



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 2  
290 BROADWAY  
NEW YORK, NY 10007-1866

MAR 27 2007

U.S. ENVIRONMENTAL  
PROTECTION AGENCY-REC  
2007 MAR 28 PM 2:25  
REGIONAL HEARING  
CLERK

**CERTIFIED MAIL - RETURN RECEIPT REQUESTED**

**Article Number: 7005 3110 0000 5972 8246**

Mr. Thomas L. Wegman, President  
Advance Biofactures Corporation  
35 Wilbur Street  
Lynbrook, New York 11563

Re: Notice of Proposed Assessment of a Civil Penalty  
Docket No. CWA-02-2007-3319  
Advance Biofactures Corporation

Dear Mr. Wegman:

Enclosed is a Complaint which the U.S. Environmental Protection Agency ("EPA") is issuing to you as a result of our determination that Advance Biofactures Corporation located at 35 Wilbur Street, Lynbrook, New York has failed to submit pretreatment reports in violation of Sections 307(d) and 308(a) of the Clean Water Act ("Act"), 33 U.S.C. §§1317(d) and 1318(a). This Complaint is filed pursuant to the authority of §309(g) of the Act, 33 U.S.C. §1319(g). The Complaint proposes that a penalty of \$20,000.00 be assessed jointly and severally against Advance Biofactures Corporation for these violations.

You have the right to a hearing to contest the factual allegations in the Complaint. If you admit the allegations, or they are found to be true after you have had an opportunity for a hearing on them, you have the right to contest the penalty proposed in the Complaint. I have enclosed a copy of the "Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits" ("CROP") (40 Code of Federal Regulations ("C.F.R.") Part 22) which the Agency follows in cases of this kind. Please note the requirements for an Answer at 40 C.F.R. §22.15. **If you wish to contest the allegations in the Complaint or the penalty proposed in the Complaint, you must file an Answer within thirty (30) days of your receipt of the enclosed Complaint to the EPA Regional Hearing Clerk at the following address:**

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

If you do not file an Answer within thirty (30) days of receipt of this Complaint, you may be judged to have defaulted (See, §22.17 of the CROP). If a default order is entered, the entire proposed penalty may be assessed without further proceedings.

1. Complaint
2. CROP
3. EPA Supplemental Environmental Projects Policy
4. Notice of SEC Registrants' Duty to Disclose Environmental Legal Proceedings
5. Small Business Information Sheet

cc: Karen Maples, Regional Hearing Clerk (w/Complaint only)  
Sandra Allen, NYSDEC (w/enclosure)  
Vincent Alonge, Nassau County (w/enclosure)

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

U.S. ENVIRONMENTAL  
PROTECTION AGENCY-REG. II  
2007 MAR 28 PM 2:25  
REGIONAL HEARING  
CLERK

**IN THE MATTER OF**

Advance Biofactures Corporation  
35 Wilbur Street  
Lynbrook, New York 11563-2358

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

Proceeding to Assess Class I  
Civil Penalty Under Section  
309(g) of the Clean Water Act

Docket No. CWA-02-2007-3319

**COMPLAINT  
FINDINGS OF VIOLATION, NOTICE OF PROPOSED  
ASSESSMENT OF A CIVIL PENALTY, AND  
NOTICE OF OPPORTUNITY TO REQUEST A HEARING**

**I. Statutory Authority**

1. This 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 and

the Revocation/Termination or Suspension of Permits” (“CROP”), 40 Code of Federal Regulations (“C.F.R.”) Part 22 (July 1, 2000), a copy of which is attached, Complainant hereby requests that the Regional Administrator assess a civil penalty against Advance Biofactures Corporation (“Respondent”) for its violations of Federal Pretreatment Standards 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. Findings of Violation**

3. Respondent is a corporation organized under the laws of the State of New York and is a "person" within the meaning of Section 502(5) of the Act, 33 U.S.C. §1362(5).

4. At all times relevant to this Administrative Complaint, Respondent owned and/or operated a facility located at 35 Wilbur Street, Lynbrook, New York (the “facility”) where it processes the crude pharmaceutically active ingredient that is contained in the product known as Collagenase Santyl Ointment, in addition to Research and Development activities.

5. The Respondent has discharged wastewater into the Nassau County Department of Public Works, Sewage Treatment Plant (Sewer District #2 - Bay Park Sewage Treatment Plant), which is a "publicly owned treatment works" ("POTW") within the meaning of 40 C.F.R. §403.3(o) since, at least, July 1987. Wastewater is a "pollutant" within the meaning of Section 502(6) of the Act, 33 U.S.C. §1362(6).

