



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

SEP 30 2011

REPLY TO THE ATTENTION OF:

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Joe Simon
Director, Environment, Health, Safety and Energy
Abbott Laboratories
Department 05G2, Building M1
1401 Sheridan Road
North Chicago, Illinois 60064-6299

Re: Abbott Laboratories
Administrative Consent Order EPA-5-11-113(a)-IL-10

Dear Mr. Simon:

Enclosed is an executed original of the Administrative Consent Order regarding the above-captioned case. If you have any questions about the Order, please contact me at 312-886-6812

Sincerely,

 *for Brent Marable*

Brent Marable
Chief
Air Enforcement and Compliance Assurance Section (IL/IN)

Enclosure: Administrative Consent Order EPA-5-11-113(a)-IL-10

cc: Ray Pilapil, Air Quality Division
Illinois Environmental Protection Agency

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5**

In the Matter of:)	EPA-5-11-113(a)-IL-10
)	
Abbott Laboratories)	Proceeding Under Sections 113(a)(3)
North Chicago, Illinois)	and 114(a)(1) of the Clean Air Act
)	42 U.S.C. §§ 7413(a)(3)
)	and 7414(a)(1)
)	
)	
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)	

Administrative Consent Order

1. The Director of the Air and Radiation Division, U.S. Environmental Protection Agency, Region 5, is issuing this Order to Abbott Laboratories (Abbott) under Sections 113(a)(3) and 114(a)(1) of the Clean Air Act (the Act), 42 U.S.C. §§ 7413(a)(3) and 7414(a)(1).

Statutory and Regulatory Background

2. Under Section 112 of the Act, 42 U.S.C. § 7412, EPA promulgated the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceuticals Production (Subpart GGG) at 40 C.F.R. §§ 1250 through 1261. The NESHAP for Pharmaceuticals Production applies to operations that manufacture a pharmaceutical product, are a major source and process, use or produce hazardous air pollutants (HAPs).

3. The Pharmaceuticals Production NESHAP, at 40 C.F.R. § 63.1254(a)(3)(i), states that for existing sources, "...uncontrolled HAP emissions from a process vent must be reduced by 98 percent ..."

4. The General Provisions of the NESHAP, at 40 C.F.R. § 63.6(e)(1)(i), state that, "At all times, including periods of startup, shutdown, and malfunction, the owner or operator

must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions.”

5. Under Section 113(a)(3) of the Act, 42 U.S.C. § 7413(a)(3), the Administrator of EPA may issue an order requiring compliance to any person who has violated or is violating the NESHAP regulations. In EPA, Region 5, the Administrator has delegated this authority to the Director of the Air and Radiation Division.

6. The Administrator of EPA may require any person who owns or operates an emission source to make reports and provide information required by the Administrator under Section 114(a)(1) of the Act, 42 U.S.C. § 7414(a)(1). The Administrator has delegated this authority to the Director of the Air and Radiation Division.

Findings

7. Abbott owns and operates a pharmaceutical manufacturing plant at 1401 Sheridan Road in North Chicago, Illinois (facility).

8. Abbott manufactures bulk pharmaceutical active ingredients by fermentation and chemical synthesis; is a major source of carbon monoxide, nitrogen oxides, particulate matter less than 10 micrometers in diameter, sulfur dioxide, volatile organic material and hazardous air pollutant (HAP) emissions; and processes, uses or produces HAPs. Thus, Abbott is subject to the Pharmaceuticals Production NESHAP.

9. Abbott owns and operates an “emission source” within the meaning of Section 114(a)(1) of the Act, 42 U.S.C. § 7414(a)(1). Therefore, Abbott is subject to the requirements of Section 114(a)(1).

10. Dichloromethane (also known as methylene chloride) is a HAP that is used at Abbott in a pharmaceutical manufacturing process that produces antibiotics, such as erythromycin, via a fermentation batch process.

11. Abbott controls dichloromethane emissions from its pharmaceutical manufacturing process with a carbon bed adsorption system. This is a three-bed system that typically operates with one bed in adsorption mode, a second bed in regeneration/cool-down mode and the third bed in standby mode.

12. On January 24, 2011, EPA issued to Abbott a Notice of Violation/Finding of Violation (NOV/FOV) alleging that Abbott violated the Pharmaceuticals Production NESHAP because dichloromethane emissions from a process vent were not reduced by 98 percent on January 23 and 24, 2010, in accordance with 40 C.F.R. § 63.1254(a)(3)(i).

