

**TENNESSEE AIR POLLUTION CONTROL BOARD**

**IN THE MATTER OF:**

**GREGORY PHARMACEUTICAL  
HOLDINGS, INC. D/B/A  
UPM PHARMACEUTICALS, INC.  
RESPONDENT**

)  
)  
) **DIVISION OF AIR POLLUTION**  
)  
)  
) **CASE NO. APC19-0007 & APC19-0074**  
)

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

Comes now, Michelle Walker Owenby, Technical Secretary of the Air Pollution Control Board, and states that:

**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"), Tennessee Department of Environment and Conservation ("Department").

**II.**

Gregory Pharmaceutical Holdings, Inc. D/B/A UPM Pharmaceuticals, Inc. ("Respondent") is a foreign corporation formed in Maryland and authorized to do business in the State of Tennessee. Respondent's facility address is 501 5<sup>th</sup> Street, Bristol, Tennessee 37620-2304. Respondent's registered agent for service of process is James M. Gregory at this same address.

**AUTHORITY**

**III.**

Pursuant to Tennessee Code Annotated ("Tenn. Code Ann.") § 68-201-116, 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 ("Act") or any rules or regulations promulgated thereunder ("Division Rules") against any person who violates said Act or Division Rules, and/or the Technical Secretary may issue an order for correction to the responsible person when provisions of the Act or Division

Rules are violated. In addition, such person may also be liable for any damages to the State resulting therefrom.

#### IV.

Respondent is a “person” within the meaning of Tenn. Code Ann. § 68-201-102 and has violated the Division Rules as hereinafter stated.

#### V.

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

#### VI.

“Air contaminant source” means any and all sources of emission of air contaminants, whether privately or publicly owned or operated, as stated in Tenn. Code Ann. § 68-201-102.

#### VII.

Respondent operates an “air contaminant source” within the meaning of Tenn. Code Ann. § 68-201-102.

### FACTS

#### VIII.

On December 9, 2016, the Technical Secretary issued Title V operating permit number 0567486 (“Permit 567486”), emission source reference number 82-0052, to Respondent for the manufacturing of pharmaceuticals. On August 28, 2017, and October 17, 2018, the Technical Secretary modified Permit 567486.

#### IX.

Condition E6-1(MM1)(b) of Permit 567486 states, in pertinent part:

The permittee shall continuously monitor (at least one reading every fifteen (15) minutes) scrubber liquid flow rate as well as scrubber liquid pH to demonstrate compliance with this limit. The scrubber liquid flow rate shall be maintained at more than 221 gallons per minute and scrubber liquid pH shall be maintained at greater than 10.4, averaged over the operating day.

**X.**

Condition E6-1(MM1)(c) of Permit 567486 states, in pertinent part:

The conductivity of the post RTO scrubber liquid shall be maintained in a range of 20 to 80 micro-Siemens per centimeter (ms/cm), and the permittee shall continuously monitor the post RTO scrubber liquid conductivity for compliance assurance with this limit.

**XI.**

Condition E6-7(MM1) of Permit 567486 states, in pertinent part:

The permittee shall maintain a minimum pressure drop of 0.5 inches of water across baghouse DCM101 and a minimum pressure drop of 0.8 inches of water across baghouse DC2977. The permittee shall monitor the pressure drop values across baghouses DCM101 and DC2977 and record in a log (see example log below) one (1) pressure drop reading each day for each baghouse. The baghouse pressure monitoring gauge(s) shall have uniform increments suitable for the optimum operating range. The designated person(s) shall note any relevant baghouse conditions/problems/concerns when recording the values and note in the log when a baghouse is not operating. This log shall be made available to the Technical Secretary or a Division representative for inspection upon request. These records must be retained at the facility for a period of at least five (5) years.

**XII.**

Condition E6-8(MM1) of Permit 567486 states, in pertinent part:

Hydrochloric acid (HCl) emitted from the scrubber shall not exceed 1.83 pounds per hour and 0.18 tons per 12 consecutive months.

**XIII.**

Condition E6-15(MM1) of Permit 567486 states, in pertinent part:

Wastewater generated by the Menest process has the potential to exceed the MACT applicability thresholds; therefore, the wastewater generated from the Menest PMPU is designated to be subject to the requirements of 40 CFR §63.1256.

**XIV.**

On or about November 28, 2018, the Division received Respondent's National Emission Standards for Hazardous Air Pollutants ("NESHAP") for Pharmaceuticals Production semiannual

report (“SAR”) for the time period of April 1, 2018, through September 30, 2018. On December 26, 2018, and January 3, 2019, Respondent submitted revised NESHAP SARs. A review of the SARs revealed the violations described in paragraphs XV and XVI.