6. At all times relevant to this Administrative Complaint, the facility was a "source" within the meaning of Section 306(a)(3) of the Act, 33 U.S.C. §1316(a)(3) and an "industrial user" ("IU") within the meaning of 40 C.F.R. §403.3(h).

7. Nassau County is an "Approved Pretreatment Program" within the meaning of 40 C.F.R. §403.3(d). Therefore, Nassau County is the "Control Authority" for the Respondent pursuant to 40 C.F.R. §403.12(a), as defined for the purposes of 40 C.F.R. §403.12(b), (d) and (e).

8. Pursuant to Sections 307(b) and 308(a) of the Act, 33 U.S.C. §§1317(b) and 1318(a), EPA has promulgated General Pretreatment Regulations for IUs as stated in 40 C.F.R. Part 403.

9. As a non-domestic user of a POTW, the Respondent is required to comply with the requirements and standards promulgated by EPA pursuant to Section 307 of the Clean Water Act, 33 U.S.C. §1317, including the General Pretreatment Regulations found at 40 C.F.R. Part 403. The facility, as owned/operated by the Respondent, has been discharging non-domestic regulated categorical waste into a POTW since, at least, July 1987 and ceased responsibility of the discharge upon sale of the pharmaceutical operations for the Collagenase Santyl Ointment process to DPT Labs, Ltd. on March 2, 2006.

10. Pursuant to the authority of Section 307(b) of the Act, 33 U.S.C. §1317(b), EPA promulgated Categorical Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category ("PMPSC") as stated in 40 C.F.R. Part 439, including §439.46 ("Pretreatment Standards for Existing Sources") and §439.47 ("Pretreatment Standards for New Sources"). The PMPSC Standards were effective December 12, 1983. Furthermore, on May 2, 1995, EPA

proposed revisions for the Pharmaceutical Manufacturing Category Effluent Limitations Guidelines. These regulations became effective on November 20, 1998 and contain final Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category. Respondent is subject to the revisions of the PMPSC as stated in 40 C.F.R. Part 439.

11. Respondent's manufacturing activities fall within the scope of PMPSC, as it is set out in 40 C.F.R. §439.40. Consequently, Respondent's discharges of non-domestic wastewater to the Nassau County Department of Public Works, Sewage Treatment Plant are subject to the Categorical Pretreatment Standards for the PMPSC set forth at 40 C.F.R. Part 439, specifically 40 C.F.R. §439.46 ("Pretreatment Standards for Existing Sources"), Subpart D - Mixing/Compounding and Formulation Subcategory.

12. Section 307(d) of the Act, 33 U.S.C. §1317(d), prohibits the owner or operator of any source from discharging pollutants into a POTW in violation of the applicable pretreatment standards for that source.

13. Pursuant to Sections 307(b) and 308(a) of the Act, 33 U.S.C. §§1317(b) and 1318(a), the Administrator of EPA promulgated 40 C.F.R. §403.12(e) that requires an industrial user subject to a categorical pretreatment standard to submit to the "Control Authority" (defined at 40 C.F.R. §403.12(a)) Periodic Reports on Continued Compliance ("Periodic Reports"). These 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 subject to the applicable Categorical Pretreatment Standards.

14. EPA conducted a compliance evaluation inspection of Respondent's facility on October 26, 2006 to determine compliance with the Federal Pretreatment Program requirements cited above.

15. Observations made and information obtained from facility personnel during the October 26, 2006 inspection resulted in findings that are cited below:

- a) Respondent was involved in the processing of the active ingredient in the product known as Collagenase Santyl Ointment.
- b) Respondent, in general, manufactured the product, as cited in (a) above, via batch blending, mixing and formulation.
- c) Respondent is registered as a manufacturer by the Department of Health and Human Services, Food and Drug Administration.
- d) The discharge of non-domestic wastewater to the POTW by the Respondent has occurred since, at least, July 1987 and ceased on March 2, 2006 after sale of the pharmaceutical process to DPT Laboratories Ltd.
- e) Records review, in addition to verification by facility personnel, indicates that no sampling has been conducted on the facility's discharge of regulated categorical and/or process wastewater.

- f) Respondent has not submitted the required Periodic Reports on Continued Compliance in December 2005, June 2005, December 2004 and June 2004 to the Control Authority (POTW).

16. Respondent is subject to the General Pretreatment Regulations and the revised Categorical Pretreatment Standards for the Pharmaceutical Manufacturing Category since it introduced the pollutants from their manufacturing operations into a POTW. Specifically, Respondent is subject to Subpart D - Mixing/Compounding and Formulation Subcategory as defined in 40 C.F.R. §439.46 ("Pretreatment Standards for Existing Sources"). They are also an "Industrial User" ("IU") within the meaning of 40 C.F.R. §403.3(h).

