

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
REGION 2  
290 Broadway  
New York, NY 10007-1866

U.S. Environmental  
Protection Agency-Reg 2  
2016 APR -4 AM 11:06  
REGIONAL HEARING  
CLERK

**IN THE MATTER OF:**

Kolmar Laboratories  
20 West King Street  
Port Jervis, New York 12771

**Respondent**

Proceeding pursuant to Section 309(g) of the  
Clean Water Act, 33 U.S.C. § 1319(g)

**Administrative Complaint  
Findings of Violation, Notice of Proposed  
Assessment of a Civil Penalty, and Notice of  
Opportunity to Request a Hearing**

**Proceeding to Assess Class I  
Civil Penalty**

**Docket No. CWA-02-2016-3313**

**I. PRELIMINARY STATEMENT**

1. This Administrative Complaint, Findings of Violation, Notice of Proposed Assessment of a Civil Penalty, and Notice of Opportunity to Request a Hearing ("Complaint") is issued under the authority vested in the Administrator of the U.S. Environmental Protection Agency ("EPA") by Section 309(g)(2)(A) of the Clean Water Act ("Act"), 33 U.S.C. § 1319(g)(2)(A). The Administrator has delegated this authority to the Regional Administrator of EPA, Region 2, who in turn has delegated it to the Director, Division of Enforcement and Compliance Assistance ("DECA") of EPA, Region 2 ("Complainant").
2. Pursuant to Section 309(g)(2)(A) of the Act, and in accordance with 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" ("CROP"), 40 C.F.R. Part 22, a copy of which is attached, Complainant hereby requests that the Regional Administrator assess a civil penalty against Kolmar Laboratories ("Respondent") for its violations of federal pretreatment standards and requirements promulgated pursuant to Section 307(b) of the Act, 33 U.S.C. § 1317(b), and enforceable pursuant to Section 307(d) of the Act, 33 U.S.C. § 1317(d).

**II. APPLICABLE LEGAL REQUIREMENTS**

1. Section 301(a) of the Act, 33 U.S.C. § 1311(a), prohibits the discharge of any pollutant by any person from a point source into navigable waters of the United States, except in compliance with, inter alia, Section 402 of the Act, 33 U.S.C. § 1342.
2. "Person" is defined by Section 502(5) of the Act, 33 U.S.C. § 1362(5), to include, among other things, an individual, corporation, partnership, association or municipality.



3. "Pollutant" is defined by Section 502(6) of the Act, 33 U.S.C. § 1362(6), to include, among other things, solid waste, dredged spoil, rock, sand, cellar dirt, sewage, sewage sludge, and industrial, municipal and agricultural waste discharged into water.
4. "Discharge of a pollutant" is defined by Section 502(12) of the Act, 33 U.S.C. § 1362(12), to include any addition of any pollutant to navigable waters from any point source.
5. "Navigable waters" is defined by Section 502(7) of the Act, 33 U.S.C. § 1362(7), to include the waters of the United States.
6. Section 306(a)(3) of the Act, 33 U.S.C. § 1316(a)(3), defines "source" as any building, structure, facility, or installation from which there is or may be the discharge of pollutants.
7. "Point source" is defined by Section 502(14) of the Act, 33 U.S.C. § 1362(14), as any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, or vessel, from which pollutants are or may be discharged.
8. Pursuant to 40 C.F.R. § 403.3(q), "Publicly Owned Treatment Works" ("POTW") is a treatment works, defined by Section 212(2)(A)-(B) of the Act, 33 U.S.C. § 1292(2)(A)-(B) [as, among other things, any devices, methods, and/or systems that, at a minimum, store, treat, or dispose of municipal waste or industrial wastes, including waste in combined storm water and sanitary sewer systems], which is owned by a State or municipality.
9. Section 301(b)(1)(A) of the Act, 33 U.S.C. § 1311(b)(1)(A), provides that effluent limitations for point sources, other than a POTW, (i) shall require the application of the best practicable control technology currently available as defined by the Administrator pursuant to Section 304(b) of the Act, 33 U.S.C. § 1314(b), or (ii) shall, in the case of a discharge into a POTW that meets the requirements of Section 301(b)(1)(B) of the Act, 33 U.S.C. § 1311(b)(1)(B), require compliance with applicable pretreatment requirements and any requirements under Section 307 of the Act, 33 U.S.C. § 1317.
10. Section 402(b)(8) of the Act, 33 U.S.C. § 1342(b)(8), along with Section 307(b) of the Act, 33 U.S.C. § 1317(b), establishes the National Pretreatment Program to regulate discharges from industries to POTWs as a component of the National Pollutant Discharge and Elimination System ("NPDES") Permitting Program. The National Pretreatment Program requires non-domestic dischargers to treat or control pollutants in their wastewater before discharging to a POTW.
11. Section 307(b) of the Act, 33 U.S.C. § 1317(b), provides that the Administrator must identify categories of sources, including Pharmaceutical Manufacturing, and propose, publish, and revise, when needed, regulations establishing Federal standards of performance ("Pretreatment Standards") for these categories. The Administrator promulgated categorical Pretreatment Standards for the Pharmaceutical Manufacturing ("PM") Point Source Category under 40 C.F.R. Part 439 ("PM Standards"), in accordance with Section 307(b) of the Act, 33 U.S.C. § 1317(b). The PM point source category applies to process wastewater discharges from facilities with pharmaceutical manufacturing operations covered by 40



