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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION IX

2007 SEP 25 PM 3:30

U.S. EPA REGION IX
REGIONAL HEARING CLERK

In the matter of:)	U.S. EPA Docket No.
)	RCRA- 0 -2007- <u>0016</u>
)	<i>09</i>
AMGEN INC.)	CONSENT AGREEMENT
)	AND FINAL ORDER PURSUANT
)	TO 40 C.F.R. SECTIONS 22.13 and 22.18
)	
)	
EPA I.D. No. CAD 983 615 964)	
)	
)	
Respondent.)	

CONSENT AGREEMENT

A. PRELIMINARY STATEMENT

1. This is a civil administrative enforcement action instituted pursuant to Section 3008(a)(1) of the Resource Conservation and Recovery Act ("RCRA"), as amended, 42 U.S.C. § 6928(a)(1), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits, 40 C.F.R. Part 22. Complainant is the United States Environmental Protection Agency, Region IX ("EPA").

2. Amgen Inc. ("Respondent") owns and operates a facility located at One Amgen Center Drive, Thousand Oaks, California 91320-1799 (the "Facility"). The Facility's EPA identification number is CAD 983 615 964. Amgen is a human therapeutics company in the biotechnology industry, and is engaged in clinical research and development. Amgen processes products based on scientific advances in recombinant DNA and molecular biology. Amgen has been at the Facility for more than 25 years, and qualifies as a large quantity generator of RCRA hazardous waste.

3. EPA and Respondent agree to settle this matter, and Respondent agrees to consent to the entry of this Consent Agreement and Final Order ("CA/FO"). This CA/FO, which contains the elements of a complaint required by 40 C.F.R. §§ 22.14(a)(1)-(3) and (8), simultaneously commences and concludes this matter in accordance with 40 C.F.R. §§ 22.13 and 22.18.

4. The parties agree that settlement of the relevant matters without litigation will save time and resources, that it is in the public interest, that it is consistent with the provisions and objectives of RCRA and applicable regulations, and that entry of this CA/FO is the most appropriate means of resolving such matters.

5. This action is based on EPA allegations that Respondent failed to: (1) comply with air emission standards for equipment leaks in violation of 22 C.C.R. §§ 66265.1050 through 66265.1064 [*see also* 40 C.F.R. §§ 265.1050 through 265.1064]¹; and (2) comply with air emission standards for tanks, surface impoundments, and containers in violation of 22 C.C.R. §§ 66265.1085, 66265.1087, and 66265.1090 [*see also* 40 C.F.R. §§ 265.1085, 265.1087, and 265.1090].

B. JURISDICTION

6. On August 1, 1992, the State of California received authorization to administer the hazardous waste management program in lieu of the federal program pursuant to Section 3006 of RCRA, 42 U.S.C. § 6926, and 40 C.F.R. Part 271. The authorized program is established pursuant to the Hazardous Waste Control Law, Chapter 6.5 of Division 20 of the California Health and Safety Code and the regulations promulgated thereunder at Title 22, Division 4.5 of the California Code of Regulations (“C.C.R.”), 22 C.C.R. §§ 66001 *et seq.*

7. Respondent is a “person” as defined in 22 C.C.R. § 66260.10 [*see also* 40 C.F.R. § 260.10].

8. Respondent is the “operator” of a facility as defined in 22 C.C.R. § 66260.10 [*see also* 40 C.F.R. § 260.10].

9. Respondent’s hazardous waste manifests (from 2003, 2004 and 2005) indicated that it is a large quantity “generator” of hazardous waste as defined in 22 C.C.R. § 66260.10 [*see also* 40 C.F.R. § 260.10].

10. Respondent is and has been engaged in “storage” of hazardous waste as defined in 22 C.C.R. § 66260.10 [*see also* 40 C.F.R. § 260.10].

¹ All citations to the “C.C.R.” refer to Division 4.5 of Title 22 of the current California Code of Regulations. EPA is enforcing the California hazardous waste management program requirements as approved and authorized by the United States on August 1, 1992 (*see* 57 Fed. Reg. 32726, July 23, 1992) and the Final Authorization of Revisions to the Hazardous Waste Management Program as approved and authorized by the United States on September 26, 2001 (*see* 66 Fed. Reg. 49118, September 26, 2001). Citations to the federal regulations are included for informational purposes.

