), each owner or operator of any Ten Ton Source subject to the EtO MACT shall comply with the emission limitations set forth in 40 C.F.R. §§ 63.362(c) and (d) and

summarized in Table 1 of 40 C.F.R. § 63.362.

21. Pursuant to 40 C.F.R. § 63.362(c), each owner or operator of any Ten Ton Source subject to the EtO MACT shall reduce EtO emissions to the atmosphere by at least ninety-nine percent (99%) from each *sterilization chamber vent*, as defined at 40 C.F.R. § 63.361.

22. Pursuant to 40 C.F.R. § 63.362(d), each owner or operator of any Ten Ton Source subject to the EtO MACT shall reduce EtO emissions to the atmosphere from each *aeration room vent*, as defined at 40 C.F.R. § 63.361, to a maximum concentration of one part per million by volume (1 ppmv) or by at least ninety-nine percent (99%), whichever is less stringent.

23. Pursuant to 40 C.F.R. §§ 63.366(c) and 63.9(b)(2), the owner or operator of any Ten Ton Source subject to the EtO MACT shall notify EPA, in writing, not later than 120 calendar days of the effective date of the "*relevant standard*," as defined at 40 C.F.R. § 63.2, or within 120 calendar days after the source becomes subject to the relevant standard, that the source is subject to the relevant standard and shall provide the information set forth in 40 C.F.R. § 63.9(b)(2).

24. Pursuant to 40 C.F.R. §§ 63.363(a)(1), 63.363(a)(2), and Table 1 of 40 C.F.R. § 63.360, the owner or operator of any Ten Ton Source subject to the EtO MACT shall conduct initial performance testing using the procedures listed in 40 C.F.R. §§ 63.7 and 63.363, and the test methods listed in 40 C.F.R. § 63.365 and shall complete performance testing within 180 days after the compliance date for the specified standard, as determined in 40 C.F.R. § 63.360(g).

25. Pursuant to 40 C.F.R. §§ 63.366(c) and 63.9(h), the owner or operator of any Ten Ton Source subject to the EtO MACT shall submit to EPA a notification of compliance status, signed by the responsible official who shall certify its accuracy, containing the information required by 40 C.F.R. § 63.9(h) and attesting to whether the source has complied with the relevant standard.

Pursuant to 40 C.F.R. §§ 63.366(c) and 63.9(h), such notification of compliance status shall be submitted before close of business on the 60th day following completion of the initial performance test and again on the 60th day following the completion of any subsequent required performance test.

26. Pursuant to 40 C.F.R. §§ 63.364 and 63.8, and Table 1 of 40 C.F.R. § 63.360, the owner or operator of any Ten Ton Source subject to the EtO MACT shall comply with the monitoring requirements in 40 C.F.R. §§ 63.8 and 63.364.

27. Pursuant to 40 C.F.R. § 63.363, the owner or operator of any Ten Ton Source subject to the EtO MACT and which uses acid-water scrubbers to control EtO emissions shall establish, as an operating limit, either of the limits specified at 40 C.F.R. §§ 63.363(b)(2)(i) or 63.363(b)(2)(ii).

28. Pursuant to 40 C.F.R. § 63.363(f), any Ten Ton Source subject to the EtO MACT must demonstrate continuous compliance with each operating limit or work practice standard required under 40 C.F.R. § 63.363, except during periods of *startup*, *shutdown*, and *malfunction* (as those terms are defined at 40 C.F.R. § 63.2), according to the methods specified in 40 C.F.R. § 63.364.

29. Pursuant to 40 C.F.R. §§ 63.367(a), 63.10(b)(2), and 63.4(a)(2), and Table 1 of 40 C.F.R. § 63.360, the owner or operator of any Ten Ton Source subject to the EtO MACT shall comply with the recordkeeping requirements in 40 C.F.R. §§ 63.10(b), 63.10(c), and 63.367 and shall, among other things, maintain files of all information (including all reports and notifications) required by 40 C.F.R. Part 63, including all required measurements needed to demonstrate compliance with the relevant standard.

30. Pursuant to 40 C.F.R. § 63.366(a)(3) and Table 1 of 40 C.F.R. § 63.360, the owner or operator of any Ten Ton Source subject to the EtO MACT shall comply with the reporting

requirements therein and at 40 C.F.R. §§ 63.10(a), (d), (e) and (f), by submitting, among other things, written reports of "*deviation[s]*," as defined at 40 C.F.R. § 63.2, within 30 days of each calendar half or quarter, as applicable.

Regulatory Background (Illinois SIP)

31. The State of Illinois has adopted a SIP within the meaning of Section 110 of the CAA, 42 U.S.C. § 7410. On or about May 31, 1972, EPA approved regulations as part of the Illinois SIP governing operating permit requirements for new sources, entitled *Operating Permits for New Sources*, presently codified at 35 IAC 201.143 (the "Illinois Regulation 201.143"). 37 Fed. Reg. 10862 (May 31, 1972).