C.F.R. Part 439 (Pretreatment Standards for Existing Sources). These standards became effective on December 12, 1983.

12. Any existing source subject to the PM Standards which engages in the manufacture of pharmaceutical products through mixing, compounding and formulating operations, as set forth in 40 C.F.R. Part 439, Subpart D, must comply with the pretreatment standards for existing sources set forth in 40 C.F.R. § 439.46, and the general pretreatment regulations under 40 C.F.R. § 403 ("General Pretreatment Regulations") if the PM source introduces pollutants, including wastewater or any other "Indirect Discharge" generated from the pharmaceutical manufacturing operations, into a POTW, except as provided in 40 C.F.R. §§ 403.7 and 403.13.
13. "Indirect Discharge" or "Discharge" means the introduction of pollutants into a POTW from any non-domestic source regulated under Section 307(b), (c) or (d) of the Act, 33 U.S.C. § 1317(b), (c), or (d), and 40 C.F.R. § 403.3(i). A source of Indirect Discharge is an Industrial User ("IU") pursuant to 40 C.F.R. § 403.3(j).
14. "Owner or operator" is defined under Section 306(a)(4) of the Act, 33 U.S.C. § 1316(a)(4), as any person who owns, leases, operates, controls, or supervises a source.
15. Owners and operators, specifically IUs, are prohibited from discharging pollutants into a POTW in violation of the applicable categorical Pretreatment Standards under Section 307(d) of the Act, 33 U.S.C. § 1317(d). The Administrator may require the owner or operator of an IU to install, use and monitor equipment, maintain records, make reports, sample effluents, and provide other information as may reasonably be required in order to carry out Section 402 of the Act, 33 U.S.C. § 1342. 33 U.S.C. § 1318.
16. In accordance with 40 C.F.R. § 403.12(b), an IU subject to categorical Pretreatment Standards and discharging into a POTW shall submit, a baseline report or baseline monitoring report ("BMR"), which includes, but is not limited to, flow measurement and measurement of pollutants to the "Control Authority." The Administrator of the Region taking the enforcement action is the "Control Authority" pursuant to 40 C.F.R. §§ 403.3(c) and (f), for POTWs that have not obtained approval authority in accordance with 40 C.F.R. § 403.11.
17. In accordance with 40 C.F.R. § 403.12(b)(5), for the measurement of pollutants, the IU shall submit the results of sampling and analysis identifying the nature and concentration (or mass) of regulated pollutants in the discharge from each regulated process, and that both daily maximum and average concentration (or mass) shall be reported to the Control Authority.
18. 40 C.F.R. § 403.12(b)(6) requires that a statement be provided, which has been reviewed by an authorized representative of the IU and certified by a qualified professional, indicating whether Pretreatment Standards are being met on a consistent basis, and, if not, whether additional operation and maintenance and/or additional pretreatment is required for the IU to meet the Pretreatment Standards and Requirements.



