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

BEFORE THE ADMINISTRATOR

IN THE MATTER OF	)	
	)	
Clariant LSM Missouri, Inc.	)	
Springfield, Missouri	)	Docket No. CAA-07-2006-0176
	)	
Respondent	)	

CONSENT AGREEMENT AND FINAL ORDER

The United States Environmental Protection Agency, Region VII (EPA) and Clariant LSM Missouri, Inc., Springfield, 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 Clariant LSM Missouri, Inc., located at 2460 West Bennett, Springfield, Missouri 65807. Clariant LSM Missouri, Inc., is a fictitious registration owned by Clariant Life Science Molecules, Inc., a Delaware corporation. Respondent is primarily engaged in the manufacture of pharmaceutical intermediates.

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. Subpart GGG contains an important and innovative pollution prevention alternative for the pharmaceutical industry that provides an option to reduce HAP emissions through reductions in HAP solvent consumption as opposed to installing end-of-pipe controls. EPA has

developed a regulation that provides a pollution prevention compliance alternative to the traditional control requirements and EPA encourages the pharmaceutical industry to meet Clean Air Act requirements through its use.

9. The NESHAP are to be developed to control HAP emissions from both new and existing sources. The Clean Air Act requires standards to reflect the maximum decree of reduction in emissions of HAP that is achievable for new or existing sources. This control level is referred to as the "maximum achievable control technology" (MACT). Subpart GGG is referred to as the Pharmaceutical MACT.

10. The MACT floor is the least stringent level of MACT standards. For new sources, the standards for a source category or subcategory "shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source, as determined by the Administrator." 42 U.S.C. § 7212(d)(3). Existing source standards should be no less stringent than the average emission limitation achieved by the best performing twelve percent of the existing sources for categories and subcategories with thirty or more sources, or the average emission limitation achieved by the best performing five sources for categories or subcategories with fewer than thirty sources. In essence, the MACT standards mandated by the Clean Air Act will ensure that all major sources of air toxic emissions achieve the level of control already being achieved by the better controlled and lower emitting sources in each category.

11. Emission points identified from pharmaceuticals production include process vents, equipment leaks, storage tanks, wastewater collection and treatment systems, and heat exchange systems.

12. Subpart GGG standards include a pollution prevention alternative that meets the MACT floor for existing sources and can be implemented in lieu of meeting the requirements for existing process vents, storage tanks, wastewater streams and equipment leaks. 40 C.F.R. § 63.1252(e). The pollution prevention alternative only applies to existing sources and includes two options. Under option 1, owners or operators can satisfy the requirements for all emission source types associated with each pharmaceutical manufacturing process unit by demonstrating that the production-indexed consumption of HAP has decreased by at least seventy-five percent from a baseline set no earlier than the 1987 calendar year. The production indexed HAP consumption factor is expressed as kg HAP consumed/kg product produced. Under the second option, owners or operators must demonstrate at least fifty percent reduction in the production-indexed HAP consumption factor, plus an additional amount of reduction in HAP emissions through the use of add-on controls, such that the overall reduction in HAP emissions is at least seventy-five percent from the baseline period.

13. For processes subject to the pollution prevention alternative, records of consumption, production, and the rolling average of production-indexed HAP and VOC consumption factors must be kept up to date and readily accessible. 40 C.F.R. § 63.1259(b)(2).

14. Whether a source controls emissions by the alternative method or an add-on control device, Subpart GGG requires monitoring on an ongoing basis. For liquid scrubbers, flow rate or pressure drop are required to be monitored every fifteen minutes, and pH is required to be measured daily. 40 C.F.R. § 63.1258(b)(ii).

15. 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

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

17. 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).

18. 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.

19. On August 13, 2003, EPA, Region VII conducted a Partial Compliance Evaluation of the Respondent's facility. On February 20, 2004, EPA, Region VII sent a follow up information request to Respondent under Section 114 of the Clean Air Act. On July 21, 2004, EPA sent a second Section 114 information request. Information collected as a result of the inspection and the responses to the information requests document work practice violations, monitoring and

recordkeeeping violations associated with two processes at the facility (the BMN Process and the BPA Process).

20. Records collected during the inspection and the responses to the information requests showed that for the BMN Process, Respondent chose to comply with the emission reduction requirements of Subpart GGG by choosing a pollution prevention alternative. Respondent failed to provide records of the BMN Process batches as required by 40 C.F.R. § 63.1259(b)(2). The record keeping violations were ongoing from October of 2002 until December of 2003.

21. Records collected during the inspection and the responses to the information requests showed that Respondent chose to control the BPA Process by a liquid scrubber. Subpart GGG requires that the pH of the scrubber be monitored every day and the flow rate of the scrubber much be measured and recorded every fifteen minutes. Respondent failed to monitor the pH of the scrubber and failed to keep records of the fifteen minute flow readings as required by 40 C.F.R. § 63.1258(b)(ii). The monitoring violation continued from October of 2002 until March of 2003. The record keeping violation continued from October of 2002 until February 2003.

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

CONSENT AGREEMENT

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

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

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

26. 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.

27. 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.

28. 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.

29. 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-two Thousand Dollars ($52,000), within thirty 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:

US EPA
Post Office Box 371099M
Pittsburgh, Pennsylvania 15251.

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

Julie M. Van Horn
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

By for Julie J. Murray
Julie M. Van Horn
Senior Assistant Regional Counsel

Date May 22, 2006

By William A Spratlin
William A. Spratlin
Director
Air, RCRA, and Toxics Division
EPA, Region VII

Date: 5/22/06

RESPONDENT:
CLARIANT LSM MISSOURI, INC.
SPRINGFIELD, MISSOURI

By Frank H Gori

Legal Dept

Title Vice President & Site Director

Date 18 May 06

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

By Karina Borromeo
Karina Borromeo
Regional Judicial Officer

Date May 23, 2006

IN THE MATTER OF Clariant LSM Missouri Inc., Respondent
Docket No. CAA-07-2006-0176

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 M. Van Horn
Senior Assistant Regional Counsel
901 N. 5th Street
Kansas City, Kansas 66101

Copy by Certified Mail Return Receipt to:

Erin S. Russell
Senior Counsel
Clariant Corporation
4000 Monroe Road
Charlotte, North Carolina 28205

5/23/06
Dated

Kathy Robinson
Regional Hearing Clerk