32. The Illinois Regulation 201.143 provides, in pertinent part, that "no person shall cause or allow the operation of any new emission source or new air pollution control equipment, or cause or allow the modification of any existing emission source or air pollution control equipment, of a type for which a construction permit is required by Section 201.142, without first obtaining an operating permit from [the Illinois Environmental Protection Agency]..."

33. The Illinois Regulation 201.143 is federally-enforceable under Section 113(b) of the Act, 42 U.S.C. § 7413(b).

THE VIOLATING FACILITIES

34. Each of the Violating Facilities is a *sterilization facility*, as defined at 40 C.F.R. § 63.361, using 10 tons (9,070 kg) or more of EtO within any consecutive 12-month period after December 6, 1996. At all times relevant to the violations alleged in this complaint, at each of the Violating Facilities, Cosmed employed one or more *sterilization chamber* and/or *aeration room*, as those terms are defined at 40 C.F.R. § 63.361, as part of the process of providing sterilization services.

35. At all times relevant to the violations alleged in this complaint, at each of the Violating Facilities, Cosmed used acid-water scrubbers, as specified at 40 C.F.R. § 63.363(b)(2), to control EtO emissions from one or more *sterilization chamber vent* and/or *aeration room vent*, as those terms are defined at 40 C.F.R. § 63.361.

36. Each of the Violating Facilities is an "*affected source*," as defined at 40 C.F.R. § 63.2, and each is a Ten Ton Source subject to the EtO MACT and not exempt under 40 C.F.R. §§ 63.360(b) through (e).

37. Each of the Violating Facilities is located in an area designated by EPA as either a "serious" or "severe" nonattainment area for ozone, or is located in an ozone transport region established by EPA under the Act.

Coventry, Rhode Island Facility

38. At all times relevant to the violations alleged in this complaint, Cosmed owned or operated a sterilization facility located at 8 Industrial Drive in Coventry, RI (the "Rhode Island Facility"). At all times relevant to the violations alleged in this complaint, the Rhode Island Facility contained approximately 7 sterilization chambers and an aeration room. Cosmed began operations at the Rhode Island Facility in or around 1991. Upon information and belief, on or about January 7, 2005, Cosmed transferred ownership and operation of the Rhode Island Facility to a third party not named in this action.

39. At all times relevant to the violations alleged in this complaint, the Rhode Island Facility was a Ten Ton Source at which Cosmed employed one or more acid-water scrubbers to control EtO emissions from sterilization chamber vents and aeration room vents there.

40. On or about December 17, 2001, duly authorized EPA and Rhode Island

Department of Environmental Management ("RIDEM") inspectors conducted an inspection at the Rhode Island Facility, pursuant to Section 114 of the CAA.

41. On or about February 21, 2002, EPA issued to Cosmed an Administrative Order and Reporting Requirement under Sections 113(a) and 114 of the Act which alleged certain violations of the EtO MACT and required defendant to perform compliance testing at the Rhode Island Facility and to provide EPA with specific information relative to compliance with the EtO MACT at that location. On or about March 14, March 20, March 22, and April 25, 2002, Cosmed provided EPA with responses to the Reporting Requirement.

42. On or about January 28, 2003, Cosmed conducted compliance testing at the Rhode Island Facility, as required by the Administrative Order and Reporting Requirement and by the EtO MACT. On or about March 25, 2003, Cosmed submitted to EPA a written report containing the results of the January 28, 2003 compliance test.

South Plainfield, New Jersey Facility

43. At all times relevant to the violations alleged in this complaint, Cosmed owned or operated a sterilization facility located at 3459 South Clinton Avenue in South Plainfield, NJ (the "New Jersey Facility"). At all times relevant to the violations alleged in this complaint, the New Jersey Facility contained approximately 7 sterilization chambers and an aeration room. Cosmed began operations at the New Jersey Facility on or about September 9, 1990. Upon information and belief, on or about January 7, 2005, Cosmed transferred ownership and operation of the New Jersey Facility to a third party not named in this action.

44. At all times relevant to the violations alleged in this complaint, the New Jersey Facility was a Ten Ton Source at which Cosmed employed one or more acid-water scrubbers to control

EtO emissions from sterilization chamber vents and aeration room vents there.

45. On or about March 13, 2002, duly authorized EPA inspectors conducted an inspection at the New Jersey Facility, pursuant to Section 114 of the CAA.

46. On or about September 27, 2002, EPA issued to Cosmed an Administrative Order under Sections 113(a) and 114 of the Act which alleged certain violations of the EtO MACT and required defendant to perform compliance testing at the New Jersey Facility and to provide EPA with specific information relative to compliance with the EtO MACT at that location.

47. On or about February 12, 2003, Cosmed conducted compliance testing at the New Jersey Facility, as required by the Administrative Order and the EtO MACT. On or about March 25, 2003, Cosmed submitted to EPA a written report containing the results of the February 12, 2003 compliance test.

Waukegan, Illinois Facility

48. At all times relevant to the violations alleged in this complaint, Cosmed owned or operated a sterilization facility located at 1160 Northpoint Boulevard in Waukegan, IL (the "Illinois Facility"). At all times relevant to the violations alleged in this complaint, the Illinois Facility contained approximately 10 sterilization chambers and 2 aeration rooms. Cosmed began operations at the Illinois Facility on or about May 29, 1994. Upon information and belief, on or about January 7, 2005, Cosmed transferred ownership and operation of the Illinois Facility to a third party not named in this action.