17. The Respondent has violated Sections 307(d) and 308(a) of the Act, and its implementing pretreatment regulations, on at least four (4) occasions by failing to submit the required Periodic Reports on Continued Compliance in December 2005, June 2005, December 2004 and June 2004.

### **III. 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 a penalty of \$20,000.00. EPA determined the proposed penalty after taking into account the applicable factors identified at 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 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, the Respondent has been found to have violated the Act in instances cited in Section II of this Administrative Penalty Order.

#### **IV. Procedures Governing This Administrative Litigation**

The rules of procedure governing this civil administrative litigation have been set forth in the CROP which have been codified at 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, New York 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 Respondent has any knowledge. 40 C.F.R. §22.15(b). Where Respondent lacks knowledge of a particular factual allegation and so states in its 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 its defense may preclude the 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 Subparts D and I of 40 C.F.R. Part 22.

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 its 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 [i.e. in accordance with the 30-day period set forth in 40 C.F.R. §22.15(a)] Answer to the Complaint, 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 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 30 days after the default order becomes final pursuant to 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.

#### **V. Informal Settlement Conference**

Whether or not 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 that it believes is 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, to reflect any settlement agreement reached with Respondent, to reflect any relevant information previously not known to Complainant or to dismiss any or all of the charges, if Respondent can demonstrate that the relevant allegations are without merit and that no cause of action as herein alleged exists. 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:

**Diane T. Gomes**  
**Assistant Regional Counsel**  
**Office of Regional Counsel**  
**U.S. Environmental Protection Agency, Region 2**  
**290 Broadway, 16th floor**  
**New York, New York 10007-1866**  
**(212) 637-3235**

The parties may engage in settlement discussions irrespective of whether Respondent has requested a hearing. 40 C.F.R. §22.18(b)(1). Respondent's request for a formal hearing does not prevent it 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. Complainant does not deem a request for an informal settlement conference as a request for a hearing as specified in 40 C.F.R. §22.15(c).

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. No penalty reduction, however, 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 its right to contest the allegations in the Complaint and waives its right to appeal the Final Order that is to accompany the Consent Agreement. 40 C.F.R. §22.18(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).

Respondent's entering into a settlement through the signing of such Consent Agreement and its complying with the terms and conditions set forth in the such Consent Agreement terminate this administrative litigation and the civil proceedings arising out of the allegations made in the Complaint. Respondent's entering into a settlement does not extinguish, waive, satisfy or otherwise affect its obligation and responsibility to comply with all applicable statutory and regulatory requirements, and to maintain such compliance.

## **VI. 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 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 Assistant Regional Counsel identified on the previous page.

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:

**Regional Hearing Clerk**  
**U. S. Environmental Protection Agency, Region 2**  
**P.O. Box 360188M**  
**Pittsburgh, Pennsylvania 15251**

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 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 in accordance with 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. 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 regulations and requirements, and to maintain such compliance.

**VII. Filing of Documents**

1. 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**  
**New York, New York 10007-1866**

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

**Diane T. Gomes**  
**Assistant Regional Counsel**  
**Office of Regional Counsel**  
**U.S. Environmental Protection Agency, Region 2**  
**290 Broadway, 16th floor**  
**New York, New York 10007-1866**  
**(212) 637-3235**

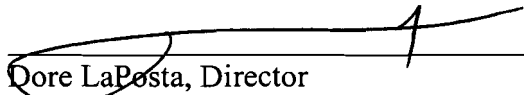
### **VIII. General Provisions**

1. Respondent has the 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



3. Neither assessment nor payment of an administrative civil penalty pursuant to Section 309(g) of the Act 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 27<sup>th</sup> DAY OF MARCH, 2007.

  
Dore LaPosta, Director  
Division of Enforcement and Compliance Assistance  
United States Environmental Protection Agency  
Region 2  
290 Broadway  
New York, New York 10007

**CWA-02-2007-3319**

To: (40 C.F.R. §22.5(b)(1))

Mr. Thomas L. Wegman, President  
Advance Biofactures Corporation  
35 Wilbur Street  
Lynbrook, New York 11563

Docket No. CWA-02-2007-3319

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
REGION 2

-----X	:	
IN THE MATTER OF	:	
	:	
Advance Biofactures Corporation	:	Proceeding to Assess Class I
35 Wilbur Street	:	Civil Penalty Under Section
Lynbrook, New York 11563-2358	:	309(g) of the Clean Water Act
	:	
Proceeding Pursuant to §309(g) of the	:	Docket No. CWA-02-2007-3319
Clean Water Act, 33 U.S.C. §1319(g)	:	
-----X	:	

