



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

DEC 23 2009

REPLY TO THE ATTENTION OF  
AE-17J

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Susan Harris  
Sidley Austin LLP  
One South Dearborn  
Chicago, Illinois 60603

Dear Ms. Harris:

Enclosed is a file-stamped Consent Agreement and Final Order (CAFO) which resolves Eli Lilly and Company (Lilly), Docket No. CAA-05-2010-0007 JW. As indicated by the filing stamp on its first page, we filed the CAFO with the Regional Hearing Clerk on DEC 23 2009.

Pursuant to paragraph 28 of the CAFO, Lilly must pay the civil penalty within 30 days of January 22, 2010. Its check must display the case name, the docket number, CAA-05-2010-0007, and the billing document number, 2751003A008.

Please direct any questions regarding this case to Deborah Carlson, Associate Regional Counsel, at (312) 353-6121.

Sincerely yours,

Bonnie Bush  
Air Enforcement and Compliance Assurance  
Section (MI/WI)

Enclosure

cc: Phil Perry, Chief  
Compliance and Enforcement Branch  
Office of Air Quality  
Indiana Department of Environmental Management

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 5

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DEC 23 2009

REGIONAL HEARING CLERK  
U.S. ENVIRONMENTAL  
PROTECTION AGENCY

<b>In the Matter of:</b>	)	<b>Docket No. CAA-05-2010-0007</b>
	)	
<b>Eli Lilly and Company --</b>	)	<b>Proceeding to Assess a Civil Penalty</b>
<b>Lafayette, Indiana Facility,</b>	)	<b>Under Section 113(d) of the Clean Air</b>
	)	<b>Act, 42 U.S.C. § 7413(d)</b>
<b>Respondent.</b>	)	
_____	)	

Consent Agreement and Final Order

Preliminary Statement

1. This is an administrative action commenced and concluded under Section 113(d) of the Clean Air Act (CAA), 42 U.S.C. § 7413(d), and Sections 22.1(a)(2), 22.13(b), and 22.18(b)(2) and (3) of the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits* (Consolidated Rules), as codified at 40 C.F.R. Part 22.
2. Complainant is the Director of the Air and Radiation Division, United States Environmental Protection Agency (U.S. EPA), Region 5.
3. Respondent is Eli Lilly and Company (Lilly), a corporation doing business in Indiana.
4. Where the parties agree to settle one or more causes of action before the filing of a complaint, the administrative action may be commenced and concluded simultaneously by the issuance of a consent agreement and final order (CAFO). 40 C.F.R. § 22.13(b).
5. The parties agree that settling this action without the filing of a complaint or the adjudication of any issue of fact or law is in their interest and in the public interest.

6. Respondent consents to entry of this CAFO and the assessment of the specified civil penalty, and agrees to comply with the terms of the CAFO.

**Jurisdiction and Waiver of Right to Hearing**

7. Respondent admits the jurisdictional allegations in this CAFO and neither admits nor denies the factual allegations in the CAFO.

8. Respondent waives its right to request a hearing as provided at 40 C.F.R. § 22.15(c), any right to contest the allegations in this CAFO, and its right to appeal this CAFO.

**Statutory and Regulatory Background**

9. Under Section 112 of the Act, U.S. EPA promulgated the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceuticals Production at 40 C.F.R. Part 63, Subpart GGG. 40 C.F.R. §§ 63.1250 through 63.1261. This commonly is referred to as “Subpart GGG” or the “Pharma MACT.”

10. The owner or operator of an existing affected facility was required to comply with the requirements of Subpart GGG by October 21, 2002.

11. The “affected source” to which Subpart GGG applies is defined as operations that manufacture a pharmaceutical product, that process, use or produce a HAP, and that are located at a plant site that is a major source. 40 C.F.R. § 63.1250(a).

12. Subpart GGG establishes general standards for pharmaceutical manufacturing operations, 40 C.F.R. § 63.1252, as well as specific standards for several sources of potential emissions from those operations, including, *inter alia*, equipment leaks, at 40 C.F.R. § 63.1255.

13. The equipment leak provisions in 40 C.F.R. § 63.1255 set forth various work practice standards and testing and recordkeeping requirements, *inter alia*, to ensure that any leaks of air pollutants from equipment used in the manufacture of pharmaceutical products are

timely detected and repaired. These provisions often are referred to as “Leak Detection and Repair” provisions, or “LDAR.”

14. The LDAR requirements in Subpart GGG refer to and incorporate many of the requirements of the National Emission Standards for Organic Hazardous Air Pollutants (HAPs) for Equipment Leaks found at 40 C.F.R. Part 63, Subpart H. 40 C.F.R. §§ 63.160 through 63.183.

15. The LDAR provisions of Subpart H and Subpart GGG apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems control devices, and closed-vent systems that are intended to operate in organic HAP service 300 hours or more during the calendar year, as stated under 40 C.F.R. §§ 63.1255(a)(1) and 63.160(a) respectively.