11. Respondent generates and accumulates, or has generated and accumulated, materials that are “wastes” as defined in 22 C.C.R. §§ 66260.10 and 66261.2 [*see also* 40 C.F.R. §§ 260.10 and 261.2 (referring to “solid wastes” in lieu of “wastes”)].

12. At the Facility, Respondent generated and accumulated a number of “hazardous wastes” as defined in California Health and Safety Code § 25117 and 22 C.C.R. §§ 66260.10 and 66261.3 [*see also* RCRA § 1004(5) (42 U.S.C. § 6903) and 40 C.F.R. §§ 260.10 and 261.3]. These hazardous wastes include, but are not limited to: 1) spent solvents (D001, D011, D022, D035, F002); 2) toxic lab debris (D022, D035, F002, F003, F005); 3) corrosive liquids (D002); 4) lab packs of waste chemicals (D001, D002, D003, D007, D008); 5) cyanide waste (D003, P030); 6) paint sludge (D001, D035); 7) gas cylinders (D001, D002, D003, U135); and 8) mercury waste (D002, D009, U151). The Facility contains several hazardous waste storage areas, which contain various types and sizes of containers and drums (e.g., one, five and 15-gallon polyethylene containers, 20-gallon fiber drums, and 55-gallon polyethylene drums).

13. On November 15, 2005, EPA conducted a compliance evaluation inspection (“CEI”) at the Facility. Based upon the findings EPA made during the CEI, and additional information obtained subsequent to the CEI, EPA determined that Respondent had violated California Health and Safety Code § 25100 *et seq.* and the regulations adopted pursuant thereto, as approved and authorized by the United States.

14. Section 3006 of RCRA, 42 U.S.C. § 6926, provides, *inter alia*, that authorized state hazardous waste programs are carried out under Subtitle C of RCRA. Therefore, a violation of any requirement of law under an authorized state hazardous waste program is a violation of a requirement of Subtitle C of RCRA.

15. A violation of California’s authorized hazardous waste program, found at California Health and Safety Code § 25100 *et seq.*, constitutes a violation of Subtitle C of RCRA and, therefore, a person who violates California’s authorized hazardous waste program is subject to the powers vested in the EPA Administrator by Section 3008 of RCRA, 42 U.S.C. § 6928.

16. Section 3008 of RCRA, 42 U.S.C. § 6928, authorizes the EPA Administrator to issue orders requiring compliance immediately or within a specified time for violation of any requirement of Subtitle C of RCRA, Section 3001 of RCRA *et seq.*, 42 U.S.C. § 6921 *et seq.*

17. The Administrator has delegated the authority under Section 3008 of RCRA, 42 U.S.C. § 6928, to the EPA Regional Administrator for Region IX, who has redelegated this authority to the Director of the Waste Management Division.

C. ALLEGED VIOLATIONS

COUNT I

Failure to Comply with Subpart BB Air Emission Standards for Equipment Leaks

18. Paragraphs 1 through 17 above are incorporated herein by this reference as if they were set forth here in their entirety.

19. Title 22 C.C.R. § 66262.34 requires large quantity generators to meet the requirements of Article 28.5 of Chapter 15 of the environmental health standards for the management of hazardous waste (Division 4.5 of Title 22) [*see also* 40 C.F.R. § 262.34 and Part 265 Subpart BB]. That article includes 22 C.C.R. §§ 66265.1050 through 66265.1064, which set forth air emission standards for equipment leaks [*see also* 40 C.F.R. §§ 265.1050 through 265.1064].