CERTIFICATE OF SERVICE

I certify that, on the date noted below, I caused to be mailed, by certified mail, return receipt requested, a copy 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 Code of Federal Regulations Part 22 (July 1, 2000)) to the following persons at the addresses listed below:

Mr. Thomas L. Wegman, President  
Advance Biofactures Corporation  
35 Wilbur Street  
Lynbrook, New York 11563-2358

Ms. Sandra Allen, Esq., Director  
Division of Water  
NYSDEC  
625 Broadway - 4<sup>th</sup> Floor  
Albany New York 12233-3506

I [hand carried / mailed] the original and a copy of the foregoing Complaint to the office of the Regional Hearing Clerk, United States Environmental Protection Agency, Region 2.

Date: 3/28/07  
New York, New York

Marie St. Germain  
[Signature of Sender]  
[NOTE: must be over 18]



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

**REGION 2**

**280 BROADWAY**

**NEW YORK, NEW YORK 10007-1866**

JAN 23 2007

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

William A. McDonald, President and Chief Executive Officer  
St. Joseph's Regional Medical Center  
703 Main Street  
Paterson, NJ 07503

Re: In the Matter of St. Joseph's Regional Medical Center  
Docket No. TSCA-02-2007-9105

Dear Mr. McDonald:

Enclosed is the Complaint and Notice of Opportunity For Hearing in the above referenced proceeding. This Complaint alleges violations of the Toxic Substances Control Act (TSCA), and regulations promulgated pursuant to TSCA set forth at 40 C.F.R. Part 761.

It is the intention of the United States Environmental Protection Agency (USEPA) to seek resolution of this Complaint in an equitable and mutually agreeable manner. As outlined in the Complaint, the Agency encourages the use of an informal conference to provide an opportunity for settlement discussions. You have been given ninety (90) days rather than the customary thirty (30) days to file an Answer to this Complaint. If you wish to attempt informal settlement, please do not file your Answer before a representative of the Division of Enforcement and Compliance Assistance (DECA) has contacted you to discuss the scheduling of an informal conference. Filing an Answer before discussions are held or at any point within these ninety (90) days will result in referral of your case to the Office of Regional Counsel.

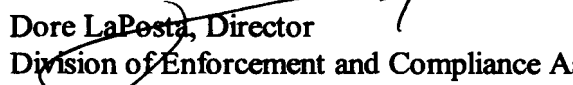
I have enclosed copies of the Consolidated Rules of Practice (40 C.F.R. Part 22) and recent revisions published at 64 Fed. Reg. 40138 (July 23, 1999), as well as a copy of the appropriate Penalty Policy referenced in the Complaint. Also enclosed is a copy of the EPA Supplemental Environmental Projects Policy (SEP Policy) for your consideration. The Agency encourages the use of SEPs where appropriate, as part of the settlement.

U.S. ENVIRONMENTAL  
PROTECTION AGENCY-REG. II  
2007 JAN 26 PM 3:27  
REGIONAL HEARING  
CLERK

- 2 -

A DECA representative will contact you shortly to discuss the possibility of scheduling an informal conference. If you have any questions regarding the Complaint or the settlement process, you or your staff should feel free to contact Ms. Ann Finnegan at (732) 906-6177.

Sincerely,

  
Dore LaPosta, Director  
Division of Enforcement and Compliance Assistance

Enclosures

cc: Karen Maples

U.S. Environmental Protection Agency  
Region 2

U.S. ENVIRONMENTAL  
PROTECTION AGENCY-REG. II  
2007 JAN 26 PM 3:27  
REGIONAL HEARING  
CLERK

----- x  
In the Matter of :

St. Joseph's Regional Medical Center, :

Respondent. :

Proceeding under Section 16(a) of  
the Toxic Substances Control Act. :

: COMPLAINT AND NOTICE OF  
: OPPORTUNITY FOR HEARING

: Docket No.  
: TSCA-02-2007-9105  
: :  
----- x

COMPLAINT

Complainant, as and for her Complaint against Respondent, hereby alleges upon information and belief:

1. This is a civil administrative action instituted pursuant to Section 16(a), 15 U.S.C. § 2615(a), of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2601 et seq.

2. The Complainant is the Director, Division of Enforcement and Compliance Assistance, United States Environmental Protection Agency ("EPA"), Region 2, who has been duly delegated the authority to institute this action.