16. Subpart GGG requires an owner or operator that is subject to the equipment leak standards of 40 C.F.R. § 63.1255 to comply with specified provisions of Subpart H, including 40 C.F.R. § 63.174. 40 C.F.R. § 63.1255(b)(4).

17. 40 C.F.R. § 63.174(d), in turn, requires that when a leak is detected, it must be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected. The owner or operator must make a first attempt at repair no later than 5 calendar days after the leak is detected. 40 C.F.R. § 63.174(d).

18. The Administrator of U.S. EPA (the Administrator) may assess a civil penalty of up to \$32,500 per day of violation up to a total of \$270,000 for violations that occurred between March 15, 2004 and January 12, 2009; and may assess a civil penalty of up to \$37,500 per day of violation up to a total of \$295,000 for violations that occur on and after January 13, 2009,

under Section 113(d)(1) of the Act, 42 U.S.C. § 7413(d)(1), and 40 C.F.R. Part 19. *73 Fed. Reg.* 75,340 (December 11, 2008).

19. Section 113(d)(1) of the CAA limits the Administrator's authority to matters where the first alleged date of violation occurred no more than 12 months prior to initiation of the administrative action, except where the Administrator and the Attorney General of the United States jointly determine that a matter involving a longer period of violation is appropriate for an administrative penalty action.

20. The Administrator and the Attorney General of the United States, each through their respective delegates, have determined jointly that an administrative penalty action is appropriate for the period of violations alleged in this CAFO.

#### **Factual Allegations and Alleged Violations**

21. Lilly owns and operates a pharmaceutical manufacturing plant at 1650 Lilly Road, Lafayette, Indiana (referred to as Tippecanoe Laboratories).

22. Tippecanoe Laboratories manufactures one or more "pharmaceutical products" within the meaning of 40 C.F.R. §63.1251.

23. Tippecanoe Laboratories processes, uses, or produces acetonitrile, hydrochloric acid, methylene chloride, and methanol which are HAPs under Section 112(b)(1) of the CAA, 42 U.S.C. § 7412(b)(1).

24. Tippecanoe Laboratories is a "stationary source" within the meaning of Sections 112(a)(3) and 302(z) of the CAA, 42 U.S.C. §§ 7412(a)(3) and 7602(z), and a "major source" of HAPs within the meaning of Section 112 (a)(1) of the CAA, 42 U.S.C. § 7412(a)(1).

25. The pharmaceutical manufacturing operations at Tippecanoe Laboratories are subject to Subpart GGG. Tippecanoe Laboratories is an existing "affected source" within the

meaning of Subpart GGG, and certain of its operations are subject to substantive requirements of Subpart GGG. 40 C.F.R. § 63.1250(a).

26. In October 2006, Lilly failed to make a first attempt to repair a leaking connector within 5 calendar days of detecting the leak at its Tippecanoe Laboratories facility, in violation of Section 112 of the CAA, 42 U.S.C. § 7412 and the implementing regulations at 40 C.F.R. §§ 63.1255(b)(4) and 63.174(d). The leak was repaired within the applicable deadlines, however.

**Civil Penalty**

27. Based on analysis of the factors specified in Section 113(e) of the Act, 42 U.S.C. § 7413(e), the facts of this case, as well as the Respondent’s cooperation and prompt return to compliance, Complainant has determined that an appropriate civil penalty to settle this action is \$12,000.

28. Within 30 days after the effective date of this CAFO, Respondent must pay a \$12,000 civil penalty by sending by express mail a cashier’s or certified check payable to the “Treasurer, United States of America,” to:

U.S. Bank  
Government Lockbox 979077 U.S. EPA Fines and Penalties  
1005 Convention Plaza  
Mail Station SL-MO-C2-GL  
St. Louis, MO 63101

The check must note the case name, docket number of this CAFO and the billing document number.

29. A transmittal letter stating Respondent’s name, complete address, the case docket number, and the billing document number must accompany the payment. Respondent must send a copy of the check and transmittal letter to:

Attn: Regional Hearing Clerk, (E-19J)  
U.S. Environmental Protection Agency, Region 5  
77 West Jackson Blvd.  
Chicago, IL 60604

Attn: Compliance Tracker, (AE-17J)  
Air Enforcement and Compliance Assurance Branch  
Air and Radiation Division  
U.S. Environmental Protection Agency, Region 5  
77 West Jackson Blvd.  
Chicago, IL 60604

Deborah Carlson, (C-14J)  
Office of Regional Counsel  
U.S. Environmental Protection Agency, Region 5  
77 West Jackson Blvd.  
Chicago, IL 60604

30. This civil penalty is not deductible for federal tax purposes.

31. If Respondent does not pay timely the civil penalty, U.S. EPA may bring an action to collect any unpaid portion of the penalty with interest, handling charges, nonpayment penalties and the United States' enforcement expenses for the collection action under Section 113(d)(5) of the Act, 42 U.S.C. § 7413(d)(5). The validity, amount, and appropriateness of the civil penalty are not reviewable in a collection action.