49. At all times relevant to the violations alleged in this complaint, the Illinois Facility was a Ten Ton Source at which Cosmed employed one or more acid-water scrubbers to control EtO emissions from sterilization chamber vents and aeration room vents there.

50. On or about June 25, 1996, duly authorized EPA representatives conducted a site visit at the Illinois Facility to provide compliance assistance prior to the initial deadline for compliance with the EtO MACT.

51. On or about March 27, 2002, duly authorized EPA and Illinois Environmental Protection Agency inspectors conducted an inspection at the Illinois Facility, pursuant to Section 114 of the CAA.

52. On or about June 3, 2002, EPA filed a civil administrative complaint against Cosmed initiating an administrative enforcement action for penalties under Section 113(d) of the Act, 42 U.S.C. § 7413(d). The complaint alleged specific violations of the EtO MACT at the Illinois Facility and was voluntarily withdrawn by EPA, without prejudice, effective on or about December 10, 2002.

53. On or about July 3, 2002, EPA issued to Cosmed an Administrative Order under Sections 113(a) and 114 of the Act which alleged certain violations of the EtO MACT and required defendant to perform compliance testing at the Illinois Facility and to provide EPA with specific information relative to compliance with the EtO MACT at that location. On or about July 17, 2002, EPA issued to Cosmed an Amended Administrative Order under Sections 113(a) and 114 of the Act which extended the deadline for conducting compliance testing at the Illinois Facility.

54. On or about August 7, September 4, and September 13, 2002, Cosmed conducted compliance testing at the Illinois Facility, as required by the Administrative Order and by the EtO MACT. Cosmed completed such compliance testing at the Illinois Facility on March 4, 2003. On or about October 11, 2002, Cosmed submitted to EPA a written report containing the results of the Aeration Rooms 1 and 2 packed tower scrubbers compliance test.

55. On or about December 24, 2002, EPA issued to Cosmed a Finding of Violation ("FOV") and Notice of Violation ("NOV") under Sections 113(a), 113(b), and 114 of the Act which alleged certain violations of the EtO MACT and federally-enforceable requirements of the Illinois SIP. The FOV and NOV required defendant to perform compliance testing at the Illinois Facility and fully comply with the EtO MACT and the Illinois SIP at that location. More than thirty days have passed since the issuance of the NOV.

Grand Prairie, Texas Facility

56. At all times relevant to the violations alleged in this complaint, Cosmed owned or operated a sterilization facility located at 1175 Isuzu Parkway in Grand Prairie, Texas (the "Texas Facility"). At all times relevant to the violations alleged in this complaint, the Texas Facility contained approximately 8 sterilization chambers. Cosmed began operations at the Texas Facility on or about March 8, 1999. Upon information and belief, on or about January 7, 2005, Cosmed transferred ownership and operation of the Texas Facility to a third party not named in this action.

57. At all times relevant to the violations alleged in this complaint, the Texas Facility was a Ten Ton Source at which Cosmed employed one or more acid-water scrubbers to control EtO emissions from sterilization chamber vents there.

58. As required by the CAA and EtO MACT, Cosmed conducted compliance testing of its pollution control equipment (i.e., acid-water scrubbers), on or about April 25-28, 2000. Based on such testing, Cosmed established the maximum tank liquor level for each of the scrubbers intended to control EtO emissions from the four sterilizers then in operation, namely, Sterilizer Nos. 1 through 4. Cosmed established the maximum liquor level for the 1st stage scrubber on each of Sterilizer No. 2 and Sterilizer No. 4 at 42.5 inches and 43.25 inches, respectively.

59. Cosmed added Sterilizer Nos. 5, 6, and 7 to the Texas Facility in or around 2001 and added Sterilizer No. 8 to the Texas Facility in or around 2002. Sterilizer No. 5 began operating at the Texas Facility on or about September 5, 2001. Sterilizer No. 6 began operating at the Texas Facility on or about September 24, 2001. Sterilizer No. 7 began operating at the Texas Facility on or about November 13, 2001. Sterilizer No. 8 began operating at the Texas Facility on or about July 2, 2002.

60. On or about June 13, 2002, duly authorized EPA inspectors conducted an inspection at the Texas Facility, pursuant to Section 114 of the CAA.

61. On or about November 19, 2002, EPA issued to Cosmed an Administrative Compliance Order, pursuant to Sections 113(a) and 114 of the Act, which alleged certain violations of the EtO MACT and required defendant to perform compliance testing at the Texas Facility and to provide EPA with specific information relative to compliance with the EtO MACT at that location. On or about January 2 and April 10, 2003, Cosmed provided EPA with responses to the Administrative Compliance Order.

62. On or about March 12, 2003, Cosmed conducted compliance testing of Sterilizer Nos. 1 through 8 at the Texas Facility, as required by the Administrative Order and by the EtO MACT.

