



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

OCT 28 2004

REPLY TO THE ATTENTION OF

(AE-17J)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Cindalee Walsh
Director of Environmental Affairs
Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, Michigan 49001

Re: Finding of Violation
Pharmacia & Upjohn Company
Kalamazoo, Michigan

Dear Ms. Walsh:

The United States Environmental Protection Agency (U.S. EPA) is issuing the enclosed Finding of Violation (FOV) to Pharmacia & Upjohn Company (you). We find that you are in violation of Section 112 of the Clean Air Act, 42 U.S.C. § 7412, at your Kalamazoo, Michigan facility.

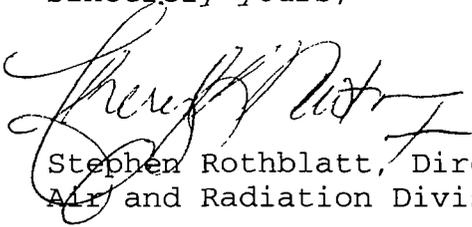
We have several enforcement options under Section 113(a)(3) of the Clean Air Act, 42 U.S.C. § 7413(a)(3). These options include issuing an administrative compliance order, issuing an administrative penalty order, and bringing a judicial civil or criminal action. The options we select may depend on, among other things, the length of time you take to achieve and demonstrate continuous compliance with the rules cited in the FOV.

We are offering you an opportunity to confer with us about the violations alleged in the FOV. The conference will give you the opportunity to present information on the specific findings of violation, the efforts you have taken to comply, and the steps you will take to prevent future violations.

Please plan for your facility's technical and management personnel to attend the conference to discuss compliance measures and commitments. You may have an attorney represent you at this conference.

The U.S. EPA contact in this matter is Shilpa Patel. You may call her at (312) 886-0120 to request a conference. You should make the request as soon as possible, but no later than 10 calendar days after you receive this letter. We should hold any conference within 30 calendar days of your receipt of this letter.

Sincerely yours,



Stephen Rothblatt, Director
Air and Radiation Division

Enclosure

**United States Environmental Protection Agency
Region 5**

IN THE MATTER OF:)
)
Pharmacia & Upjohn Company) **FINDING OF VIOLATION**
Kalamazoo, Michigan)
) **EPA-5-05-MI-01**
)
Proceedings Pursuant to)
the Clean Air Act,)
42 U.S.C. §§ 7401 et seq.)
)

FINDING OF VIOLATION

The United States Environmental Protection Agency (U.S. EPA) finds that Pharmacia & Upjohn Company (Pharmacia) is in violation of Section 112 of the Clean Air Act, 42 U.S.C. § 7412. Specifically, Pharmacia is in violation of the National Emissions Standards for Hazardous Air Pollutants (NESHAP) for Equipment Leaks at 40 C.F.R. Part 63, Subparts F and H, and the NESHAP for Pharmaceutical Production at 40 C.F.R. Part 63, Subpart GGG, along with EPA Reference Method 21 (40 C.F.R. Part 60 Appendix A) as follows:

Regulatory Authority

1. The NESHAP provisions for Equipment Leaks and the NESHAP provisions for Pharmaceutical Production apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, surge control vessel, bottoms receivers, instrumentation systems, and control devices or closed vent systems that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year.
2. The NESHAP for Equipment Leaks was proposed on December 31,

1992 and became final on April 22, 1994. The owner or operator of an existing affected source must comply with the provisions of this NESHAP no later than October 24, 1994, for the Group I category. 40 C.F.R. § 63.100(k)(3)