**XV.**

Respondent had 18 days where the baghouse pressure drops for DCM101 and 17 days where the baghouse pressure drops for DC2977 deviated below the minimum pressure drops in condition E6-7(MM1) of Permit 567486. These deviations are provided in the table below.

Date	DCM101 Pressure Drop (inches of water)	DC2977 Pressure Drop (inches of water)
July 3, 2018	0.4	0.1
July 4, 2018	0.4	0.1
July 5, 2018	0.4	0.1
July 6, 2018	0.4	0.1
July 7, 2018	0.4	0.1
July 9, 2018	0.4	0.1
July 10, 2018	0.4	0.1
July 11, 2018	0.4	0.1
July 12, 2018	0.4	0.1
July 18, 2018	0.4	0.1
August 27, 2018	0.4	0.3
August 28, 2018	0.4	0.3
August 29, 2018	0.4	0.3
August 31, 2018	0.4	
September 12, 2018	0.4	0.7
September 13, 2018*	0.4	0.7
September 14, 2018*	0.4	0.7
September 18, 2018*	0.4	0.7

\*The January 11, 2019, Notice of Violation (“NOV”) inadvertently had the wrong dates. The NOV listed these dates all as September 12, 2018.

**XVI.**

The 12-consecutive month total for hydrochloric acid emissions in condition E6-8(MM1) of Permit 567486 was exceeded for three consecutive months as indicated in the table below.

Month	Hydrochloric Acid Emissions (ton/12 consecutive months)
July 2018	0.20
August 2018	0.25
September 2018	0.30

**XVII.**

On January 11, 2019, the Division issued an NOV to Respondent for the violations described in paragraphs **XV** and **XVI**.

**XVIII.**

On February 22, February 27, and April 1 of 2019, the Division conducted on-site inspections at Respondent's facility. Based on the inspections and records received from Respondent on March 5, 2019, the Division discovered the following violations of conditions E6-1(MM1)(b) and (c), and E16-15(MM1) of Permit 567486, respectively.

- The records indicated that on November 14, 2018, the daily average scrubber flow rate was 47 gallons per minute.
- The records indicated that on November 14, 2018 that there were 19 of the 43 readings taken on this day, where the conductivity was out of the 20 - 80 ms/cm range. They were as follows:

Date/Time	Conductivity (ms/cm)
November 14, 2018 / 10:45	82
November 14, 2018 / 11:00	84
November 14, 2018 / 11:15	84
November 14, 2018 / 11:30	84
November 14, 2018 / 11:45	84
November 14, 2018 / 12:00	84
November 14, 2018 / 12:15	84
November 14, 2018 / 12:30	84
November 14, 2018 / 12:45	84
November 14, 2018 / 13:00	84
November 14, 2018 / 13:15	84

November 14, 2018 / 13:30	83
November 14, 2018 / 13:45	83
November 14, 2018 / 14:00	82
November 14, 2018 / 14:15	82
November 14, 2018 / 14:30	82
November 14, 2018 / 14:45	81
November 14, 2018 / 15:00	81
November 14, 2018 / 15:15	81

- Compliance with condition E6-15(MM1) of Permit 567486 requires the Menest wastewater to be collected and treated off-site by a facility that has certified compliance with the Pharma MACT wastewater provisions (40 CFR §63.1256(a)(5)). Additionally, a copy of the certification that the off-site disposal facility complies with the Pharma MACT wastewater provisions shall be kept at the site location. A copy of the certification from Veolia ES Technical Solutions, L.L.C. included in Respondent's Notification of Compliance Status dated September 16, 2014, was provided to the facility in an e-mail from the Division on March 8, 2019, that asked if the off-site facility for Menest wastewater had changed.

An e-mail from Respondent dated March 13, 2019, confirmed that the off-site facility had changed and a letter from Environmental Enterprises, Incorporated ("EEi") was provided that contained the material manifest information, disposal code and indicated that the wastewater will be blended for incineration at an offsite location. An email from Respondent's consultant, Appalachian Environmental Resources, Inc. dated April 17, 2019, stated, in part, "It is the understanding of the transfer facility and the offsite disposal company that Pharma MACT does not comply." The facility provided documentation that the transferee, EEi, was notified that the wastewater contained or had the potential to contain organic HAP; however, documentation that the off-site disposal facility complies with the Pharma MACT wastewater provisions had not been received.

#### XIX.

On May 3, 2019, the Division issued an NOV to Respondent for the violations described in paragraph XVIII.

## VIOLATIONS

### **XX.**

By failing to comply with conditions of the operating permit as discussed herein, Respondent has violated Tenn. Comp. R. & Regs. 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.