63. For the period covering November 2001, Cosmed submitted a semi-annual compliance status report to EPA, as required by the EtO MACT, in which Cosmed reported no excess EtO emissions or any other *deviations*, as defined in Subpart O, at the Texas Facility.

San Diego, California Facility

64. At all times relevant to the violations alleged in this complaint, Cosmed owned or operated a sterilization facility located at 7685 St. Andrews Avenue in San Diego, California (the

"California Facility"). At all times relevant to the violations alleged in this complaint, the California Facility contained approximately 4 sterilization chambers. Cosmed began operations at the California Facility when it was newly constructed, in or around 1999. Upon information and belief, on or about January 7, 2005, Cosmed transferred ownership and operation of the California Facility to a third party not named in this action.

65. At all times relevant to the violations alleged in this complaint, the California Facility was a Ten Ton Source at which Cosmed employed one or more two-stage acid-water scrubbers routed to a common packed tower scrubber to control EtO emissions from the sterilization chambers.

66. On or about February 16, 2000, the San Diego Air Pollution Control District ("SDAPCD") issued Cosmed a federally-enforceable permit to operate, which established limits for the maximum tank liquor level for the two-stage scrubbers and the packed tower scrubber controlling Sterilizer Nos. 1 and 2 at the California Facility. Specifically, the maximum tank liquor level for stage one and stage two of the scrubbers was set at 46 inches and the maximum liquor level for the packed tower scrubber was set at 77 inches. On or about June 13, 2000, the maximum tank liquor level for the stage one and stage two scrubbers was reset at 48 inches in the permit while the maximum liquor level for the packed tower scrubber remained unchanged at 77 inches.

67. On or about July 18 and 19, 2000, Cosmed conducted compliance testing, as required by the EtO MACT, at the California Facility. Based on the testing, the maximum tank liquor level for stage one of the scrubbers remained at 48 inches; the maximum tank liquor level for stage two of the scrubbers was set at 37 inches; and the maximum liquor level for the packed tower scrubber remained at 77 inches.

68. For the period covering in or around July 2000 through May 2002, Cosmed

submitted at least three (3) semi-annual compliance status reports to EPA, as required by the EtO MACT, in which Cosmed reported no excess EtO emissions or any other *deviations*, as defined in Subpart O, at the San Diego Facility.

Baltimore, Maryland Facility

69. Cosmed owns or operates a sterilization facility located at 4200 Boston Street in Baltimore, MD (the "Maryland Facility"). The Maryland Facility contains approximately 5 sterilization chambers designated by Cosmed as Units A, B, C, D, and E. Cosmed began operations at the Maryland Facility in or around 1988.

70. The Maryland Facility is a Ten Ton Source at which Cosmed employs one or more acid-water scrubbers to control EtO emissions from sterilization chamber vents there.

71. EPA granted Cosmed an extension of ninety (90) days from the deadline of December 6, 1998 to perform compliance testing at the Maryland Facility, as required under the EtO MACT.

72. On or about March 22 through March 24, 2000, Cosmed conducted compliance testing at the Maryland Facility, as required by the EtO MACT.

73. On or about March 19, 2002, duly authorized EPA and Maryland Department of the Environment inspectors conducted a CAA inspection of the Maryland Facility.

CLAIMS FOR RELIEF

Claims for Relief - Rhode Island Facility

First Claim for Relief
Rhode Island Facility (Excess Emissions - Aeration Room)

74. The United States incorporates by reference the allegations in Paragraphs 1

through 30 and 34 through 42 of this complaint.

75. Based on the inspection at the Rhode Island Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, results of emissions testing conducted by Cosmed, and EPA's investigation concerning Clean Air Act compliance at the Rhode Island Facility, Cosmed failed to install EtO control equipment for its aeration room vents at the Rhode Island Facility by the regulatory deadline of December 6, 2000 and, thus, failed to control EtO emissions from each aeration room vent at the Rhode Island Facility, as required by 40 C.F.R. §§ 63.360(g) and 63.362(a), (b), (c) and (d), causing EtO emissions to the ambient air in excess of allowable limits.

76. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Rhode Island Facility.

Second Claim for Relief
Rhode Island Facility (Initial Notification)

77. The United States incorporates by reference the allegations in Paragraphs 1 through 30 and 34 through 42 of this complaint.

78. Based on the inspection at the Rhode Island Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Rhode Island Facility, Cosmed failed to notify EPA, not later than 120 calendar days of the effective date of the relevant standard (i.e., by no later than April 5, 1995), that the Rhode Island Facility is subject to the relevant standard and to provide the information set forth in 40 C.F.R. § 63.9(b)(2), as required by 40 C.F.R. §§ 63.366(c) and 63.9(b)(2).

79. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Rhode Island Facility.

Third Claim for Relief
Rhode Island Facility (Compliance Testing - Sterilization Chamber)

80. The United States incorporates by reference the allegations in Paragraphs 1 through 30 and 34 through 42 of this complaint.

