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

DEC 3 1 2018

REPLY TO THE ATTENTION OF

VIA E-MAIL

Philip Hinerman
Fox Rothschild LLP
2000 Market Street, 20th Floor
Philadelphia, PA 19103-3222
(215) 299-2066 - direct
(215) 299-2150 - fax
PHinerman@foxrothschild.com

Dear Mr. Hinerman:

Enclosed is a file-stamped Consent Agreement and Final Order (CAFO) which resolves Kremers Urban Pharmaceuticals Inc., docket no. **CAA-05-2019-0010**. As indicated by the filing stamp on its first page, we filed the CAFO with the Regional Hearing Clerk on 12/31/18.
Pursuant to paragraph 50 of the CAFO, Kremers Urban Pharmaceuticals Inc. must pay the civil penalty within 30 days of the filing date. Your check or electronic funds transfer must display the case name and case docket number.

Please direct any questions regarding this case to Mary T. McAuliffe, Office of Regional Counsel, (312) 886-6237.

Sincerely,

Ashadee King-Hackney, Chief
Planning and Administration Section

Enclosure

cc: Ann Coyle, Regional Judicial Officer/ coyle.ann@epa.gov
Regional Hearing Clerk/ E-19J
Samuel Israel/ samuel.israel@lannett.com
Irene Reznik/ irene.reznik@lannett.com
Mary T. McAuliffe/ mcauliffe.mary@epa.gov
Phil Perry, Indiana Department of Environmental Management/via email

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	**Docket No. CAA-05-2019-0010**
	)	
Kremers Urban Pharmaceuticals Inc., Seymour, Indiana,	)	**Proceeding to Assess a Civil Penalty Under Section 113(d) of the Clean Air Act, 42 U.S.C. § 7413(d)**
	)	
Respondent.	)	
	)	

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 (the 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, U.S. Environmental Protection Agency (EPA), Region 5.

3. Respondent is Kremers Urban Pharmaceuticals Inc., 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 the assessment of the civil penalty specified in this CAFO and to the terms of this 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 this 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

National Emission Standards for Hazardous Air Pollutants

9. Pursuant to Section 112(b) of the CAA, 42 U.S.C. § 7412(b), EPA designates hazardous air pollutants (HAP), which present or may present a threat of adverse effects to human health or the environment.

10. Section 112(c) and (d) of the CAA, 42 U.S.C. § 7412(c) and (d), requires EPA to publish a list of categories of sources which EPA finds present a threat of adverse effects to human health or the environment due to emissions of HAP, and to promulgate emission standards for each source category. These standards are known as "national emission standards for hazardous air pollutants" (NESHAP). EPA codifies these requirements at 40 C.F.R. Part 63.

11. Section 112(d) of the CAA requires EPA to establish NESHAP for both major and area sources of HAP that are listed for regulation under CAA Section 112(c). A "major source" includes a "stationary source" that emits or has the potential to emit 10 tons per year (tpy) or more of any single HAP or 25 tpy or more of any combination of HAP. An "area source" is a "stationary source" that is not a major source. *See* 42 U.S.C. § 7412(a).

12. A "stationary source" is any building, structure, facility, or installation that emits or may emit any air pollutant. *See* 42 U.S.C. § 7412(a).

13. The NESHAP General Provisions (Subpart A), 40 C.F.R. §§ 63.1-63.16, apply to affected sources regulated by a relevant NESHAP, provided that the NESHAP explicitly identifies whether each General Provision is included in the NESHAP.

14. Subpart A at 40 C.F.R. § 63.4, prohibits the owner or operator of an affected source from operating such source in violation of any NESHAP applicable to such source.

NESHAP for Pharmaceuticals Production (Subpart GGG)

15. On September 21, 1998, EPA promulgated Subpart GGG, 63 Fed. Reg. 50326 (September 21, 1998).

16. Subpart GGG, at 40 C.F.R. § 63.1250(a), defines an affected source as manufacturing operations that: a) manufacture a pharmaceutical product; b) are located at a plant site that is a major source as defined in Section 112(a) of the CAA; and c) process, use or produce HAP.

17. Subpart GGG, requires owners or operators of an existing affected source to comply with 40 C.F.R. § 63.1250 through § 63.1261, no later than October 21, 2002.

