Air Enforcement: Tennessee Air Pollution Control Board Proposed Order/Civil Penalty Addressing Bristol Pharmaceutical Manufacturer

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The Tennessee Air Pollution Control Board ("Board") issued a September 1st proposed Technical Secretary's Order and Assessment of Civil Penalty ("Order") to Gregory Pharmaceutical Holdings, Inc. ("GPHI").

The Order provides that GPHI operates a pharmaceutical manufacturing operation ("Facility") in Bristol, Tennessee.

In 2016 the Facility was issued a Major Source Operating Permit ("Title V Permit").

The Tennessee Division of Air Pollution Control ("Division") is stated to have conducted a compliance inspection at the Facility on January 18th. The inspection is stated to have determined that the October 2022 through January 2023 baghouse pressure drop logs were incomplete or had not been created at the time of the inspection.

The Order further states that the monthly inspection records for the DC-10032 baghouse that controls the source 33 particulate matter emissions were reviewed. Such review is stated to have indicated that no inspection was performed in July of 2022.

The Division is stated to have received a log of the weekly pressure drops that were taken to confirm proper baghouse operation from Facility personnel on February 1st. However, the logs are stated to have been incomplete.

On February 2nd the Division is stated to have requested the complete log of weekly pressure drops that were taken to confirm proper baghouse operation.

Facility personnel on February 7th are stated to have 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.

The Division received on February 10th a copy of the complete logs requested on February 2nd. Such logs were stated to have indicated that pressure drops were not recorded for 11 days of Levoxyl production and for two days of Altace production.

The Division sent a Notice of Violation to GPHI on March 2nd. This document required the Facility to submit an amended Semiannual Report for the period April 1 through September 30, 2022, within 30 days of receipt of the Notice of Violation.

The Division is stated to have received a completed and amended Semiannual Report for the period of April 1 through September 30, 2022, on April 13th from the Facility.

The Order proposes to assess a civil penalty of $3,000.

The proposed Order provides certain appeal rights.

A copy of the proposed Order can be downloaded here.