20. Article 28.5 requires that:

- a. each valve in gas/vapor or light liquid service shall be monitored monthly to detect leaks, quarterly, if there has been no detection of a leak for any particular valve, for two successive months, or as otherwise specified in 22 C.C.R. § 66265.1057(f), (g) or (h) [*see also* 40 C.F.R. § 265.1057(f), (g), (h)], and managed in accordance with the provisions set forth in 22 C.C.R. § 66265.1057(a) [*see also* 40 C.F.R. § 265.1057(a)]; and
- b. each owner or operator keep records in accordance with the provisions set forth in 22 C.C.R. § 66265.1064 [*see also* 40 C.F.R. § 265.1064].

21. During their inspection on November 15, 2005, EPA inspectors determined that:

- a. facility equipment was not being monitored or inspected in accordance with equipment leak requirements; and
- b. records were not being kept in accordance with the relevant recordkeeping requirements.

22. Therefore, EPA alleges that Respondent failed to comply with Article 28.5 of Chapter 15 of the environmental health standards for the management of hazardous waste (Division 4.5 of Title 22) [*see also* 40 C.F.R. § 262.34 and Part 265 Subpart BB].

COUNT II

Failure to Comply With Subpart CC Air Emission Standards for Tanks

23. Paragraphs 1 through 22 above are incorporated herein by this reference as if they were set forth here in their entirety.

24. Title 22 C.C.R. § 66262.34 requires large quantity generators to meet the requirements of Article 28.5 of Chapter 15 of the environmental health standards for the management of hazardous waste (Division 4.5 of Title 22) [*see also* 40 C.F.R. § 262.34 and 40 C.F.R. Part 265 Subpart CC]. This article includes, without limitation, 22 C.C.R. §§

66265.1085, 66265.1089 and 66265.1090, which require generators to control air pollutant emissions from tanks and containers [see also 40 C.F.R. § 262.1085, 265.1089 and 265.1090].

25. Pursuant to Article 28.5, there are two levels of air emission controls for tanks (Tank Level 1 and Tank Level 2) based on the size of the tank, maximum organic vapor pressure of the waste, and whether the tank is used in a waste stabilization process. Tank Level 1 controls are applicable to Respondent's tanks.

26. Article 28.5 requires that owners or operators controlling air emissions from tanks using Tank Level 1 controls shall:

- a. inspect the air emission control equipment in accordance with applicable standards specified in 22 C.C.R. § 66265.1085(c)(4)(A) through (C), including conducting an initial and annual inspections, and maintaining a record of the inspections in accordance with 22 C.C.R. § 66265.1090(b) [see also 40 C.F.R. § 265.1085(c)(4)(i) through (iii); §265.1090(b)];
 - b. develop and implement a written plan and schedule to perform the inspections and monitoring required by Title 22 C.C.R. § 66265.1089(a), and incorporate that plan and schedule into the facility inspection plan required under 22 C.C.R. § 66265.15, as required in 22 C.C.R. § 66265.1089(b)) [see also 40 C.F.R. § 265.1089(a),(b)]; and
 - c. record and maintain information pertaining to tank equipment and inspections required under 22 C.C.R. § 66265.1085, as specified in 22 C.C.R. § 66265.1090(a) and (b), and shall maintain such information in the facility's operating record for a minimum of 3 years [see also 40 C.F.R. § 265.1090(a), (b)].
27. During their inspection in November 2005, EPA inspectors determined that:
- a. Respondent had not conducted initial or annual inspections of hazardous waste tanks, as required by 22 C.C.R. § 66265.1085(c)(4)(A) through (C);
 - b. Respondent had failed to develop and implement a written plan and schedule to perform the inspections and monitoring, as specified by Title 22 C.C.R. § 66265.1089(a), and therefore had not incorporated that plan and schedule into the facility inspection plan required under 22 C.C.R. § 66265.15, as required in 22 C.C.R. § 66265.1089(b)); and
 - c. Respondent lacked the information pertaining to tanks, as required by 22 C.C.R. § 265.1090(a) and (b) (e.g., tank identification number and record for each inspection required by 22 C.C.R. § 66265.1085), and had not maintained such information in the facility's operating record.

28. Therefore, EPA alleges that Respondent failed comply with Article 28.5 of Chapter 15 of the environmental health standards for the management of hazardous waste (Division 4.5 of Title 22) [see also 40 C.F.R. § 262.34 and Part 265 Subpart CC].