18. Subpart GGG, at 40 C.F.R. § 63.1250(c), provides that the owner or operator of an affected source subject to the provisions of Subpart GGG must also comply with the requirements of Subpart A according to the applicability of Subpart A to such source, as identified in Table 1 of Subpart GGG.

19. Subpart GGG, at 40 C.F.R. § 63.1252, requires owners or operators of any affected source subject to the provisions of this subpart to control HAP emissions to the level specified in this section on and after the compliance dates specified in 40 C.F.R. § 63.1250(f). Initial compliance with the emission limits is demonstrated in accordance with the provisions of 40 C.F.R. § 63.1257, and continuous compliance is demonstrated in accordance with the provisions of 40 C.F.R. § 63.1258.

20. Subpart GGG, at 40 C.F.R. § 63.1254, provides standards for process vents.

21. Subpart GGG, at 40 C.F.R. § 63. 1251, defines "process vent" as a vent from a unit operation or vents from multiple unit operations within a process that are manifolded together into a common header, through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Emission streams that are undiluted and uncontrolled containing less than 50 parts per million volume (ppmv) HAP are not considered process vents.

22. Subpart GGG, 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...".

23. Subpart GGG, at 40 C.F.R. § 63.1255, provides standards for equipment leaks.

24. Subpart GGG, at 40 C.F.R. § 63.1251, defines "equipment" as each pump, compressor, agitator, pressure relief device, sampling connection system, open-ended valve or line, valve, connector, and instrumentation system in HAP service; and any control devices or closed-vent systems required by Subpart GGG.

25. Subpart GGG, at 40 C.F.R. § 63.1251, defines "in HAP service" as a piece of equipment that either contains or contacts a fluid (liquid or gas) that is at least 5 percent by weight of total organic HAP's as determined according to the provisions of 40 C.F.R. § 63.180(d).

26. Subpart GGG, at 40 C.F.R. § 63.1255(a), states that provisions of this section 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 required by this section that are intended to operate in HAP pollutant service 300 hours or more during the calendar year within a source subject to the provisions of this subpart.

27. Subpart GGG, at 40 C.F.R. § 63.1255(a)(9), states that "equipment that is in organic HAP service, but is in such service less than 300 hours per calendar year, is excluded from the requirements of this section".

28. Subpart GGG, at 40 C.F.R. § 63.1256, provides standards for wastewaters.

29. Subpart GGG, at 40 C.F.R. § 63.1251, defines "process" as all equipment which collectively functions to produce a pharmaceutical product or isolated intermediate (which is also a pharmaceutical product). Cleaning operations conducted are considered part of the process.

30. Pursuant to the provisions of the Clean Air Act, the Administrator of EPA (the Administrator) may assess a civil penalty of up to $37,500 per day of violation up to a total of $295,000 for CAA violations that occurred after January 12, 2009 through December 6, 2013, $37,500 per day of violation up to a total of $320,000 for CAA violations that occurred after December 6, 2013 through November 2, 2015, and $46,192 per day of violation up to a total of $369,532 for violations that occurred after November 2, 2015 under Section 113(d)(1) of the CAA, 42 U.S.C. § 7413(d)(1), and 40 C.F.R. Part 19.

31. Section 113(d)(1) 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.

32. 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

33. Kremers owns and operates a pharmaceutical manufacturing facility at 1001 C Avenue West Seymour, Indiana (Facility), which is a "stationary source" as that term is defined in 42 U.S.C. § 7412(a).

34. The Facility is an existing source constructed prior to April 2, 1997, and is a major source of HAP as defined in Section 112(a) of the CAA, 42 U.S.C. § 7412(a).

35. Kremers uses solvents that contain HAP for its pharmaceutical manufacturing operations, and therefore it is subject to the requirements of Subpart GGG.

36. Kremers owns or operates an "emission source" within the meaning of Section 114 (a)(1) of the CAA, 42 U.S.C. § 7414(a)(1). Therefore, Kremers is subject to the requirements of Section 114(a)(1).

37. On February 1 and 2, 2016, EPA conducted a CAA inspection of the Facility (hereafter referred to as the "2016 Inspection").