## RELIEF

### **XXI.**

WHEREFORE, PREMISES CONSIDERED, I, Michelle Walker Owenby, Technical Secretary, under the authority vested in me, hereby ORDER as follows:

1. Respondent is assessed a CIVIL PENALTY in the amount of **\$6,000** for the violation of Division Rules, as discussed herein.

2. Respondent shall pay the assessed CIVIL PENALTY in full as follows: Payments of the civil penalty and/or damages shall be made payable to the "Treasurer, State of Tennessee" and sent to the Division of Fiscal Services - Consolidated Fees Section, Tennessee Department of Environment and Conservation, William R. Snodgrass Tennessee Tower, 312 Rosa L. Parks Avenue, 10th Floor, Nashville, Tennessee 37243. The case numbers, **APC19-0007 and APC19-0074**, should be clearly shown on the check or money order to ensure that the payment is properly credited. Payment shall be made on or before the 31st day after receipt of this ORDER and ASSESSMENT.

The Technical Secretary does not expressly or implicitly waive her authority pursuant to any provision of the Act or Division Rules by issuing this ORDER AND ASSESSMENT OF CIVIL PENALTY. Failure to comply with any of the requirements of this ORDER could lead to further enforcement actions which may include additional civil penalties, assessment of damages and/or recovery of costs.

## NOTICE OF RIGHTS

Tenn. Code Ann. §§ 68-201-108(a) and 68-201-116(b), allow Respondent to appeal this Order and Assessment. To do so, a written petition setting forth the grounds (reasons) for requesting a hearing must be RECEIVED by the Technical Secretary within THIRTY (30) DAYS of the date Respondent received this Order and Assessment or this Order and Assessment becomes final (not subject to review).

If an appeal is filed, an initial hearing of this appeal will be conducted by an Administrative Law Judge (“ALJ”) as a contested case hearing pursuant to the provisions of Tenn. Code Ann. § 68-201-108(a), Tenn. Code Ann. § 4-5-301 *et seq.* (the Uniform Administrative Procedures Act), and Tenn. Comp. R. & Regs. 1360-04-01 *et seq.* (the Department of State’s Uniform Rules of Procedure for Hearing Contested Cases Before State Administrative Agencies). 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 (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.

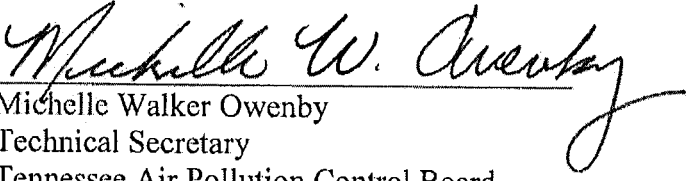
At the conclusion of any initial hearing the ALJ has the authority to affirm, modify, or deny this Order and Assessment. This includes the authority to modify (decrease or increase) the penalty within the statutory confines of Tenn. Code Ann. § 68-201-116 (up to \$25,000 per day per violation). Furthermore, the ALJ 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 ALJ and a court reporter.

Any petition for review (appeal) must be directed to the Technical Secretary, Tennessee Division of Air Pollution Control, c/o Jenny L. Howard, General Counsel, Department of Environment and Conservation, William R. Snodgrass Tennessee Tower, 312 Rosa L. Parks Avenue, 2nd Floor, Nashville, Tennessee 37243. Payments of the civil penalty and/or damages shall be made payable to the “Treasurer, State of Tennessee” and sent to the Division of Fiscal Services - Consolidated Fees Section, Tennessee Department of Environment and Conservation, William R. Snodgrass Tennessee Tower, 312 Rosa L. Parks Avenue, 10th Floor, Nashville,

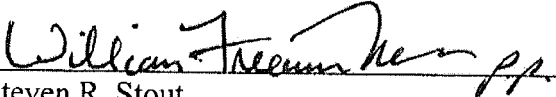


Tennessee 37243. Technical questions and other correspondence involving compliance issues should be sent to Attn: Tammy Gambill, Division of Air Pollution Control, William R. Snodgrass Tennessee Tower, 312 Rosa L. Parks Avenue, 15th Floor, Nashville, Tennessee 37243 or via e-mail to [air.pollution.control@tn.gov](mailto:air.pollution.control@tn.gov). Attorneys should contact the undersigned counsel of record. **The case numbers, APC19-0007 and APC19-0074, should be written on all correspondence regarding this matter.**

Issued by the Technical Secretary, Tennessee Air Pollution Control Board, Department of Environment and Conservation, on this 25<sup>th</sup> day of September, 2019.

  
Michelle Walker Owenby  
Technical Secretary  
Tennessee Air Pollution Control Board

Reviewed by:

  
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