D. CIVIL PENALTY

29. Section 3008(g) of RCRA, 42 U.S.C. § 6928(g), as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461, and the Debt Collection Improvement Act of 1996, 31 U.S.C. § 3701 (see 61 Fed. Reg. 69360 (Dec. 31, 1996)), authorizes a civil penalty of up to TWENTY-SEVEN THOUSAND FIVE HUNDRED DOLLARS (\$27,500) per day for violations of Subtitle C of RCRA, 42 U.S.C. § 6921 *et seq.*, occurring on January 31, 1997 but before March 16, 2004, and a penalty of up to THIRTY-TWO THOUSAND FIVE HUNDRED DOLLARS (\$32,500) per day for violations of Subtitle C of RCRA, 42 U.S.C. § 6921 *et seq.*, occurring March 15, 2004 or thereafter. Based upon the facts alleged herein and upon those factors which EPA must consider pursuant to Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), and the June 2003 "RCRA Civil Penalty Policy", including the seriousness of the violations, any good faith efforts by Respondent to comply with applicable requirements, and any economic benefit accruing to Respondent, as well as such other matters as justice may require, EPA proposes that Respondent be assessed TWENTY-FOUR THOUSAND THREE HUNDRED SIXTY EIGHT DOLLARS (\$24,368.00) as the civil penalty for the violations alleged herein. The proposed penalties were calculated in accordance with the June 2003 RCRA Civil Penalty Policy.

E. ADMISSIONS AND WAIVERS OF RIGHTS

30. For the purposes of this proceeding, Respondent admits to the jurisdictional allegations of facts and law set forth in Section B of this CA/FO. Respondent consents to and agrees not to contest EPA's jurisdiction and authority to enter into and issue this CA/FO and to enforce its terms. Further, Respondent will not contest EPA's jurisdiction and authority to compel compliance with this CA/FO in any enforcement proceedings, either administrative or judicial, or to impose sanctions for violations of this CA/FO.

31. Respondent neither admits nor denies any allegations of fact or law set forth in Paragraph 13 or Section C of this CA/FO. Respondent hereby waives any rights Respondent may have to contest the allegations set forth in this CA/FO, waives any rights Respondent may have to a hearing on any issue relating to the factual allegations or legal conclusions set forth in this CA/FO, including without limitation a hearing pursuant to Section 3008(b) of RCRA, 42 U.S.C. § 6928(b), and hereby consents to the issuance of this CA/FO without adjudication. In addition, Respondent hereby waives any rights Respondent may have to appeal the Final Order attached to this Consent Agreement and made part of this CA/FO.

F. PARTIES BOUND

32. This CA/FO shall apply to and be binding upon Respondent and its agents, successors and assigns and upon all persons acting under or for Respondent, until such time as the civil penalty required under Sections D and G has been paid in accordance with Section G.

At such time as those matters are concluded, this CA/FO shall terminate and constitute full settlement of the violations alleged herein.

33. No change in ownership or corporate, partnership or legal status relating to the Facility will in any way alter Respondent's obligations and responsibilities under this CA/FO.

34. Until the termination of this CA/FO, Respondent shall give notice of this CA/FO to any successor in interest prior to transfer of ownership or operation of the Facility and shall notify EPA at least seven (7) days prior to such transfer.

35. The undersigned representative of Respondent hereby certifies he or she is fully authorized by Respondent to enter into this CA/FO, to execute and to legally bind Respondent to it.

G. PAYMENT OF CIVIL PENALTY

36. Respondent consents to the assessment of and agrees to pay a civil penalty of TWENTY-FOUR THOUSAND THREE HUNDRED SIXTY EIGHT DOLLARS (\$24,368.00), in full settlement of the federal civil penalty claims set forth in this CA/FO.

37. Respondent shall submit payment of the TWENTY-FOUR THOUSAND THREE HUNDRED SIXTY EIGHT DOLLARS (\$24,368.00) civil penalty within thirty (30) calendar days of the Effective Date of this CA/FO. (As defined in Paragraph 52, the Effective Date of this CA/FO is the date the Regional Hearing Clerk files the Final Order signed by the Regional Judicial Officer.) All payments shall indicate the name of the Facility, EPA identification number of the Facility, Respondent's name and address, and the EPA docket number of this action.

