



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 2
290 BROADWAY
NEW YORK, NY 10007-1866

U.S. ENVIRONMENTAL
PROTECTION AGENCY-REG. II

2007 AUG 27 PM 3: 22

REGIONAL HEARING
CLERK

CERTIFIED MAIL - RETURN RECEIPT REQUESTS
ITEM NUMBER 7005 3110 0000 5935 4544

August 24, 2007

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

RE: In the Matter of. Advance Biofactures Corporation
Docket No. CWA-02-2007-3319


Dear Mr. Wegman:

Enclosed is a copy of the Consent Agreement and Final Order (CA/FO) in the above-referenced matter. This CA/FO was fully executed on August 23, 2007

Please note that the penalty of \$10,000 is required to be paid in full and received by EPA no later than forty-five (45) calendar days from the date of signature.

Please do not hesitate to contact me should you have any questions.

Sincerely,


Diane T. Gomes, Esq.

Enclosure

cc: Karen Maples
Regional Hearing Clerk (w/enclosures)

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION 2

U.S. ENVIRONMENTAL
PROTECTION AGENCY-REG. II

2007 AUG 27 PM 3: 23

REGIONAL HEARING

CLERK

IN THE MATTER OF:

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

Respondent

Proceeding to Assess a Class I
Administrative Penalty Pursuant to Section
309(g) of The Clean Water Act, 33 U.S.C.
§1319(g)

DOCKET NO. CWA-02-2007-3319

Consent Agreement and Final Order

I. Preliminary Statement

This Consent Agreement and Final Order ("CA/FO") 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"), as amended, 33 U.S.C. §1319(g)(2)(A). The Complainant in this proceeding, the Director of the Division of Enforcement and Compliance Assistance ("DECA"), Region 2, United States Environmental Protection Agency ("EPA"), issued a "Complaint, Findings of Violation, Notice of Proposed Assessment of an Administrative Penalty and Notice of Opportunity to Request a Hearing" (hereinafter, "Complaint") to Advance Biofactures Corporation. ("Respondent"), on January 12, 2007. The Complaint charged Respondent with violating Sections 307(d) and 308(a) of the Act, 33 U.S.C. §1317(d) and §1318(a), respectively, and regulations promulgated pursuant thereto at 40 C.F.R Part 403, at its facility located in Lynbrook, New York.

The following Findings are made and Order issued pursuant to the authority vested in the Administrator of the EPA by the Act, as amended, 33 U.S.C. §1251 *et seq.*, and in particular Section 309(g) of the Act, 33 U.S.C. §1319(g). The Administrator has delegated this authority to the Regional Administrator of EPA, Region 2, who in turn has delegated it to the Director of DECA. This Consent Agreement and Final Order is issued 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"), which sets forth procedures for settlement of administrative civil penalty assessment proceedings through issuance of a consent agreement and final order pursuant to §22.18(b)(2) and (3).

II. Findings of Fact and Conclusions of Law

1. 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).
2. At all times relevant to this Administrative Complaint, Respondent owned and/or operated a facility located at 35 Wilbur Street, Lynbrook, New York 11563-2358 (herein after "Facility") where it processed the crude pharmaceutically active ingredient that is contained in the product known as Collagenase Santyl Ointment, in addition to various Research and Development activities.
3. The Facility 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 "publically 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).
4. 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).
5. Nassau County has an "Approved POTW Pretreatment Program" within the meaning of 40 C.F.R. §403.3(d). Thus, 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).
6. Pursuant to Sections 307(b) and 308(a) of the Act, 33 U.S.C. §§1317(b) and 1318(a), the EPA has promulgated General Pretreatment Regulations for IUs as stated in 40 C.F.R. Part 403.
7. As a non-domestic user of a POTW, the Respondent was required to comply with the requirements and standards promulgated by the 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, had 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 on March 2, 2006.
8. Pursuant to the authority of Section 307(b) of the Act, 33 U.S.C. §1317(b), the EPA has promulgated Categorical Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category ("PMPS") 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 PMPS standards went into effect on December 12, 1983. Furthermore, on May 2, 1995, the 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.

9. Respondent's manufacturing activities fall within the scope of PMPSC, as it is set out in 40 C.F.R. §439.40. Thus, Respondent's discharges of non-domestic wastewater into 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.

10. 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.

11. 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 June and December of each year, must, among other things, indicate the nature and concentration of those pollutants in the effluent discharges of the IU subject to the applicable Categorical Pretreatment Standards.

