



STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
Division of Air Pollution Control
William R. Snodgrass Tennessee Tower
312 Rosa L. Parks Avenue, 15th Floor
Nashville, TN 37243

James M. Gregory
501 5th Street
Bristol, Tennessee 37620-2304

Certified Article Number

9414 7266 9904 2212 9404 38

SENDER'S RECORD

RE: Gregory Pharmaceutical Holdings, Inc.
Facility Id. 82-0052
Case No. APC23-0043

Dear Mr. Gregory:

Enclosed, please find an Order and Assessment of Civil Penalty issued by Michelle Walker Owenby, Technical Secretary of the Air Pollution Control Board, Department of Environment and Conservation. Please read it carefully and pay special attention to the Notice of Rights section.

If you have any questions regarding this Order and Assessment of Civil Penalty, please contact Kevin McLain at (615) 532-6819 or kevin.mclain@tn.gov. For all other questions, please contact the Division of Air Pollution Control at (615) 532-0554 or air.pollution.control@tn.gov.

Sincerely,

Kevin McLain
Section Manager, Enforcement
Division of Air Pollution Control

hln

Enclosure

**STATE OF TENNESSEE
AIR POLLUTION CONTROL BOARD**

IN THE MATTER OF:)	DIVISION OF AIR POLLUTION
)	CONTROL
)	
GREGORY PHARMACEUTICAL)	
HOLDINGS, INC.,)	
)	
RESPONDENT.)	CASE NO. APC23-0043

**TECHNICAL SECRETARY'S ORDER AND
ASSESSMENT OF CIVIL PENALTY**

Michelle Walker Owenby, Technical Secretary of the Air Pollution Control Board, states:

PARTIES

I.

Michelle Walker Owenby is the Technical Secretary of the Air Pollution Control Board ("Board") and Director of the Division of Air Pollution Control ("Division"), Department of Environment and Conservation ("Department").

II.

Gregory Pharmaceutical Holdings, Inc. ("Respondent") is a foreign for-profit corporation formed in Maryland and authorized to do business in the State of Tennessee. The Respondent's facility address is 501 5th Street, Bristol, Tennessee 37620-2304. Service of process may be made upon the Respondent's registered agent, James M. Gregory, at the same address.

AUTHORITY

III.

The Technical Secretary may assess a civil penalty of up to \$25,000.00 per day for each day of violation of the Tennessee Air Quality Act, Tenn. Code Ann. §§ 68-201-101 to -121 ("Act"), or Tennessee Air Pollution Control Regulations, Tenn. Comp. R. & Regs. 1200-03-01 to -36; 0400-30-01 to -39, ("Rules"). Tenn. Code Ann. § 68-201-116. The Technical Secretary may issue an order for correction to the responsible person when provisions of the Act or Rules are violated, and such person may be liable for resulting damages to the State. *Id.*

IV.

The Respondent is a “person,” Tenn. Code Ann. § 68-201-102(7), and has violated the Act and Rules.

V.

“Air contaminant” means particulate matter, dust, fumes, gas, mist, smoke, vapor, or any combinations thereof. Tenn. Code Ann. § 68-201-102(1).

VI.

“Air contaminant source” means any and all sources of emission of air contaminants, whether privately or publicly owned or operated. Tenn. Code Ann. § 68-201-102(2). The Respondent operates an air contaminant source.

FACTS

VII.

On December 9, 2016, the Technical Secretary issued Major Source operating permit (“Title V”) permit number 567486 (“Permit 567486”), (facility 82-0052) (“Facility”), to the Respondent for a pharmaceutical manufacturing operation. Permit 567486 was modified on August 20, 2019, and June 7, 2022.

VIII.

Condition E5-1(MM2) of Permit 567486 states:

. . . Pressure drop for each baghouse shall be maintained and recorded once daily in the log given below or a similar log approved by the Technical Secretary. . . .

IX.

Condition E7-1 of Permit 567486 states:

. . . Monthly maintenance checks for baghouse components including fan and inspection of bags will be performed. These checks shall be recorded in

a suitable permanent form and kept available for inspection by the Division.

...

X.

On January 18, 2023, Division personnel conducted a compliance inspection at the Facility. During the inspection, it was discovered that the October 2022 through January 2023 baghouse pressure drop logs were incomplete or had not been created at the time of the inspection. Additionally, the monthly inspection records for the DC-10032 baghouse that controls the source 33 particulate matter emissions were reviewed. This review indicated that no inspection was performed in July 2022.

XI.

On February 1, 2023, the Division received a log of the weekly pressure drops that were taken to confirm proper baghouse operation from Facility personnel. However, these logs were incomplete.

XII.

On February 2, 2023, the Division requested the complete log of weekly pressure drops that were taken to confirm proper baghouse operation.

XIII.

On February 7, 2023, Facility personnel confirmed that the July 2022 baghouse inspection performed on June 15, 2022, was performed in error and, therefore, no baghouse inspection was performed for July 2022.

XIV.

On February 10, 2023, the Division received a copy of the complete logs requested on February 2, 2023. These logs indicated that pressure drops were not recorded for 11 days of Levoxy1 production (controlled by baghouse DC-2-R-01) and for two days of Altace production (controlled by baghouse DC2000).

