UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION VII
901 NORTH FIFTH STREET
KANSAS CITY, KANSAS 66101

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ENVIRONMENTAL PROTECTION AGENCY-REGION VII
REGIONAL HEARING CLERK

BEFORE THE ADMINISTRATOR

IN THE MATTER OF	)	
	)	
Sigma-Aldrich MFG LLC	)	
St. Louis, Missouri	)	Docket No. CAA-07-2007-0019
	)	
Respondent	)	

CONSENT AGREEMENT AND FINAL ORDER

The United States Environmental Protection Agency, Region VII (EPA) and Sigma-Aldrich MFG LLC, St. Louis, Missouri (Respondent) have agreed to a settlement of this action before filing of a complaint, and thus this action is simultaneously commenced and concluded pursuant to Rules 22.13(b) and 22.18(b)(2) of 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 (Consolidated Rules), 40 C.F.R. §§ 22.13(b), 22.18(b)(2).

FACTUAL ALLEGATIONS

Jurisdiction

1. This is an administrative action for the assessment of civil penalties instituted pursuant to Section 113(d) of the Clean Air Act, (the Act), 42 U.S.C. § 7413(d). Pursuant to Section 113(d) of the Clean Air Act, 42 U.S.C. § 7413(d), the Administrator and the Attorney General jointly determined that this matter, where the first date of alleged violation occurred more than

12 months prior to the initiation of the administrative action, was appropriate for administrative penalty action.

2. This Consent Agreement and Final Order serves as notice that EPA has reason to believe that Respondent has violated Section 112 of the Clean Air Act, 42 U.S.C. § 7412, and the National Emission Standards for Hazardous Air Pollutants (NESHAP), 40 C.F.R. Part 63, and specifically the NESHAP for Pharmaceutical Production, 40 C.F.R. Part 63, Subpart GGG, commonly referred to as the "Pharmaceutical MACT Standard". Furthermore, this Consent Agreement and Final Order serves as notice pursuant to Section 113(d)(2)(A) of the Act, 42 U.S.C. § 7413(d)(2)(A), of EPA's intent to issue an order assessing penalties for this violation.

Parties

3. The Complainant, by delegation from the Administrator of the EPA, and the Regional Administrator, EPA, Region VII, is the Director, Air, RCRA and Toxics Division, EPA, Region VII.

4. The Respondent is Sigma-Aldrich MFG LLC, located at 3300 South 2nd Street, St. Louis, Missouri. Respondent is a limited liability company active in the State of Missouri. Respondent is primarily engaged in the manufacture of organic and inorganic chemicals. Respondent has manufactured about 30 different pharmaceuticals using batch reactors.

Statutory and Regulatory Requirements

5. Section 112 of the Clean Air Act, 42 U.S.C. § 7412, authorizes the Administrator of EPA to regulate hazardous air pollutants that may have an adverse effect on health or the environment. Section 112(a)(1) of the Clean Air Act, 42 U.S.C. § 7412(a)(1), defines "major

source" as any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, considering controls, in the aggregate, ten tons per year or more of any hazardous air pollutant (HAP) or twenty-five tons per year or more of any combination of HAPs. Section 112(f)(4) of the Clean Air Act, 42 U.S.C. § 7412(f)(4), prohibits the emission of any air pollutant to which a standard under Section 112 applies from any stationary source in violation of such standard except in compliance with the regulations promulgated by EPA.

6. Pursuant to Section 112 of the Clean Air Act, 42 U.S.C. § 7412, the Administrator established National Emission Standards for Hazardous Air Pollutants (NESHAP), 40 C.F.R. Part 63. These standards regulate specific categories of stationary sources that emit (or have the potential to emit) one or more HAPs listed in Part 63. Special provisions are set forth in the Subparts to Part 63.

7. Subpart GGG sets forth the NESHAP for Pharmaceutical manufacturing operations. Subpart GGG sets forth emission limits for sources of HAPs. Subpart GGG also contains work practice, reporting and monitoring requirements. Affected sources include facilities that: manufacture a pharmaceutical product; are located at a plant site that is a major source as defined by Section 112(a); and process, use or produce a HAP. The compliance date for existing affected sources is October 21, 2002.

8. Section 113(d) of the Clean Air Act, 42 U.S.C. § 7413(d), authorizes the Administrator to commence an action to assess civil administrative penalties of not more than $25,000 per day for each violation of Section 112 of the Clean Air Act that occurs before

January 30, 1997. Section 113(d) of the Clean Air Act, 42 U.S.C. § 7413(d), as amended by the Civil Monetary Penalties Inflation Rule, 40 C.F.R. Parts 19 and 27, authorizes the Administrator to commence an action to assess civil penalties of not more than $27,500 per day for each violation that occurs after January 30, 1997 through March 15, 2004; and $32,500 per day for each violation that occurs after March 15, 2004.