38. During the 2016 Inspection, EPA discovered the following:

a. The Facility has determined that it does not generate any wastewater from its production processes, and thus has not identified wastewater streams that require control;
b. The Facility has determined that its process unit exhaust systems are exempt from Subpart GGG; and
c. The Facility has determined that process equipment that uses pharmaceutical glaze is exempt from the leak detection and repair (LDAR) provisions of Subpart GGG.

39. On June 8, 2016, EPA issued an information request to Kremers pursuant to Section 114(a) of the CAA, 42 U.S.C. § 7414(a) (the 114 Request).

40. On June 22, 2016, Kremers submitted information to EPA, responding, in part, to the 114 Request (June 2016 Response).

41. From October 21, 2002 to the present, Kremers failed to control process vents HAP emissions from all pharmaceutical manufacturing operation at its Facility by having undiluted and uncontrolled emission streams containing greater than 50 ppmv HAP, in violation of Subpart A and Subpart GGG at 40 C.F.R. §§ 63.4, 63.1252, and 63.1254.

42. From October 21, 2002 to the present, Kremers failed to implement LDAR monitoring for the application equipment used in the pharmaceutical manufacturing operation at its Facility, in violation of the Subpart A and Subpart GGG at 40 C.F.R. §§ 63.4 and 63.1255.

43. From October 21, 2002 to the present, Kremers operated an affected source in violation of the Subpart A and Subpart GGG at 40 C.F.R. §§ 63.4 and 63.1252.

44. Following EPA's inspection, in February 2016, Kremers performed a new test that found the HAP was below the threshold for triggering Subpart GGG applicability.

45. On June 29, 2017, EPA issued to Kremers a finding of violation alleging that it violated Subpart GGG and associated Subpart A requirements.

46. On September 15, 2017, representatives of Kremers and EPA discussed the June 29, 2017 finding of violation.

47. EPA alleges that Kremers violated the NESHAP for Subpart GGG and associated Subpart A requirements.

48. Kremers has reclassified its Facility as an area source of HAP under the NESHAP for Chemical Manufacturing Area Sources at 40 C.F.R. Part 63, Subpart VVVVVV (NESHAP Subpart VVVVVV).

Civil Penalty

49. Based on analysis of the factors specified in Section 113(e) of the CAA, 42 U.S.C. § 7413(e), the facts of this case, Respondent's cooperation, prompt return to compliance, and agreement to perform a supplemental environmental project, Complainant has determined that an appropriate civil penalty to settle this action is $60,000.

50. Within 30 days after the effective date of this CAFO, Respondent must pay a $60,000 civil penalty by electronic funds transfer, payable to "Treasurer, United States of America," and sent to:

Federal Reserve Bank of New York
ABA No. 021030004
Account No. 68010727
33 Liberty Street
New York, New York 10045
Field Tag 4200 of the Fedwire message should read:
"D68010727 Environmental Protection Agency"

In the comment or description field of the electronic funds transfer, state Respondent's name and the docket number of this CAFO.

51. Respondent must send a notice of payment that states Respondent's name and the docket number of this CAFO to EPA at the following addresses when it pays the penalty:

Mary McAuliffe (C-14J)
Office of Regional Counsel
U.S. Environmental Protection Agency, Region 5
77 W. Jackson Boulevard
Chicago, Illinois 60604

Regional Hearing Clerk (E-19J)
U.S. Environmental Protection Agency, Region 5
77 W. Jackson Boulevard
Chicago, Illinois 60604

and via e-mail to R5AirEnforcement@epa.gov

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

53. If Respondent does not pay timely the civil penalty or any stipulated penalties due under Paragraph 64 or 65, below, EPA may request the Attorney General of the United States to bring an action to collect any unpaid portion of the penalty with interest, nonpayment penalties and the United States enforcement expenses for the collection action under Section 113(d)(5) of the CAA, 42 U.S.C. § 7413(d)(5). The validity, amount and appropriateness of the civil penalty are not reviewable in a collection action.

54. 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 pursuant to 26 U.S.C. § 6621(a)(2). Respondent must pay the United States enforcement expenses, including but not limited to attorneys fees and costs incurred by the United States for collection proceedings. In addition, Respondent must pay a quarterly nonpayment penalty each quarter during which the assessed penalty is overdue. 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. 42 U.S.C. § 7413(d)(5).

Supplemental Environment Project

55. Respondent must complete a supplemental environmental project (SEP) designed to protect the environment and public health, as set forth below.