19. 40 C.F.R. § 403.12(d) requires that within ninety (90) days following the date for final compliance with the applicable categorical Pretreatment Standards, any IU subject to Pretreatment Standards and Requirements shall submit to the Control Authority a report containing the information described in 40 C.F.R. §§ 403.12(b)(4)-(6). For IUs subject to the equivalent mass or concentration limits established by the Control Authority in accordance with the procedures in 40 C.F.R. § 403.6(c), this report shall contain a reasonable measure of the IU's long term production rate. For all other IUs subject to categorical Pretreatment Standards expressed in terms of allowable pollutant discharge per unit of production (or other measure of operation), this report shall include the IU's actual production during the appropriate sampling period.
20. 40 C.F.R. § 403.12(e) requires an IU subject to a categorical Pretreatment Standard to also submit to the Control Authority periodic reports on continued compliance ("Periodic Reports"). These Periodic Reports, due during the months of June and December of each year, must, among other things, indicate the nature and concentration of those pollutants in the effluent that are subject to the applicable categorical Pretreatment Standards.
21. 40 C.F.R. § 403.12(g)(2) provides that if sampling performed by an IU indicates a violation, the IU shall notify the Control Authority within twenty-four (24) hours of becoming aware of the violation. The regulation further requires that the IU shall also repeat the sampling and analysis and submit the results of the repeat analysis to the Control Authority within thirty (30) days after becoming aware of the violation.
22. Section 309(a) of the Act, 33 U.S.C. § 1319(a), authorizes the Administrator to issue an order requiring compliance or commence a civil action when any person is found to be in violation of Section 301 of the Act, 33 U.S.C. § 1311.

### **III. FINDINGS OF FACT AND CONCLUSIONS OF LAW/FINDINGS OF VIOLATION**

1. Kolmar Laboratories ("Respondent"), is a corporation incorporated under the State of Delaware. Respondent is a "person" within the meaning of Section 502(5) of the Act, 33 U.S.C. § 1362(5). Respondent has owned and operated a facility located at 20 West King Street, Port Jervis, New York (the "Facility"), where Respondent performs, among other things, pharmaceutical manufacturing operations.
2. The Facility is a "source" within the meaning of Section 306(a)(3) of the Act, 33 U.S.C. § 1316(a)(3), and an "IU" within the meaning of 40 C.F.R. § 403.3(j).
3. The Facility introduces wastewater from its manufacturing processes into the City of Port Jervis Wastewater Treatment Plant. This process wastewater is a "pollutant" within the meaning of Section 502(6) of the Act, 33 U.S.C. § 1362(6), and the City of Port Jervis Wastewater Treatment Plant receiving this pollutant is publicly owned, and therefore qualifies as a POTW, under Section 212(2)(a) of the Act, 33 U.S.C. § 1292(2)(a) (hereinafter referred to as "the POTW").
4. Since the Facility introduces pollutants from its pharmaceutical manufacturing operations into the POTW, the Facility is subject to the PM Standards. Specifically, wastewater



generated from the Facility's PM operations is subject to the categorical Pretreatment Standards at 40 C.F.R. Part 439 Pretreatment Standards for Existing Sources. As an existing source subject to the PM Standards that introduces pollutants into a POTW, the Facility must comply with and achieve the pretreatment standard limits as set forth in 40 C.F.R. § 439.46.

