



STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
Division of Air Pollution Control
Davy Crockett Tower
500 James Robertson Pkwy, 7th Floor
Nashville, TN 37243

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

Certified Article Number

9414 7266 9904 2240 2619 63

SENDER'S RECORD

RE: Gregory Pharmaceutical Holdings, Inc.
Facility Id. 82-0052
Case No. APC26-0011

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 air.pollution.control@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
[Kevin McLain \(Feb 4, 2026 15:23:53 CST\)](#)

Kevin McLain
Section Manager, Enforcement
Division of Air Pollution Control

vom

Enclosure

**STATE OF TENNESSEE
AIR POLLUTION CONTROL BOARD**

IN THE MATTER OF:)	DIVISION OF AIR POLLUTION CONTROL
)	
)	
GREGORY PHARMACEUTICAL HOLDINGS, INC.,)	
)	
)	
)	
RESPONDENT.)	CASE NO. APC26-0011

**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 corporation formed in Maryland and authorized to do business in Tennessee. The Respondent's facility address is 501 5th Street, Bristol, Tennessee 37620-2304. The Respondent's registered agent for service of process is James M. Gregory at the same address.

AUTHORITY

III.

The Technical Secretary may assess a civil penalty of up to \$25,000 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, (facility 82-0052), to the Respondent for a pharmaceutical manufacturing facility. The Technical Secretary modified Title V permit number 567486 as follows:

Type	Issued Date
Minor Modification	August 28, 2017
Minor Modification	October 17, 2018
Minor Modification	August 20, 2019
Significant Modification	June 7, 2022

VIII.

Condition E7-1 of Title V permit number 567486 states:

Particulate matter emitted from this source shall not exceed 1.13 pounds per hour.

TAPCR 1200-03-07-.01(5) and the application dated May 15, 2013.

Compliance method: 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. These records must be retained for a period of not less than five years.

IX.

Condition E8-4(MM1). of Title V permit number 567486 states, in pertinent part:

Requirements for existing emergency CI (combustion engine) located at area source of HAP emissions are:

- a. Change oil and filter every 500 hours of operation or annually, whichever comes first.

...

40 CFR Part 63 Subpart ZZZZ, Table 2(d)

Compliance Method: Records of monthly hours of operation, dates of oil changes, filter changes, inspection dates of air cleaners, and inspection dates for hoses and belts shall be kept at the source location to assure compliance with these requirements. These records must be retained for a period of not less than five years.

X.

On November 3, 2025, Division personnel conducted an inspection at the Respondent's facility. During this inspection and subsequent correspondence, the Division discovered the following violations:

- In an e-mail dated November 18, 2025, the Respondent submitted the monthly baghouse inspection records to the Division for review. These records indicated that the inspection scheduled for November 2024 was completed on December 2, 2024, and the inspection scheduled for May 2025 was completed on June 6, 2025. On December 3, 2025, the Respondent confirmed by e-mail that the source was in production in November 2024 and May 2025; therefore, the source operated for two months without completing the required monthly baghouse inspection.
- In an e-mail dated December 4, 2025, the Respondent provided the documentation for the most recent oil change on the emergency generator to the Division. According to this documentation, this oil change was completed on January 30, 2025. Given that the previous oil change was completed on December 21, 2023,

this oil change should have been completed no later than January 20, 2025. Therefore, the January 30, 2025, oil change was completed 10 days late.

XI.

On December 22, 2025, the Division issued a Notice of Violation (“NOV”) to the Respondent for the violations identified in Paragraph X. As corrective action, the NOV required that the Annual Compliance Certification (“ACC”) for the period ending in March 2025 should be updated to reflect these deviations, and the Semiannual Report (“SAR”) for the period ending in March 2025 should be updated to reflect the late November 2024 baghouse inspection and the late emergency engine oil change. The revised ACC and SAR were to be submitted to APC.JCEFO@tn.gov no later than 30 days from the receipt of the NOV. On or about January 19, 2026, the Division received the revised ACC and SAR.