3. The NESHAP for Pharmaceutical Productions was proposed on September 21, 1998 and became final on September 21, 2001. The owner or operator of an existing affected source must comply with the provisions of this NESHAP no later than October 21, 2002. 40 C.F.R. § 63.1250(f)
4. The NESHAP, at 40 C.F.R. § 63.4(a)(1), provides that no owner or operator subject to the provisions of this part shall operate any affected source in violation of this requirement of this part except under an applicable extension of compliance.
5. The NESHAP, at 40 C.F.R. § 63.168(b), requires the owner or operator of a source subject to this subpart to monitor all valves at intervals specified in this section.
6. The NESHAP, at 40 C.F.R. § 63.1255 (e)(3), requires the owner or operator of a source subject to this subpart to monitor all valves at intervals specified in this section.
7. The NESHAP, at 40 C.F.R. § 63 1255(e)(4)(iv), provides that for a group of processes with less than 0.5 percent leaking valves, the owner or operator may elect to monitor each valve once every 4 quarters.
8. The NESHAP, at 40 C.F.R. § 63.174(a)(1), requires the owner or operator of a source subject to this subpart to monitor all connectors, at intervals specified in this section.
9. The NESHAP, at 40 C.F.R. § 63.178(b), requires the owner or operator who elect to use pressure testing of batch product process equipment to demonstrate compliance with this subpart.
10. The NESHAP, at 40 C.F.R. § 63.180(f), specifies procedures to be used to pressure test batch product process equipment for pressure or vacuum loss to demonstrate compliance with the requirements of this subpart.

11. The NESHAP, at 40 C.F.R. § 63.1255(b), requires the owner or operator of a source subject to the provisions of this subpart to comply with the test methods and procedures requirements provided in this section.
12. The NESHAP, at 40 C.F.R. § 63.180(b)(1), requires the owner or operator of a source to comply with the monitoring procedures and requirements of Method 21 of 40 C.F.R Part 60 Appendix A.
13. The NESHAP, at 40 C.F.R. § 63.1258(h)(3), requires the owner or operator of a source to comply with the monitoring procedures and requirements of Method 21 of 40 C.F.R Part 60 Appendix A.
14. Method 21 of 40 C.F.R. Part 60 Appendix A requires the owner or operator to slowly sample the interface where leakage is indicated until the maximum meter reading is obtained.
15. The NESHAP, at 40 C.F.R. § 63.167(a)(1), provides that each open ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve.
16. The NESHAP, at 40 C.F.R. § 63.1255(d)(i), provides that each open ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve.
17. The NESHAP, at 40 C.F.R. § 63.167(a)(2), provides that the cap, blind flange, plug, or second valve shall seal the open end at all times except during operation requiring process fluid flow through the open-ended valve or line, or during maintenance or repair.
18. The NESHAP, at 40 C.F.R. § 63.1255(d)(1)(ii), provides that the cap, blind flange, plug, or second valve shall seal the open end at all times except during operation requiring process fluid flow through the open-ended valve or line, or during maintenance or repair.
19. The NESHAP, at 40 C.F.R. § 63.167(c), provides that when a double block and bleed system is being used, the bleed valve or line may remain open during operations that require venting the line between the block valves but shall comply with (d)(1) of this section at all times.

20. The NESHAP, at 40 C.F.R. § 63.1255 (d)(3), provides that when a double block and bleed system is being used, the bleed valve or line may remain open during operations that require venting the line between the block valves but shall comply with (d)(1) of this section at all times
21. The NESHAP, at 40 C.F.R. § 63.167 (b), provides that each open-ended valve or line equipped with a second valve shall be operated in a manner such that the valve on the process fluid end is closed before the second valve is closed.
22. The NESHAP, at 40 C.F.R. § 63.1255 (d)(2), provides that each open-ended valve or line equipped with a second valve shall be operated in a manner such that the valve on the process fluid end is closed before the second valve is closed.
23. The NESHAP, at 40 C.F.R. § 63.1255(c)(3)(i), requires that a leak detected as defined by this section be repaired as soon as practicable but no later than 15 calendar days after it is detected, except when the repair is not technically feasible without a process shutdown, or repair personnel would be exposed to an immediate danger if attempting to repair without a process shutdown.

