



Walter Wright, Jr.
wwright@mwlaw.com
(501) 688.8839

Hazardous Waste Enforcement: U.S. Environmental Protection Agency and Bensalem, Pennsylvania, Pharmaceutical Manufacturing Facility Enter into Expedited Settlement Agreement

05/09/2023

The United States Environmental Protection Agency (“EPA”) and Sigmapharm Laboratories LLC (“SLL”) entered into a May 3rd Expedited Settlement Agreement and Final Order (“ESA”) addressing alleged violations of the Resource Conservation and Recovery Act (“RCRA”) hazardous waste regulations. See Docket No.: RCRA-03-2023-0044.

The ESA provides that SLL operates a facility (“Facility”) manufacturing generic pharmaceuticals in Bensalem, Pennsylvania.

The Facility is stated to include an analytical laboratory where final products are tested to ensure they meet specifications.

SLL is stated to have submitted a notification to the Pennsylvania Department of Environmental Protection that the Facility is a large quantity generator of hazardous waste at the Facility. The Facility is stated to not have a RCRA permit or interim status for the treatment, storage, or disposal of hazardous waste.

Stored hazardous waste includes, but is not limited to, solvents and lab packs with EPA Hazardous Waste Numbers listed in the ESA and as the terms “stored” and “hazardous waste” are defined in 40 CFR § 260.10.

EPA is stated to have conducted a Compliance Evaluation Inspection at the Facility on June 7, 2022, to determine compliance with the applicable hazardous waste regulations.

The ESA cites instances in which the Facility failed to meet a condition of the generator exemption found in 40 CFR 262a.10. In addition, the Facility is stated to have failed to maintain a copy of a manifest signed by the designated Facility and provide certain records to demonstrate two employees had received annual refresher training in 2019. The Facility is stated to have failed to include the location of the spill equipment and description of evacuation routes in its contingency plan. Further, the Facility is stated to have failed to manage universal waste as required by 40 CFR § 266b.

The ESA assesses a civil penalty of \$11,250.

A copy of the ESA can be downloaded [here](#).