Alleged Violations

9. The EPA alleges that Respondent has violated the Clean Air Act and federal regulations, promulgated pursuant to the Clean Air Act, as follows:

10. Respondent is, and at all times referred to herein, was a "person" as defined by Section 302(e) of the Clean Air Act, 42 U.S.C. § 7602(e).

11. Respondent is subject to 40 C.F.R. Part 63, Subpart GGG, because it is the owner or operator of a facility that manufactures a pharmaceutical product at a facility that is a major source and processes, uses or produces HAPs.

12. On February 23, 2005, EPA Region VII conducted a Partial Compliance Evaluation of the Respondent's facility. On April 6, 2005, EPA Region VII sent a follow up information request to Respondent under Section 114 of the Clean Air Act. On June 28, 2005, EPA sent a second Section 114 information request. On September 27, 2005, EPA sent a third Section 114 information request. The responses to the information requests document work practice violations of the Pharmaceutical MACT Standard.

13. Records collected during the inspection and the responses to the information requests showed that Respondent failed to estimate correctly the emissions from their process vents in violation of 40 C.F.R. § 63.1257(d)(2). This work practice violation was ongoing from October of 2002 until present.

14. Respondent's failure to comply with 40 C.F.R. Part 63, Subpart GGG, as set forth above is a violation of Section 112 of the Clean Air Act, 42 U.S.C. § 7412.

CONSENT AGREEMENT

15. For purposes of this proceeding, Respondent admits the jurisdictional allegations set forth above.

16. Respondent neither admits nor denies the factual allegations set forth above.

17. Respondent waives its right to a judicial or administrative hearing on any issue of fact or law set forth above.

18. Respondent and EPA agree to conciliate this matter without the necessity of a formal hearing and to bear their respective costs and attorney's fees.

19. Respondent consents to the issuance of the Final Order hereinafter recited and consents to the payment of the mitigated civil penalty as set forth below.

20. Respondent understands that the failure to pay any portion of the civil penalty assessed herein in accordance with the provisions of this order may result in commencement of a civil action in Federal District Court to recover the total penalty, together with interest at the applicable statutory rate.

21. Respondent certifies by the signing of this Consent Agreement and Final Order that to the best of its knowledge, Respondent's facility is presently in compliance with all

requirements of 40 C.F.R. Part 63, Subpart GGG.

FINAL ORDER

Pursuant to the provisions of the Clean Air Act, 42 U.S.C. § 7401, and based upon the information set forth in this Consent Agreement, IT IS HEREBY ORDERED THAT:

1. Respondent shall pay a mitigated civil penalty of Fifty-five Thousand Dollars ($55,000), within thirty (30) days of entry of this Final Order. Payment shall be by cashier's or certified check made payable to the "United States Treasury" and shall be remitted to:

U.S. EPA
Post Office Box 371099M
Pittsburgh, Pennsylvania 15251.

2. A copy of the check should be sent to:

Julie L. Murray
EPA-Region VII
Office of Regional Counsel
901 North Fifth Street
Kansas City, Kansas 66101

and

Kathy Robinson
Regional Hearing Clerk
EPA-Region VII
Office of Regional Counsel
901 North Fifth Street
Kansas City, Kansas 66101.

3. Respondent and Complainant shall bear their own costs and attorneys' fees incurred as a result of this matter.

COMPLAINANT:
UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY

Julie L. Murray
Senior Assistant Regional Counsel

Date: May 25, 2007

Becky Weber
Director
Air, RCRA and Toxics Division
EPA, Region VII

Date: 5/31/07

RESPONDENT:
SIGMA-ALDRICH MFG LLC
ST. LOUIS, MISSOURI

By: Larry Hummel

Title: Vice President, St. Louis Operations

Date: 5/23/07

IT IS SO ORDERED. This Final Order shall become effective immediately.

Karina Borromeo

Karina Borromeo
Regional Judicial Officer

Date June 4, 2007

IN THE MATTER OF Sigma-Aldrich MFG LLC, Respondent
Docket No. CAA-07-2007-0019

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Consent Agreement and Final Order was sent this day in the following manner to the addressees:

Copy hand delivered to:

Julie Murray
Senior Assistant Regional Counsel
U.S. Environmental Protection Agency
Region 7
901 N. 5th Street
Kansas City, Kansas 66101

Copy by Certified Mail Return Receipt to:

Robert F. Wilkinson
Husch & Eppenberger, LLC
190 Carondelet Plaza, Suite 600
St. Louis, Missouri 63105-3441

6/4/07
Dated

Kathy Robinson
Kathy Robinson
Hearing Clerk, Region 7