5. As an IU of the POTW, the Facility is also required to comply with the requirements and standards promulgated by the EPA pursuant to Section 307 of the Act, 33 U.S.C. § 1317, including the General Pretreatment Standards found at 40 C.F.R. Part 403.
6. Pursuant to 40 C.F.R. § 403.3(f), EPA is the Control Authority responsible for implementing the General Pretreatment Standards, because the POTW does not have an "Approved Pretreatment Program" under 40 C.F.R. § 403.3(d), and the State of New York is not approved to operate a State pretreatment program in accordance with 40 C.F.R. § 403.10. Thus, pursuant to 40 C.F.R. §§ 403.12(b), (d), and (e), Respondent is required to submit to EPA the following: a BMR at least ninety (90) days prior to the commencement of discharge; a Report on Compliance with Categorical Pretreatment Standard Deadline due ninety (90) days following commencement of the discharge to the POTW ("90-day Compliance Report"); and Periodic Reports by June 30 and December 31 of each year.
7. On October 28, 2013, Respondent was issued an Administrative Compliance Order, Docket No. CWA-02-2014-3004 ("2013 Order"), for failure to submit Periodic Reports by June 30, 2013. The 2013 Order stated that "Kolmar Laboratories shall submit a copy of the Periodic Report on Continued Compliance due by June 30, 2013, as required by 40 C.F.R. § 403.12(e), as well as an explanation as to why the report was late, to this office within fifteen (15) days of receipt of this ORDER." The Order also stated that "Kolmar Laboratories shall submit all future periodic semi-annual compliance reports (due by June 30 and December 31 of each year) to USEPA Region 2 and shall ensure continued compliance with the requirements of the pretreatment regulations."
8. On November 11, 2013, Respondent signed an acknowledgment of receipt of the 2013 Order.
9. On November 15, 2013, Respondent submitted a letter dated November 12, 2013, stating that due to problems with the sampling unit, the Periodic Report was submitted on September 1, 2013. However, the report was not mailed certified, and therefore there is no proof that the report was submitted by the due date.
10. By June 30, 2015, Kolmar Laboratories was required to submit a Periodic Report to EPA. To date, Respondent has not submitted the Periodic Report to EPA as required.
11. On December 4, 2015, Respondent was issued an Administrative Compliance Order, Docket No. CWA-02-2016-3005 ("2015 Order"), for failing to submit the Periodic Report by June 30, 2015. The 2015 Order stated that "Respondent shall submit a copy of the Periodic Report due by June 30, 2015, as required by 40 C.F.R. § 403.12(e), as well as an explanation as to why the report was late, to this office within fifteen (15) days of receipt of this ORDER." Among other things, the 2015 Order also stated that "Respondent shall submit Periodic Reports in accordance with 40 C.F.R. § 403.12(e), due by June 30 and December 31



of each year, to EPA...and shall ensure continued compliance with the requirements of the pretreatment regulations.”

12. On December 17, 2015, Respondent acknowledged receipt of the 2015 Order.
13. On December 30, 2015, EPA received a letter from Respondent that attached process wastewater test results of the Facility for the testing period of June 2015. The letter stated that the test results were “not reported due to administrative changes in the Company, and overlooked.”
14. Based upon the Paragraphs above, EPA finds Respondent has violated federal pretreatment requirements set forth in the Act and its implementing regulations. Respondent is in violation of Sections 307 and 308 of the Act for failing to comply with General Pretreatment Regulations. Specifically, Respondent violated the requirements at 40 C.F.R. § 403.12(e) by failing to submit the required Periodic Reports in a timely manner. Thus, based on the Findings cited above, Respondent is liable for the administrative assessment of civil penalties in an amount not to exceed \$16,000 per violation, up to a maximum of \$37,500.

#### **IV. NOTICE OF PROPOSED ORDER ASSESSING A CIVIL PENALTY**

Based on the foregoing Findings of Violation, and pursuant to the authority of Section 309(g) of the Act, 33 U.S.C. § 1319(g), and the Debt Collection Improvement Act of 1996, EPA Region 2 hereby proposes to issue a Final Order Assessing Administrative Penalties ("Final Order") to Respondent assessing penalty of **\$5,500**. EPA determined the proposed penalty after taking into account the applicable factors identified in Section 309(g)(3) of the Act, 33 U.S.C. § 1319(g)(3). EPA has taken account of the nature, circumstances, extent and gravity of the violation (or violations), and Respondent's prior compliance history, degree of culpability, economic benefit or savings accruing to Respondent by virtue of the violations, and Respondent's ability to pay the proposed penalty. Based on the Findings set forth above, Respondent has been found to have violated the Act in one (1) instance. EPA may issue the Final Order Assessing Administrative Penalties thirty (30) days after Respondent's receipt of this Notice, unless Respondent files an Answer to the Complaint within that time and requests a Hearing on this Notice pursuant to the following section.