56. Respondent must complete a SEP designed to protect families by abating lead-based paint hazards in a number of child-occupied facilities as defined at 40 C.F.R. § 745.83, or residential properties within a 50-mile radius of the Facility. This SEP may include, but is not limited to, window replacement, the removal of lead-based paint and dust, the permanent enclosure or encapsulation of lead-based paint, and the replacement of lead-based painted surfaces or fixtures. The focus of the SEP will be lead abatement at low-income residences or

child-occupied facilities where children age six and under or pregnant women reside or regularly visit, and whose occupants are unable to afford the costs of such work. Respondent may use a contractor/consultant to implement the SEP.

57. Respondent must complete the SEP as follows: the Respondent will contract with a local not-for-profit organization (NFP) experienced in lead abatement work to promptly undertake and complete such work within a 50-mile radius of the Facility. Respondent shall require the NFP to conduct the SEP according to all applicable federal, state and local requirements including, but not limited to, the United States Department of Housing and Urban Development's Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing and the State of Indiana requirements, unless otherwise specifically provided in this CAFO. Respondent must fully fund an escrow account to pay for the SEP not later than 90 days after the effective date of this CAFO. Respondent must spend at least $225,000 for the SEP. Respondent shall complete the SEP by June 30, 2020, provided that this date may be extended by mutual written agreement between the Respondent and EPA.

58. Respondent certifies as follows:

a. It is not a party to any open federal financial assistance transaction that is funding or could fund the same activity as the SEP described in Paragraphs 55-57;

b. It has inquired of the SEP implementer whether it is a party to an open federal financial assistance transaction that is funding or could fund the same activity as the SEP and has been informed by the recipient that it is not a party to such a transaction;

c. That all cost information provided to the EPA in connection with the EPA's approval of each SEP is complete and accurate and that Defendant in good faith estimates that the cost to implement the SEP is $225,000;

d. That, as of the date of executing this CAFO, Respondent is not required to perform or develop the SEP by any federal, state, or local law or regulation and is not required to perform or develop the SEP by agreement, grant, or as injunctive relief awarded in any other action in any forum;

e. That the SEP is not a project that Respondent was planning or intending to construct, perform, or implement other than in settlement of the claims resolved in this CAFO;

f. That Respondent has not received and will not receive credit for the SEP in any other enforcement action; and

g. That Respondent will not receive reimbursement for any portion of the SEP from another person or entity.

59. Respondent must submit a SEP completion report for the SEP to EPA no later than 60 days after Respondent receives a report from the NFP that the SEP is complete. The SEP completion report must contain the following information:

a. Detailed description of the SEP as completed;

b. Description of any operating problems and the actions taken to correct the problems;

c. Itemized cost of goods and services used to complete the SEP documented by copies of invoices, purchase orders or cancelled checks that specifically identify and itemize the individual cost of the goods and services;

d. Certification that Respondent has completed the SEP in compliance with this CAFO; and

e. Description of the environmental and public health benefits resulting from the SEP (quantify the benefits and pollution reductions, if feasible).

60. Respondent must submit all notices and reports required by this CAFO by first-class mail to the Compliance Tracker of the Air Enforcement and Compliance Assurance Branch at the address provided in Paragraph 51, above.

61. In each report that Respondent submits as provided by this CAFO, it must certify that the report is true and complete by including the following statement signed by one of its officers:

> I certify that I am familiar with the information in this document and that, based on my inquiry of those individuals responsible for obtaining the information, it is true and complete to the best of my knowledge. I know

that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations.

62. Following receipt of the SEP completion report described in Paragraph 59, above, EPA must notify Respondent in writing that:

a. It has satisfactorily completed the SEP and the SEP report;

b. There are deficiencies in the SEP as completed or in the SEP report and EPA will give Respondent 30 days to correct the deficiencies; or

c. It has not satisfactorily completed the SEP or the SEP report and EPA will seek stipulated penalties under Paragraph 64 or 65.

63. If EPA exercises option b above, Respondent may object in writing to the deficiency notice within 10 days of receiving the notice. The parties will have 30 days from EPA's receipt of Respondent's objection to reach an agreement. If the parties cannot reach an agreement, EPA will give Respondent a written decision on its objection. Respondent will comply with any requirement that EPA imposes in its decision. If Respondent does not complete the SEP as required by EPA's decision, Respondent will pay stipulated penalties to the United States under Paragraph 64 or 65, below.