12. On October 26, 2006, to determine compliance with the Federal Pretreatment Program requirements cited above, the EPA conducted a compliance evaluation inspection of the Facility.

13. Observations made and information obtained from the Facility's personnel during the October 26, 2006 inspection resulted in the following findings:

- 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 by Respondent of non-domestic wastewater to the POTW has occurred since, at least, July, 1987 and ceased on March 2, 2006 upon sale of the pharmaceutical process.
- E) There is no indication, through a review of records and by verification of the Facility's personnel, that sampling was conducted of the Facility's discharge of regulated categorical and/or process wastewater.

- F) Respondent has not submitted the required Periodic Report on continued compliance in December 2005, June 2005, December 2004 and June 2004 to the Control Authority (POTW).

14. Respondent is subject to the General Pretreatment Regulations and the revised Categorical Pretreatment Standards for the Pharmaceutical Manufacturing Category since it introduces, into a POTW, the pollutants from its manufacturing operations. 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"). It is also an "Industrial User" ("IU") within the meaning of 40 C.F.R. §403.3(h).

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

III. Consent Agreement

Based upon the foregoing, and pursuant to Section 309(g) of the Act, 33 U.S.C. §1319(g), and the CROP (40 C.F.R. §22.18), it is hereby agreed by and between the parties, and Respondent voluntarily and knowingly agrees as follows:

Jurisdiction

1. For the purpose of this proceeding, Respondent a) admits the jurisdictional allegations of the Complaint and of this CA/FO; and b) neither admits nor denies the specific factual allegations.

Terms of Agreement

2. Pursuant to the authority of Section 309(g) of the Act and having taken into account the nature, circumstances, extent and gravity of the violations, Respondent's prior compliance history, degree of culpability and the economic benefit or savings accruing to Respondent by virtue of the violation, and Respondent's ability to pay the proposed penalty, and, EPA has determined an appropriate civil penalty of ten thousand dollars and zero cents (\$10,000.00).

Payment of Civil Penalty

3. Respondents shall pay, by cashier's or certified check, a civil penalty in the amount of ten thousand dollars and zero cents (\$10,000.00) payable to the "Treasurer, United States of America". 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. Such check shall be mailed to:

EPA, Region 2 (Regional Hearing Clerk)
P.O. Box 360188M
Pittsburgh, Pennsylvania 15251

Respondent shall also send copies of such payment to:

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

and to:

Chief, Water Compliance Branch
U.S. Environmental Protection Agency
290 Broadway - 20th Floor
New York, New York 10007-1866.

4. Payment must be received at the above address on or before forty-five (45) calendar days after the date of the signature of the Final Order at the end of this document (the date by which payment must be received shall hereafter be referred to as the "due date").
 - a. Failure to pay the penalty in full according to the above provisions will result in referral of this matter to the United States Department of Justice or the United States Department of the Treasury for collection of the assessed penalty as well as, but not limited to, interest and attorney's fees.
 - b. Further, if the payment is not received on or before the due date, interest will be assessed at the annual rate established by the Secretary of Treasury pursuant to the Debt Collection Act, 31 U.S.C. §3717, on the overdue amount from the due date through the date of payment. In addition, a late payment handling charge of \$15.00 will be assessed for each 30-day period (or any portion thereof) following the due date in which the balance remains unpaid.
 - c. In addition, pursuant to Section 309(g)(9) of the Act, 33 U.S.C. §1319(g)(9), if payment is not received by the due date, a quarterly nonpayment penalty will be imposed for each calendar quarter during which such nonpayment persists. The quarterly nonpayment penalty is 20% of the aggregate amount of penalties and quarterly nonpayment penalties which are unpaid as of the beginning of such quarter. Respondent also may be required to pay attorneys fees and costs for collection proceedings in connection with nonpayment.
5. The penalty specified in Paragraph 3, above, shall represent a civil penalty assessed by EPA and shall not be deductible from Respondent's federal or state taxes.