#### **V. PROCEDURES GOVERNING THIS ADMINISTRATIVE ACTION**

The rules of procedure governing this civil administrative litigation have been set forth in the CROP, 40 C.F.R. Part 22. A copy of these rules accompanies this Complaint.

##### **A. Answering the Complaint**

Where Respondent intends to contest any material fact upon which the Complaint is based, to contend that the proposed penalty is inappropriate or to contend that Respondent is entitled to judgment as a matter of law, Respondent must file with the Regional Hearing Clerk of EPA, Region 2, both an original and one copy of a written Answer to the Complaint, and such Answer must be filed within thirty (30) days after service of the Complaint. 40 C.F.R. § 22.15(a). The address of the Regional Hearing Clerk of EPA, Region 2, is:



**Regional Hearing Clerk  
U.S. Environmental Protection Agency, Region 2  
290 Broadway, 16th floor  
New York, NY 10007-1866**

Respondent shall also then serve one copy of the Answer to the Complaint upon Complainant and any other party to the action. 40 C.F.R. § 22.15(a). Respondent's Answer to the Complaint must clearly and directly admit, deny, or explain each of the factual allegations that are contained in the Complaint and with regard to which the Respondent has any knowledge. 40 C.F.R. § 22.15(b). Where Respondent lacks knowledge of a particular factual allegation and so states in the Answer, the allegation is deemed denied. 40 C.F.R. § 22.15(b). The Answer shall also set forth: (1) the circumstances or arguments that are alleged to constitute the grounds of defense, (2) the facts that Respondent disputes (and thus intend to place at issue in the proceeding), (3) the basis for opposing the proposed relief and (4) whether Respondent requests a Hearing. 40 C.F.R. § 22.15(b).

Respondent's failure to affirmatively raise in the Answer facts that constitute or that might constitute the grounds of a defense may preclude Respondent, at a subsequent stage in this proceeding, from raising such facts and/or from having such facts admitted into evidence at a Hearing.

**B. Opportunity to Request a Hearing**

If requested by Respondent in its Answer, a Hearing upon the issues raised by the Complaint and Answer may be held. 40 C.F.R. § 22.15(c). If however, Respondent does not request a Hearing, the Presiding Officer (as defined in 40 C.F.R. § 22.3) may hold a Hearing if the Answer raises issues appropriate for adjudication. 40 C.F.R. § 22.15(c).

Any Hearing in this proceeding will be held at a location determined in accordance with 40 C.F.R. § 22.21(d). A Hearing of this matter will be conducted in accordance with the applicable provisions of the Administrative Procedure Act, 5 U.S.C. §§ 551-59, and the procedures set forth in Subpart D of the CROP, at 40 C.F.R. §§ 22.21-22.26.

Should Respondent request a Hearing on this proposed penalty assessment, members of the public to whom EPA is obligated to give notice of this proposed action, will have a right under Section 309(g)(4)(B) of the Act, 33 U.S.C. § 1319(g)(4)(B), to be heard and to present evidence on the appropriateness of the penalty assessment. Should Respondent not request a Hearing, EPA will issue a Final Order, and only members of the public who submit timely comment on this proposal will have an additional thirty (30) days to petition EPA to set aside the Final Order and to hold a Hearing thereon. EPA will grant the petition and will hold a Hearing only if the petitioner's evidence is material and was not considered by EPA in the issuance of the Final Order.

**C. Failure to Answer**

If Respondent fails in any Answer to admit, deny, or explain any material factual allegation contained in the Complaint, such failure constitutes an admission of the allegation. 40 C.F.R. § 22.15(d). If Respondent fails to file a timely Answer to the Complaint [i.e. not in accordance with



the 30-day period set forth in 40 C.F.R. § 22.15(a)], Respondent may be found in default upon motion. 40 C.F.R. § 22.17(a). Default by Respondent constitutes, for purposes of the pending proceeding only, an admission of all facts alleged in the Complaint and a waiver of Respondent's right to contest such factual allegations. 40 C.F.R. § 22.17(a). Following a default by Respondent for a failure to timely file an Answer to the Complaint, any order issued therefore shall be issued pursuant to 40 C.F.R. § 22.17(c).