XV.

On March 2, 2023, the Division sent a Notice of Violation (NOV) to the Respondent for the violations discussed in paragraph X. and paragraph XIV. The NOV required the Facility to submit an amended Semiannual Report (SAR) for the period of April 1 through September 30, 2022, within 30 days of receipt of the NOV.

XVI.

On April 13, 2023, the Division received a completed and amended SAR for the period of April 1 through September 30, 2022, from the Facility.

VIOLATIONS

XVII.

By failing to comply with Condition E5-1(MM2) and E7-1 of Permit 567486, the Respondent violation Rule 1200-03-09-.02(6), which states:

Operation of each air contaminant source shall be in accordance with the provisions and stipulations set forth in the operating permit, all provisions of these regulations, and all provisions of the Tennessee Air Quality Act. . . .

ORDER AND ASSESSMENT OF CIVIL PENALTY

XVIII.

The Respondent is assessed a civil penalty of \$3,000.00 for violation of the Act and Rules, to be paid to the Department at the following address:

Treasurer, State of Tennessee
Division of Fiscal Services - Consolidated Fees Section
Department of Environment and Conservation
William R. Snodgrass Tennessee Tower, 10th Floor
312 Rosa L. Parks Avenue
Nashville, Tennessee 37243

The civil penalty shall be delivered to the Department on or before the thirty-first day after receipt of this Order and Assessment of Civil Penalty. The case number, APC23-0043, should be clearly written on all correspondence.

RESERVATION OF RIGHTS

In issuing this Order and Assessment of Civil Penalty, the Department does not implicitly or expressly waive any provision of the Act or Rules promulgated thereunder or the authority to assess costs, civil penalties, and/or damages incurred by the State against the Respondent. The Department expressly reserves all rights it has at law and in equity to order further corrective action, assess civil penalties and/or damages, and to pursue further enforcement action including, but not limited to, monetary and injunctive relief. Compliance with this order will be considered as a mitigating factor in determining the need for future enforcement action.

NOTICE OF RIGHTS

The Respondent may appeal this Order and Assessment. Tenn. Code Ann. §§ 68-201-108(a) and 68-201-116(b). To do so, a written petition setting forth the reasons for requesting a hearing must be received by the Technical Secretary within 30 days of the date the Respondent received this Order and Assessment or this Order and Assessment becomes final. Any petition for review must be directed to:

Commissioner of the Department of Environment and Conservation
c/o Jenny L. Howard, General Counsel
Department of Environment and Conservation
William R. Snodgrass Tennessee Tower, 2nd Floor
312 Rosa L. Parks Avenue
Nashville, Tennessee 37243

The petition may be mailed or delivered to this address, or it may be sent to TDEC.Appeals@tn.gov. If an appeal is filed, an initial hearing of this matter will be conducted by an Administrative Judge as a contested case hearing. Tenn. Code Ann. § 68-201-108(a); Tenn. Code Ann. § 4-5-301 to -325; Tenn. Comp. R. & Regs. 1360-04-01. Such hearings are legal proceedings in the nature of a trial. Individual respondents may represent themselves or be represented by an attorney licensed to practice law in Tennessee. Artificial respondents (*e.g.*, corporations, limited partnerships, limited liability companies, etc.) cannot engage in the practice of law and therefore may only pursue an appeal through an attorney licensed to practice law in Tennessee. Low-income individuals may be eligible for representation at reduced or no cost through a local bar association or legal aid organization.

At the conclusion of any initial hearing, the Administrative Judge has the authority to affirm, modify, or deny this Order and Assessment of Civil Penalty, including the authority to increase or decrease the penalty. Tenn. Code Ann. § 68-201-116. The Administrative Judge, on behalf of the Board, has the authority to assess additional damages incurred by the Department including, but not limited to, all docketing expenses associated with the setting of the matter for a hearing, and the hourly fees incurred due to the presence of the Administrative Judge and a court reporter.

Technical questions and other correspondence involving compliance issues should be sent to:

Kevin McLain, Division of Air Pollution Control
Department of Environment and Conservation
William R. Snodgrass Tennessee Tower, 15th Floor
312 Rosa L. Parks Avenue
Nashville, Tennessee 37243

Attorneys should contact the undersigned counsel of record. The case number, APC23-0043, should be written on all correspondence regarding this matter.

Issued by the Technical Secretary, Air Pollution Control Board, Department of Environment and Conservation, on September 1, 2023.



Michelle Walker Owenby
Technical Secretary
Air Pollution Control Board

Reviewed by:

A handwritten signature in black ink, appearing to read "Grant Ruhl". The signature is written in a cursive, flowing style.

Grant LeMaster Ruhl
BPR # 036182
Associate Counsel
Department of Environment and Conservation
312 Rosa L. Parks Avenue, 2nd Floor
Nashville, Tennessee 37243
(629) 201-0016
Grant.Ruhl@tn.gov

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Division of Air Pollution Control
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501 5th Street
Bristol, TN 37620-2304

Reference Information

APC23-0043 HLN

PS Form 3800, Facsimile, July 2015

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Division of Air Pollution Control
William R. Snodgrass Tower, 15th Floor
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2. Certified Mail (Form 3800) Article Number

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