81. Based on the inspection at the Rhode Island Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Rhode Island Facility, Cosmed failed to conduct initial performance testing of the sterilization chamber vent control equipment using the procedures listed in 40 C.F.R. §§ 63.7 and 63.363 and the test methods listed in 40 C.F.R. § 63.365, and to complete such testing within 180 days after the compliance date for controlling EtO from sterilization chamber vents (i.e., by no later than June 4, 1999), as required by 40 C.F.R. §§ 63.363(a)(1) and 63.363(a)(2).

82. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Rhode Island Facility.

Fourth Claim for Relief
Rhode Island Facility (Compliance Testing - Aeration Room)

83. The United States incorporates by reference the allegations in Paragraphs 1 through 30 and 34 through 42 of this complaint.

84. Based on the inspection at the Rhode Island Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Rhode Island Facility, Cosmed failed to conduct initial performance testing of the aeration room vent control equipment using the procedures listed in 40 C.F.R. §§ 63.7 and 63.363 and the test methods listed in 40 C.F.R. § 63.365, and to complete such testing within 180 days after the compliance date for controlling EtO from aeration room vents (i.e., by no later than June 4, 2001), as required by 40 C.F.R. §§ 63.363(a)(1) and 63.363(a)(2).

85. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Rhode Island Facility.

Fifth Claim for Relief
Rhode Island Facility (Notice of Compliance Status - Sterilization Chamber)

86. The United States incorporates by reference the allegations in Paragraphs 1 through 30 and 34 through 42 of this complaint.

87. Based on the inspection at the Rhode Island Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Rhode Island Facility, Cosmed failed to submit to EPA, within 60 days following the date for completion of initial performance testing (i.e., by no later than August 3, 1999), a signed and certified notification of compliance status attesting to whether the Rhode Island Facility has complied with the standard for controlling EtO emissions from the sterilization chamber vents, as required by 40 C.F.R. §§ 63.366(c) and 63.9(h).

88. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Rhode Island Facility.

Sixth Claim for Relief
Rhode Island Facility (Notice of Compliance Status - Aeration Room)

89. The United States incorporates by reference the allegations in Paragraphs 1 through 30 and 34 through 42 of this complaint.

90. Based on the inspection at the Rhode Island Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Rhode Island Facility, Cosmed failed to submit to EPA, within 60 days following the date for completion of initial performance testing (i.e., by no later than August 3, 2001), a signed and certified notification of compliance status attesting to whether the Rhode Island Facility has complied with the standard for controlling EtO emissions from the aeration room vents, as required by 40 C.F.R. §§ 63.366(c) and 63.9(h).

91. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Rhode Island Facility.

Claims for Relief - New Jersey Facility

Seventh Claim for Relief
New Jersey Facility (Excess Emissions - Sterilization Chamber)

92. The United States incorporates by reference the allegations in Paragraphs 1

through 30, 34 through 37, and 43 through 47 of this complaint.

93. Based on the inspection at the New Jersey Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, results of emissions testing conducted by Cosmed, and EPA's investigation concerning Clean Air Act compliance at the New Jersey Facility, Cosmed failed to operate EtO control equipment for its sterilization chamber vents at the New Jersey Facility such that EtO emissions to the atmosphere from each sterilization chamber vent were reduced by at least 99% on and after the regulatory deadline of December 6, 1998, as required by 40 C.F.R. §§ 63.360(g) and 63.362(a), (b), (c) and (d), that Cosmed, thus, caused EtO emissions to the ambient air in excess of allowable limits.

94. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the New Jersey Facility.

Eighth Claim for Relief
New Jersey Facility (Excess Emissions - Aeration Room)

95. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 43 through 47 of this complaint.

96. Based on the inspection at the New Jersey Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, results of emissions testing conducted by Cosmed, and EPA's investigation concerning Clean Air Act compliance at the New Jersey Facility, Cosmed failed to install EtO control equipment for its aeration room vents at the New Jersey Facility by the regulatory deadline of December 6, 2000 and, thus, failed to control EtO emissions from aeration room

vents at the New Jersey Facility, as required by 40 C.F.R. §§ 63.360(g) and 63.362(a), (b), (c) and (d), causing EtO emissions to the ambient air in excess of allowable limits.

97. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the New Jersey Facility.

Ninth Claim for Relief
New Jersey Facility (Initial Notification)

98. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 43 through 47 of this complaint.

99. Based on the inspection at the New Jersey Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the New Jersey Facility, Cosmed failed to notify EPA, not later than 120 calendar days of the effective date of the relevant standard (i.e., by no later than April 5, 1995), that the New Jersey Facility is subject to the relevant standard and to provide the information set forth in 40 C.F.R. § 63.9(b)(2), as required by 40 C.F.R. §§ 63.366(c) and 63.9(b)(2).

100. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the New Jersey Facility.

Tenth Claim for Relief
New Jersey Facility (Compliance Testing - Sterilization Chamber)

101. The United States incorporates by reference the allegations in Paragraphs 1

through 30, 34 through 37, and 43 through 47 of this complaint.