Any penalty assessed in the default order shall become due and payable by Respondent without further proceedings thirty (30) days after the Default Order becomes final pursuant to 40 C.F.R. § 22.27(c). 40 C.F.R. § 22.17(d). If necessary, EPA may then seek to enforce such Final Order of Default against Respondent, and to collect the assessed penalty amount, in federal court.

## **VI. INFORMAL SETTLEMENT CONFERENCE**

Regardless of whether Respondent requests a formal Hearing, EPA encourages settlement of this proceeding consistent with the provisions of the Act and its applicable regulations. 40 C.F.R. § 22.18(b). At an informal conference with a representative(s) of Complainant, Respondent may comment on the charges made in this Complaint and Respondent may also provide whatever additional information it believes to be relevant to the disposition of this matter, including: (1) actions Respondent has taken to correct any or all of the violations herein alleged, (2) any information relevant to Complainant's calculation of the proposed penalty, (3) the effect the proposed penalty would have on Respondent's ability to continue in business and/or (4) any other special facts or circumstances Respondent wishes to raise.

Complainant has the authority to modify the amount of the proposed penalty, where appropriate, in response to any relevant information previously not known to Complainant that demonstrates that any of the findings herein are without merit, or that the proposed penalty is not warranted. Respondent is referred to 40 C.F.R. § 22.18.

Any request for an informal conference or any questions that Respondent may have regarding this Complaint should be directed to:

Lauren Fischer, Esq.  
Assistant Regional Counsel  
Office of Regional Counsel  
U.S. Environmental Protection Agency, Region 2  
290 Broadway, 16th Floor  
New York, NY 10007-1866  
Telephone (212) 637-3231

The parties may engage in settlement discussions regardless of whether Respondent has requested a Hearing. 40 C.F.R. § 22.18(b)(1). Respondent's requesting a formal Hearing does not prevent Respondent from also requesting an informal settlement conference; the informal conference procedure may be pursued simultaneously with the formal adjudicatory hearing procedure. A request for an informal settlement conference constitutes neither an admission nor a denial of any of the matters alleged in the Complaint.



A request for an informal settlement conference does not affect Respondent's obligation to file a timely Answer to the Complaint pursuant to 40 C.F.R. § 22.15. Note that no penalty reduction will be made simply because an informal settlement conference is held.

Any settlement that may be reached as a result of an informal settlement conference shall be embodied in a written Consent Agreement. 40 C.F.R. § 22.18(b)(2). In accepting the Consent Agreement, Respondent waives any right to contest the allegations in the Complaint and waives any right to appeal the Final Order that is to accompany the Consent Agreement. 40 C.F.R. § 2.18(b)(2). In order to conclude the proceeding, a Final Order ratifying the parties' agreement to settle will be executed. 40 C.F.R. § 22.18(b)(3).

Entering into a settlement through the signing of such Consent Agreement and complying with the terms and conditions set forth in such Consent Agreement and Final Order terminates this administrative litigation and these civil proceedings against Respondent (note that a new enforcement action may be initiated based on continued non-compliance). Entering into a settlement agreement does not extinguish, waive, satisfy or otherwise affect Respondent's obligation and responsibility to comply with all applicable statutory and regulatory requirements, and to maintain such compliance.

## **VII. RESOLUTION OF THIS PROCEEDING WITHOUT HEARING OR CONFERENCE**

Instead of filing an Answer, Respondent may choose to pay the total amount of the proposed penalty, **\$5,500**, within 30 days after receipt of the Complaint, provided that Respondent files with the Regional Hearing Clerk, Region 2 (at the address noted above), a copy of the check or other instrument of payment. 40 C.F.R. § 22.18(a). A copy of the check or other instrument of payment should be provided to the EPA Attorney identified in Section VI above. Payment of the penalty assessed should be made by sending a cashier's or certified check payable to the "Treasurer, United States of America", in the full amount of the penalty assessed in this Complaint to the following addressee:

U.S. Environmental Protection Agency  
Fines and Penalties  
Cincinnati Finance Center  
P.O. Box 979077  
St. Louis, MO 63197-9000  
Docket No. CWA-02-2016-3313

Wire transfers should be directed to the Federal Reserve Bank of New York

Federal Reserve Bank of New York  
ABA = 021030004  
Account = 68010727  
SWIFT address = FRNYUS33  
33 Liberty Street  
New York, NY 10045



Field Tag 4200 of the Fedwire message should read "D 68010727 Environmental Protection Agency".