32. Pursuant to 31 C.F.R. § 901.9, Respondent must pay the following on any amount overdue under this CAFO. Interest will accrue on any overdue amount from the date payment was due at a rate established by the Secretary of the Treasury. Respondent must pay a \$15 handling charge each month that any portion of the penalty is more than 30 days past due. In addition, Respondent must pay a quarterly nonpayment penalty each quarter during which the assessed penalty is overdue according to Section 113(d)(5) of the Act, 42 U.S.C. § 7413(d)(5). This nonpayment penalty will be 10 percent of the aggregate amount of the outstanding penalties and nonpayment penalties accrued from the beginning of the quarter.

**General Provisions**

33. This CAFO resolves only Respondent's liability for federal civil penalties for the violations alleged in this CAFO.

34. The CAFO does not affect the right of U.S. EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violation of law.

35. This CAFO does not affect Respondent's responsibility to comply with the CAA and other applicable federal, state, and local laws. Except as provided in paragraph 33, above, compliance with this CAFO will not be a defense to any actions subsequently commenced pursuant to federal laws administered by Complainant.

36. Respondent certifies that it is currently in compliance with Subpart GGG.

37. This CAFO constitutes an "enforcement response" as that term is used in U.S. EPA's *Clean Air Act Stationary Source Civil Penalty Policy* to determine Respondent's "full compliance history" under Section 113(e) of the Act, 42 U.S.C. § 7413(e).

38. The terms of this CAFO bind Respondent, its successors, and assigns.

39. Each person signing this consent agreement certifies that he or she has the authority to sign for the party whom he or she represents and to bind that party to its terms.

40. Each party agrees to bear its own costs and attorneys' fees in this action.

41. This CAFO constitutes the entire agreement between the parties.

**Eli Lilly and Company, Respondent**

14 Dec 2009  
Date

Frank M Deane jfm  
Frank M. Deane, President  
Manufacturing Operations  
Eli Lilly and Company



**CONSENT AGREEMENT AND FINAL ORDER**

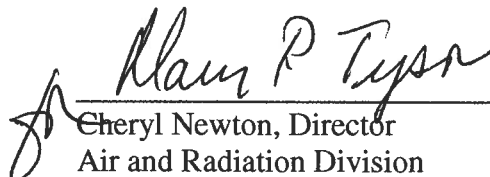
**In the Matter of:**

**Eli Lilly and Company**

**Docket No.**

**United States Environmental Protection Agency, Complainant**

12/18/09  
Date

  
\_\_\_\_\_  
Cheryl Newton, Director  
Air and Radiation Division  
U.S. Environmental Protection  
Agency, Region 5 (A-18J)

**CONSENT AGREEMENT AND FINAL ORDER**

**In the Matter of:**

**Eli Lilly and Company**

**Docket No. CAA-05-2010-0007**

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PROTECTION AGENCY

**Final Order**

This Consent Agreement and Final Order, as agreed to by the parties, shall become effective immediately upon filing with the Regional Hearing Clerk. This Final Order concludes this proceeding pursuant to 40 C.F.R. §§ 22.18 and 22.31. IT IS SO ORDERED.

Date

12/22/09



Bharat Mathur  
Acting Regional Administrator  
U.S. Environmental Protection  
Agency, Region 5

U.S. ENVIRONMENTAL  
PROTECTION AGENCY  
DEC 23 2009  
OFFICE OF REGIONAL  
COUNSEL

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PROTECTION AGENCY

**In the Matter of:**  
**Eli Lilly and Company, Lafayette Indiana Facility**  
**Docket No.**

**CAA-05-2010-0007**      **Certificate of Service**

I certify that I filed the original and one copy of the Consent Agreement and Final Order in this matter with the Regional Hearing Clerk as follows:

La Dawn Whitehead  
Regional Hearing Clerk  
U.S. EPA Region 5 (E-19J)  
77 West Jackson Boulevard  
Chicago, Illinois 60604,

and that I mailed by Certified Mail, the second original to Respondent and copy to Respondent's Counsel, addressed as follows:

Kenny McCleary, Site Services Manager  
Eli Lilly and Company  
Tippecanoe Laboratories  
1650 Lilly Road  
Lafayette, Indiana 47909

Susan Harris  
Sidley Austin LLP  
One South Dearborn  
Chicago, Illinois 60603

and that I delivered a correct copy by intra-office mail, addressed as follows:

Marcy Toney, Regional Judicial Officer (C-14J)  
United States Environmental Protection Agency  
Region 5  
77 West Jackson Boulevard  
Chicago, Illinois 60604

On this 23<sup>rd</sup> day of December, 2009

  
Cynthia Dixon

Administrative Program Assistant,  
Section 1, Multi Media Branch 1

CERTIFIED MAIL RECEIPT NUMBER: 7001 0320 0005 8917 7451