64. If Respondent violates any requirement of this CAFO relating to the SEP, Respondent must pay stipulated penalties to the United States as follows: If Respondent fails to implement the SEP, or halts or abandons work on the SEP, Respondent shall pay a stipulated penalty to EPA equal to $25,000 plus the difference between $225,000 and the amount expended in satisfactory performance of the SEP as demonstrated in certified cost reports. If Respondent fails to implement the SEP, and Respondent's failure to implement the SEP is caused by the failure of the NFP to perform any obligation under its contract with Respondent, Respondent shall pay a stipulated penalty equal to the difference between $225,000 and the amount expended in satisfactory performance of the SEP as demonstrated in certified cost reports. The penalty

under this Paragraph shall apply as of the date specified for completing the SEP or the date performance ceases, whichever is earlier.

65. If Respondent did not submit timely a SEP completion report for the SEP, Respondent must pay penalties in the following amounts for each day after each SEP completion report was due until it submits the report:

Penalty per violation per day	Period of violation
$500	1st through 14th day
$750	15th through 30th day
$1,000	31st day and beyond

66. EPA's determinations of whether Respondent completed the SEP satisfactorily and whether Respondent made good faith and timely efforts to complete the SEP will bind Respondent.

67. Provided it receives notice and has the opportunity to discuss stipulated penalties with EPA, Respondent must pay any stipulated penalties within 15 days of receiving EPA's written demand for the penalties. Respondent will use the method of payment specified in Paragraph 50, above, and will pay interest and nonpayment penalties on any overdue amounts.

68. Any public statement that Respondent makes referring to the SEP must include the following language: "Kremers Urban Pharmaceuticals Inc. undertook this project under the settlement of the United States Environmental Protection Agency's enforcement action against Kremers Urban Pharmaceuticals Inc. for violations of the Clean Air Act."

69. For federal income tax purposes, Respondent will neither capitalize into inventory or basis, nor deduct any costs or expenditures incurred in performing the SEP.

General Provisions

70. The parties consent to service of this CAFO by e-mail at the following e-mail addresses: mcauliffe.mary@epa.gov (for Complainant), and samuel.isreael@lannett.com; PHinerman@foxrothschild.com; and irene.reznik@lannett.com

71. (for Respondent). The parties waive their right to service by the methods specified in 40 C.F.R. § 22.6.

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

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

74. 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 71, above, compliance with this CAFO will not be a defense to any actions subsequently commenced pursuant to federal laws administered by EPA. Nothing in this CAFO shall be construed to create any rights in or grant any causes of action to any person, entity or government body which is not a party hereto.

75. Respondent certifies that it is complying fully with the NESHAP Subpart VVVVVV.

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

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

78. 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.

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

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

Kremers Urban Pharmaceuticals Inc., Respondent

12/21/2018
Date

Grant Brock, President
Kremers Urban Pharmaceuticals Inc.

United States Environmental Protection Agency, Complainant

12/26/2019
Date

Douglas Ahrens for EN
Edward Nam
Director
Air and Radiation Division
U.S. Environmental Protection Agency, Region 5

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.

12/31/18
Date

Ann L. Coyle
Regional Judicial Officer
U.S. Environmental Protection Agency
Region 5

Consent Agreement and Final Order
In the matter of: Kremers Urban Pharmaceuticals Inc.
Docket Number:

CERTIFICATE OF SERVICE

I certify that I served a true and correct copy of the foregoing **Consent Agreement and Final Order**, docket number CAA-05-2019-10, which was filed on 12/31/18, in the following manner to the following addressees:

Copy by E-mail to Attorney for Complainant:	Mary T. McAuliffe mcauliffe.mary@epa.gov
Copy by E-mail to Attorney for Respondent:	Philip Hinerman PHinerman@foxrothschild.com
Copy by E-mail to Attorney for Respondent:	Samuel Israel samuel.israel@lannett.com
Copy by E-mail to Attorney for Respondent:	Irene Reznik irene.reznik@lannett.com
Copy by E-mail to Regional Judicial Officer:	Ann Coyle coyle.ann@epa.gov

Dated: 12/31/18

Arthur Anderson for
LaDawn Whitehead
Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 5