



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

ELECTRONIC MAIL
CONFIRMATION OF RECEIPT EMAIL REQUESTED

Cannon Mauldin
Staff Environmental Engineer
Janssen Pharmaceuticals, Inc.
1440 Olympic Drive
Athens, Georgia 30601-1645
Cmauldin@its.jnj.com

SUBJ: Opportunity to Show Cause
Resource Conservation Recovery Act (RCRA) Compliance Evaluation Inspection (CEI)
Janssen Pharmaceuticals, Inc., EPA ID: GAD980726491

Dear Cannon Mauldin:

On April 18, 2023, the U.S. Environmental Protection Agency, along with the Georgia Environmental Protection Division (GAEPD), conducted a RCRA CEI at Janssen Pharmaceuticals, Inc. located in Athens, Georgia to determine the facility's compliance status with RCRA and applicable regulations. This RCRA CEI was an EPA-lead inspection.

The EPA has determined that the facility may not be in compliance with several requirements of the Georgia Hazardous Waste Management Act, Ga. Code Ann. § 12-8-60 et seq. [Subtitle C of RCRA, 42 U.S.C. §§ 6921 to 6939(g)], and the regulations promulgated pursuant thereto, found at Georgia Hazardous Waste Management Rules, Ga. Comp. R. and Regs. 391-3-11.01 to 391-3-11.18 [Title 40 of the Code of Federal Regulations (C.F.R.) Parts 260 through 279] [Title 40 of the Code of Federal Regulations (C.F.R.) Parts 260 through 279] based on potential violations observed during the CEI. The observations made during the inspection are summarized in the attached RCRA CEI Report.

Please provide a detailed written response within fourteen (14) days following receipt of this letter describing any actions that Janssen Pharmaceuticals, Inc. has taken and/or intends to take related to the observations and potential violations documented in the RCRA CEI Report. Your response should be emailed to:

Tarin Tischler
Tischler.Tarin@epa.gov
U.S. Environmental Protection Agency, Region 4
RCRA Enforcement Section
Chemical Safety and Land Enforcement Branch
Enforcement and Compliance Assurance Division

Information currently available to the EPA suggests that Janssen Pharmaceuticals, Inc. may be in violation of, or have committed violations of, RCRA. By this letter, the EPA is extending to you an opportunity to advise the Agency, via a conference call, of any further information the EPA should consider with respect to the potential violations. Janssen Pharmaceuticals, Inc. may elect to be represented by legal counsel at this meeting and should be prepared to present relevant information and documentation pertaining to the EPA's observed potential violations.

The EPA may determine that a formal enforcement action is appropriate and may assess civil penalties pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a). Therefore, Janssen Pharmaceuticals, Inc. has the opportunity to present factors and documentation that could mitigate any penalties that may be assessed against the facility, including information on Janssen Pharmaceuticals, Inc. ability to pay a penalty. Prior to the meeting, Janssen Pharmaceuticals, Inc. may review the following documents:

- **RCRA Civil Penalty Policy** found at: <https://www.epa.gov/sites/default/files/2020-05/documents/june2003rcracivilpenaltypolicyamended050620.pdf>
- **Amendments to EPA's Civil Penalty Policies to Account for Inflation:** https://www.epa.gov/system/files/documents/2022-01/2022amendmentstopenaltypoliciesforinflation_0.pdf, and
- **Inflation Adjustments** found at: <https://www.govinfo.gov/content/pkg/FR-2022-01-12/pdf/2022-00349.pdf>

Please be advised that any information provided by Janssen Pharmaceuticals, Inc. at the meeting may be used by the EPA in any civil or criminal proceedings related to this or other matters. Any false, fictitious, or fraudulent material omissions, statements or representations may subject Janssen Pharmaceuticals, Inc. to criminal penalties under Section 3008(d)(3) of RCRA, 42 U.S.C. § 6928(d)(3).

If Janssen Pharmaceuticals, Inc. chooses to accept this offer to meet with the EPA, the facility should contact Tarin Tischler **within fourteen (14) days** following receipt of this letter to schedule a conference call. Tarin can be reached at (404) 562-9702 or by email at Tischler.Tarin@epa.gov. If you decide not to accept this offer to meet to discuss the observed potential violations, the EPA may proceed with enforcement action against Janssen Pharmaceuticals, Inc. as authorized under Section 3008(a) of RCRA, 42 U.S.C.

§ 6928(a), including the assessment of appropriate civil penalties and injunctive relief.

If Janssen Pharmaceuticals, Inc. is a Small Business or a Small Community, you can find compliance and enforcement resources specifically designed to meet your needs at: <http://www2.epa.gov/enforcement/small-businesses-and-enforcement>. In that webpage you can find information about the Small Business Regulatory Enforcement Fairness Act (SBREFA) that accords some rights to small businesses and is aimed at providing assistance to small businesses and other small entities, making tools available for better understanding of the regulatory and enforcement processes, and seeing that there is no unfair treatment relating to the regulatory enforcement process.

Please feel free to contact Tarin Tischler if you have any technical questions regarding the observations and findings from the inspection performed at Janssen Pharmaceuticals, Inc.'s facility.

Sincerely,

KIMBERLY Digitally signed by
BINGHAM KIMBERLY BINGHAM
Date: 2023.08.08
07:51:28 -04'00'

Kimberly L. Bingham
Chief
Chemical Safety and Land Enforcement Branch

Enclosure

cc: Chuck Mueller, GA EPD (Chuck.Mueller@dnr.ga.gov)
Holly Nelson, GA EPD (holly.nelson1@dnr.ga.gov)
Andrew Matuza, GA EPD (andrew.matuza@dnr.ga.gov)
Sara Porter, GA EPD (Sara.Porter@dnr.ga.gov)