

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

U.S. ENVIRONMENTAL
PROTECTION AGENCY-REG. II
2007 DEC -7 AM 11:39
REGIONAL HEARING
CLERK

-----X
IN THE MATTER OF: :
: :
Applied Genetics Inc., Dermatics : Proceeding to Assess Class I
205 Buffalo Avenue : Civil Penalty Under Section
Freeport, New York 11520 : 309(g) of the Clean Water Act
: :
Proceeding pursuant to §309(g) : Docket No. CWA-02-2008-3305
of the Clean Water Act, :
33 U.S.C. §1319(g) :
-----X

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 Applied Genetics Inc., Dermatics

("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), and for its violations of Section 308 of the Act, 33 U.S.C. §1318.

II. Findings of Violation

3. Respondent is a corporation organized under the laws of the State of Delaware 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 205 Buffalo Avenue, Freeport, New York (the "facility") where it manufactures liposome systems primarily containing enzymes for skin care applications 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 #3 - Cedar Creek Water Pollution Control Plant), which is a "publicly owned treatment works" ("POTW") within the meaning of 40 C.F.R. §403.3(q), since, at least, April 1994. 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(i).

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. §403.3(f).

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.

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 became 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. Section 308 of the Act, 33 U.S.C. §1318, provides, in relevant part, that the Administrator of EPA may require the owner or operator of any point source to, among other things: maintain such records; make such reports; install, use and monitor such equipment; sample such effluents; and provide such other information as may reasonably be required in order to carry out Section 402 of the Act, 33 U.S.C. §1342.

14. Pursuant to 40 C.F.R. §403.12(b), Applied Genetics Inc., Dermatics was required to submit, to the Control Authority, a Baseline Monitoring Report ("BMR") regarding the discharge of wastewater from the IU to the treatment works, including, among other things, the following:

- a) A description of the operations at the IU, including a measurement of the IU's average production rate;
- b) A record of measurement of the average daily flow and maximum daily flow of regulated process wastewater from the IU to the POTW; and

- c) A sampling and analysis of the nature and concentration of regulated pollutants present in the IU's wastewater from each regulated process. The sample shall be representative of daily operations.

15. Pursuant to 40 C.F.R. §403.12(b), and 40 C.F.R. §439.46, Applied Genetics Inc., Dermatics was required to submit a BMR to the Control Authority at least 180 days after the effective PMPSC rule of November 20, 1998. The BMR was due no later than May 19, 1999.

16. 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 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.

17. Pursuant to 40 C.F.R. §403.12(d), and 40 C.F.R. §439.46, Applied Genetics Inc., Dermatics was required to submit to the Control Authority, within ninety (90) days following the compliance date of September 21, 2001 for revised PMPSC, a report on Compliance with Categorical Pretreatment Standard Deadline (a "90-day Compliance Report") containing the information listed in 40 C.F.R. 403.12(b)(4)-(6). The ninety (90)-day Compliance Report was due no later than December 20, 2001.

18. During the inspection of August 17, 2006, the following information was obtained from facility personnel and inspection findings:

- a) Respondent is involved in the manufacture of liposome systems primarily containing repair enzymes for skin care applications in addition to Research and Development activities.
- b) Respondent, in general, manufactures the products, as cited in (a) above, via batch blending, mixing compounding 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 has occurred since, at least, April 1994.
- e) Records review, in addition to verification from facility personnel, indicates that no sampling has been conducted on the facility's discharge to the POTW.
- f) Respondent has not submitted the required BMR, ninety (90)-day Compliance Report or Periodic Reports to the Control Authority.

19. At the time of EPA's August 17, 2006 inspection, EPA requested that the respondent provide the Standard Industrial Codes (SIC) applicable to the facility. Facility personnel did not

provide the SIC information for the facility's general operations, as well as the specific SIC codes for the products manufactured on-site as per EPA's request.

20. In follow-up communications with the respondent, occurring on August 21, 2006, August 31, 2006, September 13, 2006 and October 4, 2006, EPA again requested the SIC codes for the facility.