102. Based on the inspection at the New Jersey Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the New Jersey Facility, Cosmed failed to conduct initial performance testing of the sterilization chamber vent control equipment using the procedures listed in 40 C.F.R. §§ 63.7 and 63.363 and the test methods listed in 40 C.F.R. § 63.365, and to complete such testing within 180 days after the compliance date for controlling EtO from sterilization chamber vents (i.e., by no later than June 4, 1999), as required by 40 C.F.R. §§ 63.363(a)(1) and 63.363(a)(2).

103. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the New Jersey Facility.

Eleventh Claim for Relief
New Jersey Facility (Compliance Testing - Aeration Room)

104. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 43 through 47 of this complaint.

105. Based on the inspection at the New Jersey Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the New Jersey Facility, Cosmed failed to conduct initial performance testing of the aeration room vent control equipment using the procedures listed in 40 C.F.R. §§ 63.7 and 63.363 and the test methods listed in 40 C.F.R. § 63.365, and to complete such testing within 180 days after the compliance date for controlling EtO emissions from aeration room vents (i.e., by no later than June 4,

2001), as required by 40 C.F.R. §§ 63.363(a)(1) and 63.363(a)(2).

106. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the New Jersey Facility.

Twelfth Claim for Relief
New Jersey Facility (Notice of Compliance Status - Sterilization Chamber)

107. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 43 through 47 of this complaint.

108. Based on the inspection at the New Jersey Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the New Jersey Facility, Cosmed failed to submit to EPA, within 60 days following the date for completion of initial performance testing (i.e., by no later than August 3, 1999), a signed and certified notification of compliance status attesting to whether the New Jersey Facility has complied with the standard for controlling EtO emissions from the sterilization chamber vents, as required by 40 C.F.R. §§ 63.366(c) and 63.9(h).

109. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the New Jersey Facility.

Thirteenth Claim for Relief
New Jersey Facility (Notice of Compliance Status - Aeration Room)

110. The United States incorporates by reference the allegations in Paragraphs 1

through 30, 34 through 37, and 43 through 47 of this complaint.

111. Based on the inspection at the New Jersey Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the New Jersey Facility, Cosmed failed to submit to EPA, within 60 days following the date for completion of initial performance testing (i.e., by no later than August 3, 2001), a signed and certified notification of compliance status attesting to whether the New Jersey Facility has complied with the standard for controlling EtO emissions from the aeration room vents, as required by 40 C.F.R. §§ 63.366(c) and 63.9(h).

112. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the New Jersey Facility.

Fourteenth Claim for Relief
New Jersey Facility (Monitoring)

113. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 43 through 47 of this complaint.

114. Based on the inspection at the New Jersey Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the New Jersey Facility, Cosmed failed to install a *continuous monitoring system* ("CMS"), as defined at 40 C.F.R. § 63.2, by no later than December 6, 1998 for sterilization chamber vent control equipment and by no later than December 6, 2000 for aeration room vent control equipment, used for demonstrating compliance with EtO MACT emissions limits for sterilization

chamber and aeration room vents and, thus, failed to comply with the monitoring requirements of 40 C.F.R. § 63.8, according to the applicability in Table 1 of 40 C.F.R. § 63.360, and in 40 C.F.R. § 63.364.

115. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the New Jersey Facility.

Fifteenth Claim for Relief
New Jersey Facility (Recordkeeping)

116. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 43 through 47 of this complaint.

117. Based on the inspection at the New Jersey Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the New Jersey Facility, Cosmed failed to maintain files of all required measurements needed to demonstrate compliance with the EtO MACT emissions limits for sterilization chamber and aeration room vents and, thus, failed to comply with the recordkeeping requirements in 40 C.F.R. §§ 63.10(b) and (c), according to the applicability in Table 1 of 40 C.F.R. § 63.360, and in 40 C.F.R. § 63.367, as required by 40 C.F.R. §§ 63.367(a), 63.10(b)(2), and 63.4(a)(2).

118. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the New Jersey Facility.

Claims for Relief - Illinois Facility

Sixteenth Claim for Relief
Illinois Facility (Excess Emissions - Aeration Room)

119. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 48 through 55 of this complaint.

120. Based on the inspection at the Illinois Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, results of emissions testing conducted by Cosmed, and EPA's investigation concerning Clean Air Act compliance at the Illinois Facility, Cosmed failed to operate EtO control equipment for its aeration room vents at the Illinois Facility such that EtO emissions to the atmosphere from each aeration room vent were reduced to a maximum concentration of 1 ppmv or by at least 99%, whichever is less stringent, on and after the regulatory deadline of December 6, 2000, as required by 40 C.F.R. §§ 63.360(g) and 63.362(a), (b), (c) and (d), that Cosmed, thus, caused EtO emissions to the ambient air in excess of allowable limits.

121. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Illinois Facility.

Seventeenth Claim for Relief
Illinois Facility (Compliance Testing - Aeration Room)

122. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 48 through 55 of this complaint.

123. Based on the inspection at the Illinois Facility, Cosmed's responses to the

Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Illinois Facility, Cosmed failed to conduct initial performance testing of the aeration room vent control equipment at the Illinois Facility using the procedures listed in 40 C.F.R. §§ 63.7 and 63.363 and the test methods listed in 40 C.F.R. § 63.365, and failed to complete such testing within 180 days after the compliance date for controlling EtO from aeration room vents (i.e., by no later than June 4, 2001), as required by 40 C.F.R. §§ 63.363(a)(1) and 63.363(a)(2).

124. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Illinois Facility.

Eighteenth Claim for Relief
Illinois Facility (Monitoring)

125. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 48 through 55 of this complaint.

126. Based on the inspection at the Illinois Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Illinois Facility, Cosmed failed to install a *continuous monitoring system* ("CMS"), as defined at 40 C.F.R. § 63.2, by on or about June 4, 2001 for aeration room vent control equipment, used for demonstrating compliance with EtO MACT emissions limits for aeration room vents and, thus, failed to comply with the monitoring requirements of 40 C.F.R. § 63.8, according to the applicability in Table 1 of 40 C.F.R. § 63.360, and in 40 C.F.R. § 63.364.

127. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable

for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Illinois Facility.

Nineteenth Claim for Relief
Illinois Facility (Recordkeeping)

128. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 48 through 55 of this complaint.

129. Based on the inspection at the Illinois Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Illinois Facility, Cosmed failed to maintain files of all required measurements needed to demonstrate compliance with the EtO MACT emissions limits for sterilization chamber and aeration room vents and, thus, failed to comply with the recordkeeping requirements in 40 C.F.R. §§ 63.10(b), 63.10(c), and 63.367, as required by Table 1 of 40 C.F.R. § 63.360 and by 40 C.F.R. §§ 63.367(a), 63.10(b)(2), and 63.4(a)(2).

130. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Illinois Facility.

Twentieth Claim for Relief
Illinois Facility (Illinois State Implementation Plan)

131. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 48 through 55 of this complaint.

132. Based on the inspection at the Illinois Facility, Cosmed's responses to the

Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Illinois Facility, Cosmed failed to obtain a permit to operate, as required by federally-enforceable provisions of the Illinois State Implementation Plan at 35 IAC 201.143. *See* 37 Fed. Reg. 10862 (May 31, 1972).

133. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Illinois Facility.

Claims for Relief - Texas Facility

Twenty-First Claim for Relief
Texas Facility (Compliance Testing - Sterilization Chamber No. 5)

134. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 56 through 63 of this complaint.

135. Based on the inspection at the Texas Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Texas Facility, Cosmed failed to conduct initial performance testing of the sterilization chamber vent control equipment for Sterilization Chamber No. 5 at the Texas Facility using the procedures listed in 40 C.F.R. §§ 63.7 and 63.363 and the test methods listed in 40 C.F.R. § 63.365, and to complete such testing within 180 days after the compliance date for controlling EtO from sterilization chamber vents from Sterilization Chamber No. 5 (i.e., by no later than March 4, 2002), as required by 40 C.F.R. §§ 63.363(a)(1) and 63.363(a)(2).

136. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable

for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Texas Facility.

Twenty-Second Claim for Relief
Texas Facility (Compliance Testing - Sterilization Chamber No. 6)

137. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 56 through 63 of this complaint.

138. Based on the inspection at the Texas Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Texas Facility, Cosmed failed to conduct initial performance testing of the sterilization chamber vent control equipment for Sterilization Chamber No. 6 at the Texas Facility using the procedures listed in 40 C.F.R. §§ 63.7 and 63.363 and the test methods listed in 40 C.F.R. § 63.365, and to complete such testing within 180 days after the compliance date for controlling EtO from sterilization chamber vents from Sterilization Chamber No. 6 (i.e., by no later than March 23, 2002), as required by 40 C.F.R. §§ 63.363(a)(1) and 63.363(a)(2).

139. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Texas Facility.

Twenty-Third Claim for Relief
Texas Facility (Compliance Testing - Sterilization Chamber No. 7)

140. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 56 through 63 of this complaint.

141. Based on the inspection at the Texas Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Texas Facility, Cosmed failed to conduct initial performance testing of the sterilization chamber vent control equipment for Sterilization Chamber No. 7 at the Texas Facility using the procedures listed in 40 C.F.R. §§ 63.7 and 63.363 and the test methods listed in 40 C.F.R. § 63.365, and to complete such testing within 180 days after the compliance date for controlling EtO from sterilization chamber vents from Sterilization Chamber No. 7 (i.e., by no later than May 12, 2002), as required by 40 C.F.R. §§ 63.363(a)(1) and 63.363(a)(2).

142. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Texas Facility.

Twenty-Fourth Claim for Relief
Texas Facility (Compliance Testing - Sterilization Chamber No. 8)

143. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 56 through 63 of this complaint.

144. Based on the inspection at the Texas Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Texas Facility, Cosmed failed to conduct initial performance testing of the sterilization chamber vent control equipment for Sterilization Chamber No. 8 (i.e., by no later than December 29, 2002) at the Texas Facility using the procedures listed in 40 C.F.R. §§ 63.7 and 63.363 and the test methods listed in 40 C.F.R. § 63.365, and to complete such testing within 180 days after

the compliance date for controlling EtO from sterilization chamber vents from Sterilization Chamber No. 8 (i.e., by no later than December 29, 2002), as required by 40 C.F.R. §§ 63.363(a)(1) and 63.363(a)(2).

145. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Texas Facility.

Twenty-Fifth Claim for Relief
Texas Facility (Compliance Operating Limits - Sterilization Chambers)

146. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 56 through 63 of this complaint.

147. Based on the inspection at the Texas Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Texas Facility, on at least three separate days, Cosmed failed to demonstrate continuous compliance with operating limits established pursuant to 40 C.F.R. § 63.363 and specified at 40 C.F.R. §§ 63.363(b)(2)(i) and 63.363(b)(2)(ii), for EtO control equipment known as Scrubber No. 2 and Scrubber No. 4 at the Texas Facility, as required by 40 C.F.R. § 63.363(f).

148. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Texas Facility.

Twenty-Sixth Claim for Relief
Texas Facility (Reporting)

149. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 56 through 63 of this complaint.

150. Based on the inspection at the Texas Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Texas Facility, Cosmed failed to comply with the reporting requirements in 40 C.F.R. § 63.366(a) and 40 C.F.R. §§ 63.10(a), (d), (e), and (f), according to the applicability in Table 1 of 40 C.F.R. § 63.360, by failing to submit a written report of deviation for the period including November 2001, within 30 days of each calendar half or quarter, as applicable, as required by 40 C.F.R. § 63.366(a)(3). Specifically, Cosmed reported continuous compliance with the EtO MACT for the period including November 2001 in a written report to EPA when, in fact, there were periods of noncompliance with the EtO MACT at the Texas Facility in that same timeframe.

151. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the Texas Facility.

Claims for Relief - California Facility

Twenty-Seventh Claim for Relief
California Facility (Compliance with Operating Limits - Sterilization Chambers)

152. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 64 through 68 of this complaint.

153. Based on inspections at the California Facility, Cosmed's responses to the

Administrative Order and Reporting Requirement, and EPA's investigation concerning CAA compliance at the California Facility, on at least three separate days between July 2000 and May 2002, Cosmed failed to demonstrate continuous compliance with operating limits established pursuant to 40 C.F.R. § 63.363 and specified at 40 C.F.R. §§ 63.363(b)(2)(i) and 63.363(b)(2)(ii), for EtO control equipment at the California Facility, as required by 40 C.F.R. § 63.363(f).

154. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the California Facility.

Twenty-Eighth Claim for Relief
California Facility (Reporting)

155. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 64 through 68 of this complaint.

156. Based on inspections at the California Facility, Cosmed's responses to the Administrative Order and Reporting Requirement, and EPA's investigation concerning CAA compliance at the California Facility, Cosmed failed to comply with the reporting requirements in 40 C.F.R. § 63.366(a) and 40 C.F.R. §§ 63.10(a), (d), (e), and (f), according to the applicability in Table 1 of 40 C.F.R. § 63.360, by failing to submit written reports of deviation for the period including July 2000 through May 2002, inclusive, within 30 days of each calendar half or quarter, as applicable, as required by 40 C.F.R. § 63.366(a)(3). Specifically, Cosmed reported continuous compliance with the EtO MACT in at least three (3) written reports to EPA covering the period of July 2000 through May 2002 when, in fact, there were periods of noncompliance with the EtO MACT at the California Facility

in or around July 2000, November 2001, and May 2002.

157. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 at the California Facility.

Claims for Relief - Maryland Facility

Twenty-Ninth Claim for Relief
Maryland Facility (Compliance Testing - Sterilization Chamber)

158. The United States incorporates by reference the allegations in Paragraphs 1 through 30, 34 through 37, and 69 through 73 of this complaint.

159. Based on the inspection at the Maryland Facility, Cosmed's responses to the Reporting Requirement, and EPA's investigation concerning Clean Air Act compliance at the Maryland Facility, Cosmed failed to conduct initial performance testing of the sterilization chamber vent control equipment using the procedures listed in 40 C.F.R. §§ 63.7 and 63.363 and the test methods listed in 40 C.F.R. § 63.365, and to complete such testing within 180 days after the compliance date for controlling EtO from sterilization chamber vents (i.e., by no later than September 2, 1999), as required by 40 C.F.R. §§ 63.363(a)(1) and 63.363(a)(2).

160. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Cosmed is liable for injunctive relief and civil penalties not to exceed $27,500 per day for each violation of the CAA occurring after January 30, 1997 and $32,500 per day for each violation of the Act occurring after March 15, 2004 and, unless restrained by this Court, Cosmed may violate the CAA and the EtO MACT in the future at the Maryland Facility.

REQUEST FOR RELIEF

WHEREFORE, the United States respectfully request that the Court grant the following relief:

1. Order Cosmed to comply with the CAA and its implementing regulations, including but not limited to, the EtO MACT and federally-enforceable requirements of the Illinois SIP;

2. Assess civil penalties against Cosmed of not more than $27,500 per day for each violation of the CAA occurring after January 30, 1997 and not more than $32,500 per day for each violation of the CAA occurring after March 15, 2004;

3. Award the costs and fees of this action to the United States; and,

4. Grant the United States such other relief as this Court deems just and proper.

Respectfully submitted,

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