All penalties shall be made payable by certified or cashier's check to "Treasurer of the United States" and shall be remitted to:

Mellon Bank
U.S. Environmental Protection Agency - Region 9
P.O. Box 371099M
Pittsburgh, PA 15251

At the time payment is made, Respondent shall send a copy of the check to:

Danielle Carr
Regional Hearing Clerk (RC-1)
U.S. Environmental Protection Agency - Region 9
75 Hawthorne Street
San Francisco, CA 94105

and

Loren Henning (WST-3)
Waste Management Division
U.S. Environmental Protection Agency - Region IX
75 Hawthorne Street
San Francisco, CA 94105

38. In accordance with the Debt Collection Improvement Act of 1982 and U.S. Treasury directive (TFRM 6-8000), the payment must be received within thirty (30) calendar days of the Effective Date of this CA/FO to avoid additional charges. If payment is not received within thirty (30) calendar days, interest will accrue from the Effective Date of this CA/FO at the current rate published by the United States Treasury as described in 40 C.F.R. § 13.11. A late penalty charge of \$15.00 will be imposed after thirty (30) calendar days with an additional \$15.00 charge for each subsequent 30-day period. A 6% per annum penalty will further apply on any principal amount not paid within ninety (90) calendar days of the due date. Respondent further will be liable for stipulated penalties as set forth below for any payment not received by its due date.

H. DELAY IN PERFORMANCE/STIPULATED PENALTIES

39. In the event Respondent fails to meet any requirement set forth in this CA/FO, Respondent shall pay stipulated penalties as set forth below:

For failure to submit a payment to EPA by the time required in this CA/FO: ONE THOUSAND DOLLARS (\$1,000.00) per day for the first to fifteenth day of delay, ONE THOUSAND FIVE HUNDRED DOLLARS (\$1,500.00) per day for the sixteenth to thirtieth day of delay, and TWO THOUSAND FIVE HUNDRED DOLLARS (\$2,500.00) per day for each day of delay thereafter.

40. All penalties shall begin to accrue on the date that performance is due or a violation occurs, and shall continue to accrue through the final day of correction of the noncompliance. Nothing herein shall prevent the simultaneous accrual of separate penalties for separate violations. EPA will notify Respondent when penalties are due.

41. All penalties owed to EPA under this Section shall be due within thirty (30) days of receipt of a notification of noncompliance. Such notification shall describe the noncompliance and shall indicate the amount of penalties due. Interest at the current rate published by the United States Treasury, as described at 40 C.F.R. § 13.11, shall begin to accrue on the unpaid balance at the end of the thirty-day period.

42. All penalties shall be made payable by certified or cashier's check to "Treasurer of the United States" and shall be remitted as described in Paragraph 37.

43. The payment of stipulated penalties shall not alter in any way Respondent's obligation to complete the performance required hereunder.

44. The stipulated penalties set forth in this Section do not preclude EPA from pursuing any other remedies or sanctions which may be available to EPA by reason of Respondent's failure to comply with any of the requirements of this CA/FO.

J. RESERVATION OF RIGHTS

45. EPA hereby reserves (i) all of its statutory and regulatory powers, authorities, rights, and remedies, both legal and equitable, including the right to require that Respondent perform tasks in addition to those required by this CA/FO, and (ii) all of its statutory and regulatory powers, authorities, rights and remedies, both legal and equitable, which may pertain to Respondent's failure to comply with any of the requirements of this CA/FO, including without limitation, the assessment of penalties under Section 3008(c) of RCRA, 42 U.S.C. § 6928(c). This CA/FO shall not be construed as a covenant not to sue, release, waiver or limitation of any rights, remedies, powers or authorities, civil or criminal, the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended ("CERCLA"), or any other statutory, regulatory or common law enforcement authority of the United States.