3. This Complaint serves notice of Complainant's preliminary determination that Respondent has violated the federal regulations concerning polychlorinated biphenyls ("PCBs") promulgated pursuant to the authority granted by Section 6(e) of TSCA, 15 U.S.C. § 2605(e), and set forth at 40 C.F.R. Part 761, and that Respondent has thereby violated Section 15 of TSCA, 15 U.S.C. § 2614.

4. Respondent is St. Joseph's Regional Medical Center.

5. Respondent is a "person" within the meaning of 40 C.F.R. § 761.3.

6. Respondent owns, operates, and/or controls the facility in and around 703 Main Street, Paterson, NJ 07503 (hereinafter "Respondent's facility").

7. Respondent has owned, used and maintained, or stored for reuse or disposal "PCBs" and "PCB Items", as those terms are defined at 40 C.F.R. § 761.3, at Respondent's facility.

8. Respondent is subject to the regulations and requirements pertaining to PCBs and PCB Items promulgated pursuant to Section 6(e) of TSCA, 15 U.S.C. § 2605(e), and set forth at 40 C.F.R. Part 761.

9. On or about June 22, 2006, duly designated representatives of the EPA conducted an inspection of and at Respondent's facility pursuant to Section 11 of TSCA, 15 U.S.C. § 2610 (hereinafter "the inspection").

COUNT 1

Unauthorized Use

(Use of Radial PCB Transformer Without Electrical Protection  
in or near Commercial Buildings)

10. Paragraphs 1 through 9, above, are incorporated and realleged, as if fully set forth herein.

11. Pursuant to 40 C.F.R. § 761.20(a), no person may use any PCB, or any PCB Item regardless of concentration, in any manner other than in a totally enclosed manner within the United States unless authorized under 40 C.F.R. § 761.30.

12. Pursuant to 40 C.F.R. § 761.30(a)(1)(iv)(E), as of February 25, 1991, all lower secondary voltage radial PCB Transformers [in use in or near commercial buildings] must be equipped with electrical protection, such as current-limiting fuses or other equivalent technology, to detect sustained high current faults and provide for the complete deenergization of the faulted transformer within several hundredths of a second.

13. As of the date of the EPA inspection, Respondent was using or storing for reuse a transformer at Respondent's facility at a location commonly known as the Maternity Courtyard.

14. The transformer described in paragraph 13, above, contained PCBs over 500 parts per million in the dielectric fluid and therefore constitutes a "PCB Transformer" and a "PCB Item" as those terms are defined at 40 C.F.R. § 761.3.

15. The transformer described in paragraph 13, above, is a radial transformer with lower secondary voltage (below 480 volts).

16. The transformer described in paragraph 13, above, is located "in or near commercial buildings" as that term is defined at 40 C.F.R. § 761.3.

17. As of the date of the inspection, Respondent's radial PCB Transformer located in near a commercial building, as described in paragraphs 13 through 16, above, was not equipped with the electrical protection specified at 40 C.F.R. § 761.30(a)(1)(iv)(E).

18. Respondent's use of a radial PCB Transformer which was not equipped with enhanced electrical protection in near a commercial building, as described in paragraphs 13 through 17, above, constitutes an authorized use of PCBs.

19. Respondent's unauthorized use of PCBs, as alleged in paragraph 18, above, constitutes a failure or refusal to comply with 40 C.F.R. §§ 761.20 and 761.30, which is a violation of Section 15(1)(C) of TSCA, 15 U.S.C. § 2614(1)(C).

COUNT 2  
Unauthorized Use  
(Use of Unregistered PCB Transformers)

20. Paragraphs 1 through 9, above, are incorporated and realleged, as if fully set forth herein.

21. Pursuant to 40 C.F.R. § 761.20(a), no person may use any PCB, or any PCB Item regardless of concentration, in any manner other than in a totally enclosed manner within the United States unless authorized under 40 C.F.R. § 761.30.

22. Pursuant to 40 C.F.R. § 761.30(a)(1)(vi)(A), all owners of PCB Transformers, including those in storage for reuse, were required to register their transformers with the Environmental Protection Agency no later than December 28, 1998.

23. Pursuant to 40 C.F.R. § 761.30(a)(1)(vi)(D), the owner of a PCB Transformer must comply with all requirements of paragraph (a)(1)(vi)(A) of that section to continue the PCB Transformer's authorization for use or storage for reuse.

24. As of the date of the EPA inspection, Respondent was using at least two transformers in two separate locations at Respondent's facility. These locations are commonly known as the Maternity Courtyard and the Powerhouse.