VIOLATIONS

XII.

By failing to comply with conditions E7-1. and E8-4(MM1). of Title V permit number 567486, the Respondent violated Division Rule 1200-03-09-.02(6), which states, in pertinent part:

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

XIII.

The Respondent is assessed a civil penalty of \$7,500 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
Davy Crockett Tower
500 James Robertson Pkwy, 6th Floor
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 **APC26-0011**, 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 TDEC.Appeals@tn.gov. The petition may also be mailed or delivered to Commissioner of the Department of Environment and Conservation, c/o Jenny L. Howard, General Counsel, Department of Environment and Conservation, Davy Crockett Tower, 500 James Robertson Pkwy, 5th Floor, Nashville, Tennessee 37243.

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 -326; 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
Davy Crockett Tower
500 James Robertson Pkwy, 7th Floor
Nashville, Tennessee 37243

Attorneys should contact the undersigned counsel of record. The case number, **APC26-0011**, should be written on all correspondence regarding this matter.

Issued by the Technical Secretary, Air Pollution Control Board, Department of Environment and Conservation, on Feb 11, 2026



Michelle W Owenby (Feb 11, 2026 08:59:58 CST)

Michelle Walker Owenby
Technical Secretary
Air Pollution Control Board

Reviewed by:



William Freeman Miller
BPR #028826
Senior Associate Counsel
Department of Environment & Conservation
Davy Crockett Tower, 5th Floor
500 James Robertson Parkway
Nashville, TN 37243-1204
(615) 626-4275
william.f.miller@tn.gov

Label #1
 James M. Gregory
 501 5th Street
 Bristol, TN 37620-2304

Label #2

Label #3

USPS® Postal Service
CERTIFIED MAIL™ RECEIPT
 Domestic Mail Only

TEAR ALONG THIS LINE

USPS® ARTICLE NUMBER 9414 7266 9904 2240 2619 63	
Certified Mail Fee	\$
Return Receipt (Hardcopy)	\$ 4.35
Return Receipt (Electronic)	\$ 3.55
Certified Mail Restricted Delivery	\$ 0.00
Postage	\$ 0.00
Total Postage and Fees	\$ 0.63
Postmark Here	
Sent to: 8.53 James M. Gregory 501 5th Street Bristol, TN 37620-2304	
Reference Information	
APC26-0011 / vom	

PS Form 3800, Facsimile, July 2015

FOLD AND TEAR THIS WAY → OPTIONAL

Label #5 (OPTIONAL)

TN Dept. of Environment & Conservation
 Division of Air Pollution Control
 Davy Crockett Tower
 500 James Robertson Pkwy, 7th Floor
 Nashville, TN 37243

Label #6 - Return Receipt Barcode (Sender's Record)



9590 9266 9904 2240 2619 66

Label #7 - Certified Mail Article Number



FOLD AND TEAR THIS WAY →

DLRM 2-12-2026

Thank you for using Return Receipt Service

RETURN RECEIPT REQUESTED
 USPS® MAIL CARRIER
 DETACH ALONG PERFORATION

 9590 9266 9904 2240 2619 66	
1. Article Addressed to: James M. Gregory 501 5th Street Bristol, TN 37620-2304	
2. Certified Mail (Form 3800) Article Number 9414 7266 9904 2240 2619 63	

<input checked="" type="checkbox"/> Agent <input type="checkbox"/> Addressee	
B. Received by (Printed Name)	C. Date of Delivery
D. Is delivery address different from item 1? <input type="checkbox"/> Yes If YES, enter delivery address below: <input type="checkbox"/> No	
3. Service Type: <input checked="" type="checkbox"/> Certified Mail	
Reference Information	
APC26-0011 / vom	

Thank you for using Return Receipt Service

PS Form 3811, Facsimile, July 2015

Domestic Return Receipt

