

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2

U.S. ENVIRONMENTAL
PROTECTION AGENCY-REG. II
2007 DEC -7 AM 11:38
REGIONAL HEARING
CLERK

DATE: DEC 5 2007

SUBJECT: Administrative Penalty Assessment - Class I
Applied Genetics Inc., Dermatics
(CWA-02-2008-3305)

FROM: Philip Greco, CHMM *PG*,
Enforcement Specialist, DECA-SET

TO: File

We have determined an appropriate proposed penalty for assessment against Applied Genetics Inc., Dermatics ("Respondent") whose facility is located at 205 Buffalo Avenue, Freeport, New York, through the following application of the statutory factors in §309(g) of the Act.

(A) Nature, Circumstances, Extent and Gravity of the Violation

The Respondent has failed to monitor its process wastewater discharge as required by the applicable Categorical Pretreatment Standards for Pharmaceutical Manufacturing Point Source Category ("PMPSC")(40 C.F.R. §439). In addition, the Respondent failed to satisfy the reporting requirements as required by the General Pretreatment Standards (40 C.F.R. §403.12). Respondent is classified as an "Existing Source" pursuant to 40 C.F.R. §439.46.

Respondent did not submit the biannual Periodic Reports on Continued Compliance ("Periodic Report") to the Control Authority as required. The Periodic Reports that are cited have not been submitted for the December 2006, June 2006, December 2005, June 2005 and December 2004 reporting periods.

The Respondent is in violation of Sections 307 and 308 of the Clean Water Act (CWA). Presently, there is no data to assess the violation's effect on human health.

(B) Prior History of Such Violations

Respondent began operations at the Freeport manufacturing facility on or about April 1985. Manufacturing operations discharging regulated categorical waste commenced on or about April 1994. An EPA inspection conducted on August 17, 2006 verified that Respondent did not submit any pretreatment reports as required at that time.

(C) Degree of Culpability

The Respondent should be aware of its obligation to monitor and report in accordance with the applicable Pretreatment Standards, as the applicable Pretreatment Standards had been promulgated and subsequently revised and/or effective for a number of years, have been noticed and subsequently revised.

(D) Recalcitrance

Respondent has not cooperated with EPA. Respondent refused to submit information such as SIC codes and manufacturing operations citing CBI and did not provide such information even after discussion issues related to CBI with ORC. Respondent did not submit in a timely fashion the information as requested in the Ordered Provisions of the 309(a) Compliance Order issued to the Respondent on May 24, 2007.

(E) Economic Benefit

The Economic Benefit of non-compliance was incurred as a result of Respondent's failure to sample and analyze the regulated discharge as required for reporting pursuant to 40 CFR §403.12. Non-submittal of biannual Periodic Reports on Continued Compliance was considered for the "Economic Benefit" calculation as applicable. Consequently, penalties for failure to submit Periodic Reports due December 2006, June 2006, December 2005, June 2005 and December 2004 were applied as per the criteria.

Cost data which was inputted into the "BEN" computer program was obtained from contract laboratories as reasonable expenditure for wastewater analysis. Consequently, appropriate costing data for specific parameters as required in a Periodic Report was utilized. In addition, a conservative estimate of the administrative costs for preparing a Periodic Report was inputted for calculation of the "Economic Benefit". The economic benefit was, therefore, computed to be \$3172.00.

(E) Ability to Pay

Presently, EPA possesses no information to include an inability to pay consideration.

In conclusion, the application of the statutory factors in §309(g) fully supports the proposed penalty of \$32,500.00.

bcc: Karen Maples, Regional Hearing Clerk
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