Factual Background

24. Pharmacia, a subsidiary of Pfizer Inc., manufactures prescription medicines for humans and animals.
25. Pharmacia owns and operates a chemical plant located at 7000 Portage Road in Kalamazoo, Michigan 49001.
26. Pharmacia is an existing source required to demonstrate compliance with 40 C.F.R. Part 63 Subparts GGG, H and F.
27. During March 10 and August 10-12, 2004 inspections, U.S. EPA conducted records review and "leak detection and repair" (LDAR) monitoring on process equipment and components at the Pharmacia facility subject to 40 C.F.R. Part 63, Subpart GGG, H and F per EPA Reference Method 21 (40 C.F.R. 60 Appendix A).

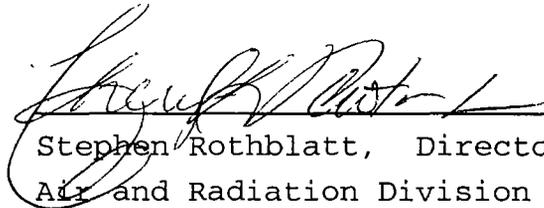
Violations

28. Pharmacia failed to monitor all valves at specified intervals, in violation of 40 C.F.R. § 63.168(b) and 40 C.F.R. § 63.1255(e)(3) and § 63.1255(e)(4)(iv).
29. Pharmacia failed to monitor all connectors at specified intervals, in violation of 40 C.F.R. § 63.174(a)(1).
30. Pharmacia failed to comply with the monitoring procedures and requirements of Method 21, in violation of 40 C.F.R. § 63.180(b)(1) and 40 C.F.R. § 63.1258(h)(3).
31. Pharmacia failed to monitor in accordance with Method 21 and to find the maximum leak during LDAR monitoring of valves and connectors for the period of 1996 (when initial monitoring was required under the regulations at issue) to the present. This is a violation of 40 C.F.R. § 63.168(b)(1), 40 C.F.R. § 63.174(a)(1), 40 C.F.R. § 63.180(b)(1), Method 21 of 40 C.F.R. Part 60 Appendix A, and 40 C.F.R. § 63.4(a)(1).
32. Pharmacia failed to equip each open valve or line with a cap, blind flange, plug, or a second valve, in violation of 40 C.F.R. § 63.167(a)(1) and 40 C.F.R. § 63.1255(d)(i).
33. Pharmacia failed to seal each open end at all times except during operation requiring process fluid flow through the open-ended valve or line, or during maintenance or repair, in violation of 40 C.F.R. § 63.167(a)(2) and 40 C.F.R. § 63.1255(d)(1)(ii).
34. Pharmacia allowed bleed valves or lines to remain open, when a double block was in place, during operations other than venting the lines between the block valves, in violation of 40 C.F.R. § 63.167(c) and 40 C.F.R. § 63.1255(d)(3).
35. Pharmacia failed to operate in a manner such that the valve on the process fluid end is closed before the second valve is closed, in violation of 40 C.F.R. § 63.167(b) and 40 C.F.R. § 63.125(d)(2).
36. Pharmacia failed to demonstrate compliance with the pressure testing regulations for batch product process equipment, in

violation of 40 C.F.R. § 63.178(b), 40 C.F.R. § 63.180(f), and 40 C.F.R. § 63.1255(e)(3).

- 37. Pharmacia failed to repair leaks in a timely manner, in violation of 40 C.F.R. § 63.1255(c)(3)(i).
- 38. Pharmacia operated an affected source in violation of the requirements of 40 C.F.R. § 63.4(a)(1).

10/28/04
Date


Stephen Rothblatt, Director
Air and Radiation Division

CERTIFICATE OF MAILING

I, Loretta Shaffer, certify that I sent a Finding of Violation, No. EPA-5-05-MI-01, by Certified Mail, Return Receipt Requested, to:

Cindalee Walsh, Director of Environmental Affairs
Pharmacia & Upjohn Company
7000 Portage Road
Kalamazoo, Michigan 49001

I also certify that I sent copies of the Finding of Violation by first class mail to:

Dale Turton
Michigan Environmental Protection Agency
7953 Adobe Road
Kalamazoo, MI 49009

on the 1st day of November, 2004.



Loretta Shaffer,
Administrative Program Assistant
AECAS, (MN/OH)

CERTIFIED MAIL RECEIPT NUMBER: 7001 0320 0006 1558 5236