25. The transformers described in paragraph 24, above, contained PCBs over 500 parts per million in the dielectric fluid and therefore constitute "PCB Transformers" and a "PCB Items" as those terms are defined at 40 C.F.R. § 761.3.

26. As of the date of the date of the inspection, Respondent had not registered the PCB Transformers described in paragraphs 24 and 25, above, with the Environmental Protection Agency.

27. Respondent's use of an unregistered PCB Transformer, as described in paragraphs 24 through 26, above, constitutes an authorized use of PCBs.

28. Respondent's unauthorized use of PCBs, as alleged in paragraph 27, above, constitutes a failure or refusal to comply with 40 C.F.R. §§ 761.20 and 761.30(a)(1)(vi), which is a violation of Section 15(1)(C) of TSCA, 15 U.S.C. § 2614(1)(C).

COUNT 3  
Annual Documents

29. Paragraphs 1 through 9, above, are incorporated and realleged as if fully set forth herein.

30. Pursuant to 40 C.F.R. § 761.180(a), each owner or operator of a facility (other than a commercial storer or a disposer of PCB waste) using or storing at any one time at least one PCB Transformer, 45 kilograms of PCBs contained in PCB Containers, or 50 Large PCB Capacitors is required to develop and maintain annual records and an annual document log on the disposition of PCBs and PCB Items. These records and annual document logs are required to be maintained for at least three years after the facility ceases using or storing PCBs and/or PCB Items in the quantities specified above, and are required to be available for inspection by EPA representatives.

31. During at least the years 2000 to the date of the inspection, Respondent was using at least two transformers in two separate locations at Respondent's facility. These locations are commonly known as the Maternity Courtyard and the Powerhouse.

32. The transformers described in paragraph 31, above, contained PCBs over 500 parts per million in the dielectric fluid and therefore constitute "PCB Transformers" and a "PCB Items" as those terms are defined at 40 C.F.R. § 761.3.

33. As of the date of the inspection, Respondent had not compiled and maintained annual document logs on the disposition of Respondent-owned PCBs and PCB Items for at least the years 2000 through 2005.

34. Respondent's failure to compile and maintain annual document logs on the disposition of Respondent-owned PCBs and PCB Items, as alleged in paragraph 33 above, constitutes a failure or refusal to comply with 40 C.F.R. § 761.180(a), which is a violation of Section 15(1)(C) of TSCA, 15 U.S.C. § 2614(1)(C).

COUNT 4  
Marking PCB Transformers

35. Paragraphs 1 through 9, above, are incorporated and realleged as if fully set forth herein.



36. Pursuant to 40 C.F.R. §§ 761.40(a)(2) and (c)(1), all PCB Transformers are required to be marked with the PCB mark "M<sub>L</sub>" as described and illustrated at 40 C.F.R. § 761.45.

37. As of the date of the EPA inspection, Respondent was using at least two transformers in separate locations at Respondent's facility. These locations are commonly known as the Maternity Courtyard and the Powerhouse.

38. The transformers described in paragraph 37, above, contained PCBs over 500 parts per million in the dielectric fluid and therefore constitute "PCB Transformers" and a "PCB Items" as those terms are defined at 40 C.F.R. § 761.3.

39. As of the date of the EPA inspection, Respondent had not marked the PCB Transformers described in paragraphs 37 and 38, above, with the PCB mark "M<sub>L</sub>".

40. Respondent's failure or refusal to mark Respondent's PCB Transformers with the PCB Mark "M<sub>L</sub>", as alleged in paragraph 39, above, constitutes a failure or refusal to comply with 40 C.F.R. § 761.40, which is a violation of Section 15(1)(C) of TSCA, 15 U.S.C. § 2614(1)(C).

#### COUNT 5

##### Marking Access to PCB Transformers

41. Paragraphs 1 through 9, above, are incorporated and realleged as if fully set forth herein.

42. Pursuant to 40 C.F.R. § 761.40(j)(1), Respondent was required to mark the means of access to each PCB Transformer with the PCB mark "M<sub>L</sub>" as described and illustrated in 40 C.F.R. § 761.45.

43. As of the date of the inspection, Respondent was using at least two transformers in two separate locations in the Respondent's facility. These locations are commonly known as the Maternity Courtyard and the Powerhouse.

44. The transformers described in paragraph 43, above, contained PCBs over 500 parts per million in the dielectric fluid and therefore constitute "PCB Transformers" and a "PCB Items" as those terms are defined at 40 C.F.R. § 761.3.

45. As of the date of the EPA inspection, Respondent had not marked the means of access to Respondent's PCB Transformers described in paragraphs 43 and 44, above, with the PCB mark "M<sub>L</sub>".