46. Compliance by Respondent with the terms of this CA/FO shall not relieve Respondent of its obligations to comply with RCRA or any other applicable local, State or federal laws and regulations.

47. The entry of this CA/FO and Respondent's consent to comply shall not limit or otherwise preclude EPA from taking additional enforcement actions should EPA determine that such actions are warranted except as it relates to Respondent's liability for federal civil penalties for the specific alleged violations and facts as set forth in Section C of this CA/FO.

48. This CA/FO is not intended to be nor shall it be construed as a permit. This CA/FO does not relieve Respondent of any obligation to obtain and comply with any local, State or federal permits.

K. OTHER CLAIMS

49. Nothing in this CA/FO shall constitute or be construed as a release from any other claim, cause of action or demand in law or equity by or against any person, firm, partnership, entity or corporation for any liability it may have arising out of or relating in any way to the generation, storage, treatment, handling, transportation, release, or disposal of any hazardous constituents, hazardous substances, hazardous wastes, pollutants, or contaminants found at, taken to, or taken from the Facility.

L. MISCELLANEOUS

50. This CA/FO may be amended or modified only by written agreement executed by both EPA and Respondent.

51. The headings in this CA/FO are for convenience of reference only and shall not affect interpretation of this CA/FO.

52. The Effective Date of this CA/FO is the date the Final Order, signed by the Regional Judicial Officer, is filed by the Regional Hearing Clerk.

IT IS SO AGREED.

Respondent

8/28/2007

Date



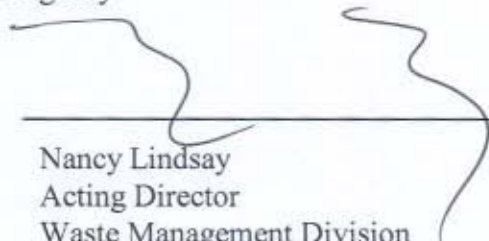
Mark Frankcom
Vice President, Environmental, Health & Safety
Amgen Inc.



United States Environmental Protection Agency

9/24/07

Date



Nancy Lindsay
Acting Director
Waste Management Division
United States Environmental Protection Agency,
Region IX

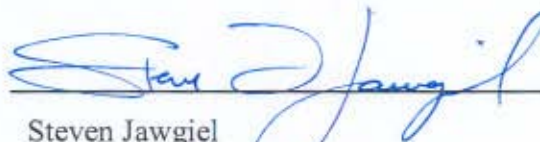
FINAL ORDER

IT IS HEREBY ORDERED that this Consent Agreement and Final Order Pursuant to 40 C.F.R. Sections 22.13 and 22.18 (U.S. EPA Docket No. RCRA-09-2007-0016) be entered and that Amgen Inc. pay a civil penalty of TWENTY-FOUR THOUSAND THREE HUNDRED SIXTY EIGHT DOLLARS (\$24,368.00), due within thirty (30) days from the Effective Date of this Consent Agreement and Final Order. Payment must be made by certified or cashier's check made out to the Treasurer of the United States, and sent to Mellon Bank, P.O. Box 371099M, Pittsburgh, PA 15251. A copy of the check shall be sent to the EPA Region IX address specified in Section G of this Consent Agreement and Final Order within such 30-day period.

This Final Order shall be effective upon filing by the Regional Hearing Clerk.

09/25/07

Date



Steven Jawgiel
Regional Judicial Officer
United States Environmental Protection Agency,
Region IX

CERTIFICATE OF SERVICE

I hereby certify that the original of the foregoing Consent Agreement and Final Order was filed with the Regional Hearing Clerk, Region IX, and that a copy was sent, certified mail, return receipt requested, to:

Matt Wein, Esq.
Amgen Inc.
One Amgen Center Drive
Mailstop 28-1-A
Thousand Oaks, CA 91320-1799

and

Zachary R. Walton, Esq.
of Paul, Hastings, Janofsky & Walker LLP
55 Second Street, 24th Floor
San Francisco, CA 94105

SEP 26 2007

Date

Danielle E. Carr
Danielle E. Carr
Hazardous Waste Management Division
Regional Hearing Clerk
U.S. EPA, Region 9