13. In addition to the above-mentioned allegation, during the malfunction that occurred at the automatic control system for carbon bed adsorption system operation on January 23 and 24, 2010, EPA alleges that Abbott did not operate and maintain its pharmaceutical manufacturing process emission sources and carbon bed adsorption system in a manner consistent with safety and good air pollution control practices for minimizing emissions in accordance with 40 C.F.R. § 63.6(e)(1)(i) because Abbott failed to:

- a. Check the status of timer alarm, fault and shutdown conditions along with any other alarms during each shift so as to prevent excess emissions;
- b. Comply with its startup, shutdown and malfunction plan (SSM Plan) by not porting emissions to the two other adsorbers to prevent the use of the malfunctioning adsorber until it was operating properly;

- c. Comply with its SSM Plan by not taking actions to shut down the pharmaceutical manufacturing process equipment when there was a malfunction and excess emissions were being released to the atmosphere; and
- d. Have an adequate alarm system in place to provide effective communication to staff to prevent excess emissions.

EPA finds that failure to follow good air pollution control practices resulted in a release of 3,000 pounds of dichloromethane in a 16.8-hour period.

14. On February 24, 2011, representatives of Abbott and EPA discussed the January 24, 2011 NOV/FOV.

15. EPA alleges that Abbott violated the Pharmaceuticals Production NESHAP at 40 C.F.R. § 63.1254(a)(3)(i).

Compliance Program

16. By the effective date of this Order, Abbott must achieve, demonstrate and maintain compliance with the Pharmaceuticals Production NESHAP at its North Chicago, Illinois facility.

17. Abbott shall operate such that if any of the fault conditions listed below occur on any of the three carbon beds, the carbon bed adsorption system will switch from a 3-bed to 2-bed operation mode:

- a. Bed or inlet or outlet valves are not in the required position;
- b. The minimum bed steam temperature for regeneration is not achieved;
- c. The maximum bed cooling temperature for cooling is not achieved;
- d. The cooling blower fails during cooling sequences; or

e. Low steam flow rate.

18. Abbott shall operate such that if a fault condition continues or another fault condition occurs on any of the three carbon beds while the carbon bed adsorption system is in a 2-bed mode of operation, the carbon bed adsorption system and the entire associated pharmaceutical manufacturing processes (including all emission units) will shut down.

19. Abbott shall operate such that if any of the shutdown conditions listed below occur on any of the three carbon beds, the carbon bed adsorption system and the entire associated pharmaceutical manufacturing processes (including all emission units) will shut down:

- a. Solvent laden air blower stops;
- b. Cooling water supply valve is not in correct position;
- c. Decanter solvent pump stops;
- d. Any fault occurs while operating in a 2-bed mode;
- e. A fully regenerated carbon bed is not available for adsorption;
- f. A timer fault/alarm condition exists, such as the adsorption timer does not decrement;
- g. High solvent level in decanter;
- h. High water level in decanter;
- i. A rupture disk integrity sensor indicates a failure; or
- j. High condenser vent temperature; or
- k. High decanter temperature.

20. During a shutdown, Abbott shall stop all emission units and related motors, vents, blowers, valves, heating/cooling operations, etc. in the pharmaceutical manufacturing process such that all emissions are isolated and confined in the piping system and not released to the atmosphere.

21. Abbott shall start the carbon bed adsorption system and ensure a properly regenerated carbon bed is available prior to the startup of the pharmaceutical manufacturing process emission units.

22. Abbott shall continue to operate under a changed system logic such that in the case a fault condition is detected, there will not be a period during which the system is confirming that conditions are appropriate to switch to using a different carbon bed; i.e. switching to use a different carbon bed will be instantaneous. If after the switch another fault condition or a shutdown condition is detected, Abbott shall shut down the carbon bed adsorption system and the entire associated pharmaceutical manufacturing processes (including all emission units).

23. Abbott shall check the status of timer alarms, fault and shutdown conditions along with any other alarms during each shift, which means the status checks will minimally occur every eight hours. Abbott shall maintain a log of the status checks. Abbott shall submit to EPA three months of status logs within 30-days after the end of the three-month period for a year after the effective date of this Order.

24. Abbott shall ensure all pharmaceutical manufacturing process employees with responsibility for the carbon bed adsorption system are trained to maintain a status check log of the system and properly respond to an alarm notification. Employees shall also be trained in the procedure of performing a manual shutdown of the pharmaceutical manufacturing process and carbon bed adsorption system.

25. Abbott shall perform a preventative maintenance inspection on the alarm system at minimum once every month and make adjustments on the system as necessary so as to minimize system failure in the future. After this Order terminates, Abbott shall perform

preventative maintenance inspections at minimum according to best engineering judgment that is based on the manufacturer's recommendation for preventative maintenance frequency.

26. Abbott shall perform a preventative maintenance inspection on the carbon bed adsorption system at minimum once every month and make adjustments and/or replace components on the system as necessary so as to minimize system failure in the future. After this Order terminates, Abbott shall perform preventative maintenance inspections at minimum according to best engineering judgment that is based on the manufacturer's recommendation for preventative maintenance frequency.