46. Respondent's failure or refusal to mark the means of access to Respondent's PCB Transformers with the PCB Mark "M<sub>L</sub>", as alleged in paragraph 45, above, constitutes a failure or refusal to comply with 40 C.F.R. § 761.40(j), which is a violation of Section 15(1)(C) of TSCA, 15 U.S.C. § 2614(1)(C).

PROPOSED CIVIL PENALTY

The proposed civil penalty has been determined in accordance with Section 16 of TSCA, 15 U.S.C. § 2615, which authorizes the assessment of a civil penalty of up to \$25,000 per day for each violation of TSCA and the regulations promulgated pursuant thereto. Pursuant to the Civil Monetary Penalty Inflation Adjustment Final Rule dated February 13, 2004, effective March 15, 2004 (69 Fed. Reg. 7121), a penalty of up to \$32,500 may be assessed per day for each violation of TSCA occurring after that effective date.

For purposes of determining the amount of any penalty to be assessed, Section 16 of TSCA requires EPA to take into account the nature, circumstances, extent and gravity of the violations. Section 16 of TSCA also requires EPA to take into account the following with respect to the violator: ability to pay, effect of the penalty on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

To develop the proposed penalty in this Complaint, Complainant has taken into account the particular facts and circumstances of this case, to the extent known at this time, with specific reference to EPA's "Guidelines for Assessment of Civil Penalties Under Section 16 of the Toxic Substances Control Act," which was published on September 10, 1980 in the Federal Register (45 Fed. Reg. 59,770), and EPA's April 9, 1990 "PCB Penalty Policy". A copy of each is enclosed. These policies provide rational, consistent and equitable calculation methodologies for applying the statutory penalty factors enumerated above to particular cases.

The Complainant proposes, subject to receipt and evaluation of further relevant information, that Respondent be assessed the following civil penalties for the violations alleged in the Complaint:

COUNT 1: Use of PCBs - Radial PCB Transformer Without Electrical Protection

Circumstance Level - 2

major use category

Extent Category - **significant**

Between 220 and 1,100 gallons

Proposed Assessment for this Count:

\$ 16,764

<u>COUNT 2: Use of PCBs - Unregistered Transformers</u> Circumstance Level - 2 major use category Extent Category - <b>significant</b> Between 200 and 1,100 gallons Proposed Assessment for this Count:	\$ 16,764
<u>COUNT 3: PCB Annual Documents</u> Circumstance Level - 6 minor recordkeeping category Extent Category - <b>significant</b> Between 220 and 1,100 gallons Proposed Assessment for this Count:	\$ 1,676
<u>COUNT 4: Marking PCB Transformers</u> Circumstance Level - 5 minor marking category Extent Category - <b>significant</b> between 220 and 1,100 gallons Number of locations: 2 Proposed Assessment for this Count: 2x \$3,869 Total Proposed Assessment for this Count:	\$ 7,738
<u>COUNT 5: Marking Access to PCB Transformers</u> Circumstance Level - 2 major marking category Extent Category - <b>significant</b> between 220 and 1,100 gallons Number of locations: 2 Proposed Assessment for this Count: 2x \$16,764 Total Proposed Assessment for this Count:	\$ 33,528
<b>Total:</b>	<b>\$ 76,470</b>

In accordance with Agency policies regarding modifications to the relevant penalty policies, the total gravity-based penalty amount is rounded to the nearest unit of 100 dollars.

**Total Proposed Penalty (rounded off per EPA policy): \$ 76,500**

PROCEDURES GOVERNING THIS ADMINISTRATIVE LITIGATION

The rules of procedure governing this civil administrative litigation have been set forth in 64 Fed. Reg. 40138 (July 23, 1999), entitled, "Consolidated Rules of Practice Governing the

Administrative Assessments of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits”, and which are codified at 40 C.F.R. Part 22. A copy of these rules accompanies this “Complaint and Notice of Opportunity for Hearing” (hereinafter referred to as the “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. 40 C.F.R. § 22.15(a). While that provision requires that an Answer must be filed within 30 days after service of a Complaint, EPA, Region 2, has administratively extended the deadline for such filing in this proceeding, and Respondent’s Answer accordingly must be filed within 90 days of service of the Complaint. 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, New York 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 Respondent has any knowledge. 40 C.F.R. § 22.15(b). Where Respondent lacks knowledge of a particular factual allegation and so states in its 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 intends to place at issue in the proceeding) and (3) whether Respondent requests a hearing. 40 C.F.R. § 22.15(b).

