



EPA REGION 2
CARIBBEAN ENVIRONMENTAL PROTECTION DIVISION

November 20, 2023

SENT VIA EMAIL

Ruben Lugo
EHS Director
TEVA PR LLC
Union Street Road 195 Km. 1.1
Fajardo, PR 00738-1005
Email: Ruben.lugolopez@tevapharm.com

RE: **RCRA § 3008 – NOTICE OF VIOLATION**
TEVA PR LLC
EPA ID: PRD981086960

Dear Mr. Lugo:

The U.S. Environmental Protection Agency (EPA) is charged with the protection of human health and the environment under the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6901 et seq. Pursuant to RCRA, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), EPA promulgated rules, regulations, and standards governing the handling and management of hazardous waste as set forth in 40 Code of Federal Regulations (C.F.R.) Parts 260-272. For the purposes of this Notice of Violation (NOV), the hazardous waste regulations governing the generation of hazardous waste were promulgated in 1980 and amended by HSWA in 1984. The Commonwealth of Puerto Rico is not authorized by the EPA to conduct a hazardous waste program and to enforce RCRA under Section 3006 of RCRA, 42 U.S.C. § 6926.

On July 19, 2023, a duly authorized representative of the EPA conducted a Compliance Evaluation Inspection (CEI) of the TEVA PR LLC Facility located in Fajardo, Puerto Rico, (the "Facility") pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927. As a result of the CEI, EPA representatives found the Facility in violation of 40 CFR §262 Subpart C of the RCRA Regulations.

This Notice of Violation (Enclosure I) is issued pursuant to Section 3008 of the Solid Waste Disposal Act, as amended by RCRA and HSWA, 42 U.S.C. §§ 6901 and 6928. Issuance of this NOV and compliance with its terms does not preclude EPA from taking formal enforcement action against you and/or your company, including a monetary penalty, under Section 3008 of RCRA, 42 U.S.C. § 6928, or any other applicable regulation or statute.

If you have not already done so, you must take immediate action to correct the violation described in Enclosure I. Please submit, within thirty (30) days of the receipt of this letter, a response which includes (1) a description of the actions you have taken to correct the violation noted in Enclosure I, (2) documentation that the violation has been corrected, and (3) a description of the procedures that will be put into place to prevent such violation from occurring in the future. For consistency, please provide your answers in a format which is keyed to the sections as outlined in Enclosure I to this letter.

The response must be mailed to the following address:

Khrystian M. Vazquez, Enforcement Officer
Response and Remediation Branch
U.S. Environmental Protection Agency - Region 2
Caribbean Environmental Protection Division
City View Plaza II, suite 7000
#48 PR-165 km 1.2
Guaynabo, PR 00968-8069

Failure to respond in full to the above requirements may result in federal enforcement action pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, including the assessment of a monetary penalty. If you have any questions regarding this matter, please contact Khrystian M. Vazquez from my staff at 787-977-5860 or via e-mail at vazquez.khrystian@epa.gov

Sincerely,



Carmen R. Guerrero Pérez
Director

Enclosures: Enclosure I - Notice of Violation

cc: Lorna Rodríguez Díaz, RCRA Enforcement Section Chief
Puerto Rico Department of Natural and Environmental Resources

ENCLOSURE I- NOTICE OF VIOLATION

TEVA PR LLC

EPA ID No. PRD901144709

On July 19, 2023, duly authorized representatives of the EPA conducted a Compliance Evaluation Inspection (CEI) of the TEVA PR LLC Facility located in Fajardo, Puerto Rico, (the "Facility") pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927.

As a result of the CEI, EPA representatives found the Facility in violation of the RCRA regulation.

40 CFR §262 Subpart C

§ 262.15 (5. (i) (ii) Satellite accumulation area regulations for small and large quantity generators.

5. A generator must mark or label its container with the following:

(i) The words "Hazardous Waste" and

(ii) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704).

At the time of the inspection the following areas were not compliance with pictogram labels or indication of the hazardous waste characteristic content:

- 90-Days Storage Warehouse
- Wastewater Treatment Plant (SAA)
- Quality Laboratory (SAA) Building 3
- RAW Lab 210.2 Building 2
- RAW Lab (SAA) near SAA- FAJ- L010
- SAA-PK-001- Washroom 2031