Pursuant to 40 C.F.R. § 22.18(a)(3), if Respondent elects to pay the full amount of the penalty proposed in the Complaint within thirty (30) days of receiving the Complaint, then, upon EPA's receipt of such payment, the Regional Administrator of EPA, Region 2 (or, if designated, the Regional Judicial Officer), shall issue a Final Order pursuant to 40 C.F.R. § 22.18(a)(3). In accordance with 40 C.F.R. § 22.45(c)(3), no Final Order shall be issued until at least ten (10) days after the close of the comment period on this Complaint. Issuance of a Final Order terminates this administrative litigation and the civil proceedings arising out of the allegations made in the Complaint (note that a new enforcement action may be initiated based on continued non-compliance). Further, pursuant to 40 C.F.R. § 22.18(a)(3), the making of such payment by Respondent shall constitute a waiver of Respondent's right both to contest the allegations made in the Complaint and to appeal said Final Order to federal court. Such payment does not extinguish, waive, satisfy or otherwise affect Respondent's obligation and responsibility to comply with all applicable statutory and regulatory requirements, and to maintain such compliance, and EPA may initiate a new enforcement action based on evidence of new or continued violations.

#### **VIII. FILING OF DOCUMENTS**

The Answer and any Hearing Request and all subsequent documents filed in this action should be sent to:

Regional Hearing Clerk  
U.S. Environmental Protection Agency  
290 Broadway - 16th Floor (Room 1631)  
New York, New York 10007-1866

A copy of the Answer, any Hearing Request and all subsequent documents filed in this action shall be sent to:

Lauren Fischer, Esq., Assistant Regional Counsel  
Office of Regional Counsel  
U.S. Environmental Protection Agency  
290 Broadway - 16<sup>th</sup> Floor  
New York, New York 10007-1866  
(212) 637-3231

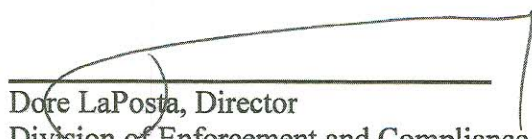
#### **IX. GENERAL PROVISIONS**

1. Respondent has a right to be represented by an attorney at any stage of these proceedings.
2. This Complaint does not constitute a waiver, suspension or modification of the requirements of the Act, regulations promulgated there under, or any applicable permit.



3. Neither assessment nor payment of an administrative civil penalty pursuant to Section 309(g) of the Act, 33 U.S.C. § 1319(g), will affect Respondent's continuing obligation to comply with the Act, and with any separate Compliance Order issued under Section 309(a) of the Act, 33 U.S.C. § 1319(a), for the violations alleged herein.

ISSUED THIS 18<sup>th</sup> DAY OF March, 2016.

  
Dore LaPosta, Director  
Division of Enforcement and Compliance Assistance  
U.S. EPA - Region 2  
290 Broadway  
New York, New York 10007-1866

To: Mr. Kelvin Cruz, Environmental, Health and Safety Administrator  
Kolmar Laboratories  
20 West King Street  
Port Jervis, New York 12771



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**CERTIFICATE OF SERVICE**

I certify that, on the date noted below, I caused to be mailed, by certified mail, return receipt requested, the original of the foregoing "ADMINISTRATIVE COMPLAINT" and a copy of the "Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits," 40 C.F.R. Part 22 (July 1, 2011) to the following persons at the addresses listed below:

Mr. Kelvin Cruz, EHS Administrator  
Kolmar Laboratories  
20 West King Street  
Port Jervis, New York 12771

Mr. Joseph DiMura, P.E., Director  
Bureau of Water Compliance Programs  
Division of Water  
New York State Department of Environmental Conservation  
625 Broadway  
Albany, New York 12233-3506

I hand carried 2 copies of the foregoing Complaint to the Office of the Regional Hearing Clerk, United States Environmental Protection Agency, Region 2.

Date: 4/4/16  
New York, New York

  
Marie St. Germain, Branch Secretary