Respondent’s failure affirmatively to raise in the Answer facts that constitute or that might constitute the grounds of its 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). See generally Section 16(a)(2)(A) of TSCA, 15 U.S.C. § 2615(a)(2)(A). 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 40 C.F.R. Part 22.

If Respondent fails to request a hearing, such failure may operate to preclude Respondent from obtaining judicial review of an adverse EPA final order. See 16 U.S.C. § 2615(a)(3), which states, in part: "Any person who requested in accordance with paragraph (2)(A) [15 U.S.C. § 2615(a)(2)(A)] a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business".

#### C. Failure To Answer

If Respondent fails in its 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 [*i.e.* in accordance with the period set forth in 40 C.F.R. § 22.15(a); extended to 90 days for this Complaint] Answer to the Complaint, 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 therefor 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 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.

#### D. Exhaustion Of Administrative Remedies

Where Respondent fails to appeal an adverse initial decision to the Environmental Appeals Board pursuant to 40 C.F.R. § 22.30, and that initial decision thereby becomes a final order pursuant to the terms of 40 C.F.R. § 22.27(c), Respondent waives its right to judicial review. 40 C.F.R. § 22.27(d).

In order to appeal an initial decision to the Agency's Environmental Appeals Board [EAB; see 40 C.F.R. § 1.25(e)], Respondent must do so "within 30 days after the initial decision is served". 40 C.F.R. § 22.30(a). Pursuant to 40 C.F.R. § 22.07(c), where service is effected by

mail, "five days shall be added to the time allowed by these rules for the filing of a responsive pleading or document". Note that the 45-day period provided for in 40 C.F.R. § 22.27(c) [discussing when an initial decision becomes a final order] does not pertain to or extend the time period prescribed in 40 C.F.R. § 22.30(a) for a party to file an appeal to the EAB of an adverse initial decision.

#### INFORMAL SETTLEMENT CONFERENCE

Whether or not 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 that it believes is 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, to reflect any settlement agreement reached with Respondent, to reflect any relevant information previously not known to Complainant, or to dismiss any or all of the charges if Respondent can demonstrate that the relevant allegations are without merit and that no cause of action as herein alleged exists. 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 the EPA staff member listed below:

Ann M. Finnegan, Life Scientist  
Pesticides and Toxic Substances Branch  
U.S. Environmental Protection Agency, Region 2  
2890 Woodbridge Avenue  
Edison, New Jersey 08837-3679  
(732) 906-6177

The parties may engage in settlement discussions irrespective of whether Respondent has requested a hearing. 40 C.F.R. § 22.18(b)(1). Respondent's requesting a formal hearing does not prevent it 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. Complainant does not deem a request for an informal settlement conference as a request for a hearing as specified in 40 C.F.R. § 22.15(c).

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. No penalty reduction, however, 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 its right to contest the allegations in the Complaint and waives its right to appeal the final order that is to accompany the consent agreement. 40 C.F.R. § 22.18(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).

Respondent's entering into a settlement through the signing of such Consent Agreement and its complying with the terms and conditions set forth in the such Consent Agreement terminate this administrative litigation and the civil proceedings arising out of the allegations made in the Complaint. Respondent's entering into a settlement does not extinguish, waive, satisfy or otherwise affect its obligation and responsibility to comply with all applicable statutory and regulatory requirements, and to maintain such compliance.

#### RESOLUTION OF THIS PROCEEDING WITHOUT HEARING OR CONFERENCE

Instead of filing an Answer, Respondent may resolve this proceeding by paying the specific penalty proposed in the Complaint and filing a copy of the check or other instrument of payment with the Regional Hearing Clerk, Region 2 (at the New York address noted above) 40 C.F.R. § 22.18(a). 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:

Regional Hearing Clerk  
U.S. Environmental Protection Agency  
Region 2  
P.O. Box 360188M  
Pittsburgh, Pennsylvania 15251


The check shall be identified with a notation of the name and docket number of this case, set forth in the caption on the first page of this document. A copy of the check or other instrument of payment should be provided to the EPA staff member identified previously.

Pursuant to 40 C.F.R. § 22.18(a)(3), 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. Issuance of this final order terminates this administrative litigation and the civil proceedings arising out of the allegations made in the Complaint. 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 regulations and requirements, and to maintain such compliance.

Dated:

January 23, 2007

  
Dore LaPosta, Director  
Division of Enforcement and  
Compliance Assistance  
U.S. Environmental Protection Agency  
Region 2  
290 Broadway  
New York, NY 10007

TO: William A. McDonald  
President and Chief Executive Officer  
St. Joseph's Regional Medical Center  
703 Main Street  
Paterson, NJ 07503

Enclosures