27. Abbott shall update its SSM Plan so that it includes the provisions outlined in the Compliance Plan of this Order. The revised SSM shall be submitted to EPA within 6 months of the effective date of this Order.

28. Abbott shall maintain a log of the dates, times, duration and causes of the carbon bed adsorption system switching from a 3-bed to 2-bed operation mode. Abbott shall submit to EPA three months of these logs within 30-days after the end of a three-month period for a year after the effective date of this Order.

29. Abbott shall maintain a log of the dates, times, duration and causes a carbon bed adsorption system shutdown. Abbott shall submit to EPA three months of these logs within 30-days after the end of a three-month period for a year after the effective date of this Order.

30. Abbott must send all reports required by this Order and under Section 114(a)(1) of the Act, 42 U.S.C. § 7414(a)(1) to:

Attention: Compliance Tracker (AE-17J)
Air Enforcement and Compliance Assurance Branch
U.S. Environmental Protection Agency, Region 5
77 W. Jackson Boulevard
Chicago, Illinois 60604

General Provisions

31. This Order does not affect Abbott's responsibility to comply with other federal, state and local laws.

32. This Order does not restrict EPA's authority to enforce the NESHAP or any other section of the Act.

33. Nothing in this Order limits the EPA's authority to seek appropriate relief, including penalties, under Section 113 of the Act, 42 U.S.C. § 7413, for Abbott's violation of the Pharmaceuticals Production NESHAP.

34. Failure to comply with this Order may subject Abbott to penalties of up to \$32,500 per day for each violation under Section 113 of the Act, 42 U.S.C. § 7413, and 40 C.F.R. Part 19.

35. The terms of this Order are binding on Abbott, its assignees and successors. Abbott must give notice of this Order to any successors in interest prior to transferring ownership and must simultaneously verify to EPA, at the above address, that it has given the notice.

36. Abbott may assert a claim of business confidentiality under 40 C.F.R. Part 2, Subpart B, for any portion of the information submitted to EPA. Information subject to a business confidentiality claim is available to the public only to the extent allowed by 40 C.F.R. Part 2, Subpart B. If Abbott fails to assert a business confidentiality claim, EPA may make all submitted information available, without further notice, to any member of the public who requests it. Emission data provided under Section 114 of the Act, 42 U.S.C. § 7414, is not entitled to confidential treatment under 40 C.F.R. Part 2, Subpart B. "Emission data" is defined at 40 C.F.R. § 2.301.

37. This order is not subject to the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq., because it seeks collection of information by an agency from specific individuals or entities as part of an administrative action or investigation. To aid in our electronic recordkeeping efforts, please furnish an electronic copy on CD or thumb drive. If not possible, provide your response to this Order without staples; paper clips and binder clips, however, are acceptable.

38. Abbott neither admits nor denies the facts alleged in the Findings section of this Order.

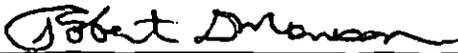
39. EPA may use any information submitted under this Order in an administrative, civil judicial or criminal action.

40. Abbott agrees to the terms of this Order.

41. This Order is effective on the date of signature by the Director of the Air and Radiation Division. This Order will terminate one year from the effective date, provided that Abbott has complied with all terms of the Order throughout its duration.

9/29/11

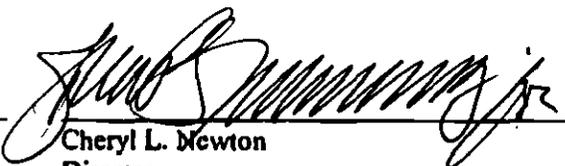
Date



Robert D. Morrison
Divisional Vice President, Environmental,
Health, Safety and Energy
Abbott Laboratories

9/30/11

Date



Cheryl L. Newton
Director
Air and Radiation Division

CERTIFICATE OF MAILING

I, Betty Williams, certify that I sent an executed original of the Administrative Consent Order, EPA Order No. EPA-5-11-113(a)-IL-10, by certified mail, return receipt requested, to:

Joe Simon
Director, Environment, Health, Safety and Energy
Abbott Laboratories
Department 05G2, Building M1
1401 Sheridan Road
North Chicago, Illinois 60064-6299

I also certify that I sent a copy of the executed original of the Administrative Consent Order by First-Class Mail to:

Ray Pilapil, Chief
Bureau of Air
Compliance and Enforcement Section
Illinois Environmental Protection Agency
1021 North Grand Avenue East
Springfield, Illinois 62702

on the 5th day of October 2011.



Betty Williams
Administrative Program Assistant
Planning and Administration Section

CERTIFIED MAIL RECEIPT NUMBER: 7009 1680 00007672 7884