21. EPA conducted Pretreatment Compliance Sampling Inspections of Respondent's facility on November 14, 2006 (preliminary inspection) and January 9, 2007 (sampling inspection).

22. During the inspections, referenced in paragraph 21 above, the following information was obtained from facility personnel and inspection findings:

- a) Applied Genetics Inc., Dermatics (formerly Applied Genetics, Inc.) began operation of the current facility in 1985, conducting Research and Development activities.
- b) Respondent commenced, on or about April 1994, the production for sale of liposome systems primarily containing repair enzymes for skin care applications via mixing, blending and formulation in batch-type manufacturing.
- c) Respondent discharges the wastewater from the manufacturing operations, described in paragraph 22(b) above, via the Village of Freeport sanitary sewer system into the Nassau County Department of Public Works, Sewage Treatment Plant (Sewer District #3 - Cedar Creek Water Pollution Control Plant).

23. At the time of EPA's inspections of November 14, 2006 and January 9, 2007, facility personnel did not provide the SIC codes for the facility's general operations, as well as the specific SIC codes for the products manufactured on-site as per EPA's request.

24. Respondent did not provide the information regarding the SIC Codes as requested during the inspections and communications, cited in paragraphs 19, 21, and 23, above, until June 27, 2007. Such information was provided subsequent to the issuance of an Administrative Order, CWA-02-2007-3033.

25. On May 24, 2007, EPA issued a proceeding pursuant to §309(a) of the Clean Water Act (CWA-02-2007-3033), 33 U.S.C. §1319(a). Respondent was cited for failure to submit pretreatment reports as required by the General Pretreatment Regulations found at 40 C.F.R. Part 403 and the Categorical Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category found at 40 C.F.R. Part 439.

26. Respondent is subject to the General Pretreatment Regulations and the revised Categorical Pretreatment Standards for the Pharmaceutical Manufacturing Category since they introduce 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"). Respondent is also an "Industrial User" ("IU") within the meaning of 40 C.F.R. §403.3(i).

27. The Respondent has violated Sections 307(d) and 308(a) of the Act, and its implementing pretreatment regulations, on at least five (5) occasions by failing to submit the

required Periodic Reports on Continued Compliance in December 2006, June 2006, December 2005, June 2005 and December 2004, and has violated Section 308 of the Act by failing to respond to requests for information.

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 \$32,500.00. 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 their 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), (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 them 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
Fines and Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, MO 63197-9000

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, Region 2
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:

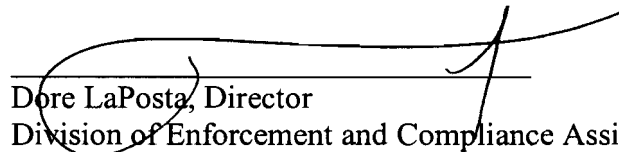
Diane T. Gomes
Assistant Regional Counsel
Office of Regional Counsel
U.S. Environmental Protection Agency, Region 2
290 Broadway, 16th floor
New York, New York 10007-1866
(212) 637-3235

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 of the Act, regulations promulgated thereunder, or any applicable permit.

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 5th DAY OF DECEMBER, 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-02-2008-3305

To: (40 C.F.R. §22.5(b)(1))

Daniel Yarosh, President and CEO
Applied Genetics Inc., Dermatics
205 Buffalo Avenue
Freeport, New York 11520

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION 2

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IN THE MATTER OF	:	
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Applied Genetics Inc., Dermatics	:	Proceeding to Assess Class I
205 Buffalo Avenue	:	Civil Penalty Under Section
Freeport, New York 11520	:	309(g) of the Clean Water Act
	:	
Proceeding Pursuant to §309(g) of the	:	Docket No. CWA-02-2008-3305
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. Daniel Yarosh, President and CEO
Applied Genetics Inc., Dermatics
205 Buffalo Avenue
Freeport, New York 11520

Ms. Sandra Allen, Esq., Director
Division of Water
NYSDEC
625 Broadway - 4th 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: 12/05/07
New York, New York

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