IV. General Provisions

6. This Consent Agreement is being voluntarily and knowingly entered into by the parties in full and final settlement of the civil liabilities that might have attached as a result of the allegations contained in the Complaint. Respondent has read the Consent Agreement, understands its terms, finds it to be reasonable and consents to its issuance and its terms. Respondent consents to the issuance of the accompanying Final Order. Respondent agrees that all terms of settlement are set forth herein.
7. Respondent explicitly and knowingly consents to the assessment of the civil penalty as set forth in this Consent Agreement and agrees to pay the penalty in accordance with the terms of this Consent Agreement.
8. Respondent knowingly and explicitly waives its right under CWA Section 309(g)(2) and (8), 33 U.S.C. §1319(g)(2) and (8), to request or to seek any Hearing on or Judicial Review of the Complaint or on any of the allegations therein asserted, on this Consent Agreement or the Findings of Fact and Conclusions of Law herein, or on the accompanying Final Order.
9. Respondent waives any right it may have pursuant to 40 C.F.R. § 22.8 to be present during discussions with or to be served with and to reply to any memorandum or communication addressed to the Director of DECA where the purpose of such discussion, memorandum, or communication is to discuss a proposed settlement of this matter or to recommend that such official accept this Consent Agreement and issue the accompanying Final Order.
10. Issuance of the Consent Agreement and Final Order does not constitute a waiver by EPA of its right to enforce the substantive legal requirements underlying this penalty assessment, either administratively or judicially pursuant to Sections 309(a), (b) and (c) of the Act, 33 U.S.C. §§1319(a), (b) and (c). Pursuant to Section 309(g)(7) of the Act, 33 U.S.C. § 1319(g)(7), issuance or compliance with this Consent Agreement and Final Order does not waive, extinguish or otherwise affect Respondent's obligation to comply with all applicable requirements of the Clean Water Act, of regulations promulgated thereunder and of any legal order or permit issued thereunder.
11. Nothing in this Consent Agreement shall be construed to create any rights in, or grant any cause of action to, any person not a Party to this Agreement.
12. Each undersigned signatory to this Consent Agreement certifies that he or she is duly and fully authorized to enter into and ratify this Consent Agreement and all the terms and conditions set forth in this Consent Agreement.

13. The provisions of this Consent Agreement and Final Order shall be binding upon the Respondent, its officers, directors, agents, servants, authorized representatives and successors or assigns.
14. Each party hereto agrees to bear its own costs and fees in this matter.
15. Respondent consents to service upon Respondent by a copy of this Consent Agreement and Final Order by an EPA employee other than the Regional Hearing Clerk.

For Advance Biofactures Corporation:



Thomas L. Wegman, President

Date: _____

8/2/07

**For the U.S. Environmental Protection Agency
Region 2:**



Dore LaPosta, Director

Division of Enforcement and Compliance Assistance

Date: _____

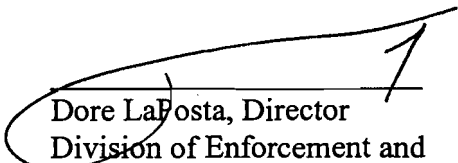
AUGUST 23, 2007

In the Matter of : Advance Biofactures Corporation
Docket No. CWA-02-2007-3319

V. Final Order

The Director of the Division of Enforcement and Compliance Assistance of the U.S. Environmental Protection Agency, Region 2, ratifies the foregoing Consent Agreement. The Agreement entered into by the parties is hereby approved, incorporated herein, and issued as an Order. The effective date of this Order shall be the date of filing with the Regional Hearing Clerk, U.S. Environmental Protection Agency, Region 2, New York, New York.

ISSUED AND ORDERED THIS 23rd DAY OF AUGUST, 2007



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

In the Matter of : Advance Biofactures Corporation
Docket No. CWA-02-2007-3319

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION 2

IN THE MATTER OF:

Advance Biofactures Corporation
35 Wilbur Street
Lynbrook, New York 11563-2356

Respondent.

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

**PROCEEDING TO ASSESS A CLASS
II CIVIL PENALTY**

**DOCKET NO.
CWA-02-2007-3319**

I certify that on August 24, 2007, I served the foregoing fully executed Consent Agreement and Final Order, bearing the above referenced docket number, on the persons listed below, in the following manner:

Original and One Copy
By Hand:

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

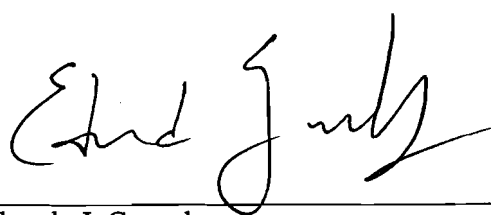
Copy by Certified Mail
Return Receipt Requested:

Thomas L. Wegman
President
Advance Biofactures Corporation
35 Wilbur Street
Lynbrook, New York 11563-2356

Copy By
Internal Mail (pouch) :

Helen Ferrara
Regional Judicial Officer
U.S. Environmental Protection Agency - Region 2
290 Broadway, 16th floor
New York, New York 10007-1866

Dated: 8/24/07



Eduardo J. Gonzalez
New York, New York