

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4

In the Matter of:

Janssen Pharmaceuticals, Inc.,
1440 Olympic Drive,
Athens, GA 30601,
EPA ID No.: GAD980726491
Respondent.

Docket No. RCRA-04-2024-4003(b)

Proceeding Under Section 3008(a) of the
Resource Conservation and Recovery Act,
42 U.S.C. § 6928(a)

CONSENT AGREEMENT**I. NATURE OF ACTION**

1. This is an administrative penalty assessment proceeding brought under Section 3008(a) of the Resource Conservation and Recovery Act (RCRA or the Act), 42 U.S.C. § 6928(a), and Sections 22.13(b) and 22.18 of the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits* (Consolidated Rules), as codified at Title 40 of the Code of Federal Regulations (C.F.R.), Part 22.
2. This Consent Agreement and the attached Final Order shall collectively be referred to as the CAFO.
3. Having found that settlement is consistent with the provisions and objectives of the Act and applicable regulations, the Parties have agreed to settle this action pursuant to 40 C.F.R. § 22.18 and consent to the entry of this CAFO without Respondent's admission of violation or adjudication of any issues of law or fact herein.

II. PARTIES

4. Complainant is the Chief of the Chemical Safety and Land Enforcement Branch, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency (EPA) Region 4, who has been delegated the authority on behalf of the Administrator of the EPA to enter into this CAFO pursuant to 40 C.F.R. Part 22 and Section 3008(a) of the Act.
5. The Respondent is Janssen Pharmaceuticals, Inc., a corporation doing business in the State of Georgia. This proceeding pertains to the Respondent's facility located at 1440 Olympic Drive, Athens, Georgia 30601 (Facility).

III. GOVERNING LAW

6. Pursuant to Section 3006(b) of RCRA, 42 U.S.C. § 6926(b), the State of Georgia (State) has received final authorization to carry out a hazardous waste program in lieu of the federal program set forth in RCRA. The requirements of the authorized State program are found in the Georgia Hazardous Waste Management Act (GHWMA), Ga. Code Ann. §§ 12-8-60 *et seq.*, and the Georgia Hazardous Waste Management Rules (GHWMR), Ga. Comp. R. and Regs. 391-3-11-.01 to 391-3-11-.18
7. Pursuant to Section 3006(g) of RCRA, 42 U.S.C. § 6926(g), the requirements established by the Hazardous and Solid Waste Amendments of 1984 (HSWA), Pub. L. 98-616, are immediately effective in all states regardless of their authorization status and are implemented by the EPA until a state is granted final authorization with respect to those requirements. The State has received final authorization for certain portions of HSWA, including those recited herein.
8. Although the EPA has granted the State authority to enforce its own hazardous waste program, the EPA retains jurisdiction and authority to initiate an independent enforcement action pursuant to Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2). This authority is exercised by the EPA in the manner set forth in the Memorandum of Agreement between the EPA and the State.
9. As the State's authorized hazardous waste program operates in lieu of the federal RCRA program, the citations for the violations of those authorized provisions alleged herein will be to the authorized State program; however, for ease of reference, the federal citations will follow in brackets.
10. Pursuant to Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2), Complainant has given notice of this action to the State before issuance of this CAFO.
11. Ga. Code Ann. § 12-8-64(1)(A) [Section 3002(a) of RCRA, 42 U.S.C. § 6922(a)], requires the promulgation of standards applicable to generators of hazardous waste. The implementing regulations for these standards are found at Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. Part 262].
12. Ga. Code Ann. § 12-8-66 [Section 3005 of RCRA, 42 U.S.C. § 6925], sets forth the requirement that a facility treating, storing, or disposing of hazardous waste must have a permit or interim status. The implementing regulations for this requirement are found at Ga. Comp. R. and Regs. 391-3-11-.10(2) (permitted) and Ga. Comp. R. and Regs. 391-3-11-.10(1) (interim status) [40 C.F.R. Parts 264 (permitted) and 265 (interim status)].
13. Pursuant to Ga. Comp. R. & Regs. 391-3-11-.07(1) [40 C.F.R. § 261.2], a "solid waste" is any discarded material that is not otherwise excluded from the regulations. A discarded material includes any material that is abandoned by being stored in lieu of being disposed.
14. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. § 261.3], a solid waste is a "hazardous waste" if it meets any of the criteria set forth in Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. § 261.3(a)(2)] and is not otherwise excluded from regulation as a hazardous waste by Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. § 261.4(b)].

15. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. §§ 261.3(a)(2)(i) and 261.20], solid wastes that exhibit any of the characteristics identified in Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. §§ 261.21-24] are characteristic hazardous waste and are provided with the EPA Hazardous Waste Numbers D001 through D043.
16. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. §§ 261.20 and 261.21], a solid waste that exhibits the characteristic of ignitability is a hazardous waste and is identified with the EPA Hazardous Waste Number D001.
17. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. §§ 261.20 and 261.24], a solid waste that exhibits the characteristic of toxicity is a hazardous waste and is identified with the EPA Hazardous Waste Number associated with the toxic contaminant causing it to be hazardous. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. § 261.24], a solid waste that exhibits the characteristic of toxicity for Methyl Ethyl Ketone is identified with the EPA Hazardous Waste Number D035.
18. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. §§ 261.20 and 261.24], a solid waste that exhibits the characteristic of toxicity is a hazardous waste and is identified with the EPA Hazardous Waste Number associated with the toxic contaminant causing it to be hazardous. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. § 261.24], a solid waste that exhibits the characteristic of toxicity for Pyridine is identified with the EPA Hazardous Waste Number D038.
19. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. §§ 261.3(a)(2)(ii) and 261.30], a solid waste is a listed "hazardous waste" if it is listed in Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. Part 261, Subpart D].
20. Listed hazardous wastes include the F-Listed wastes from non-specific sources identified in Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. § 261.31].
21. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. § 261.31], the following spent non-halogenated solvents: Xylene, acetone, ethyl acetate, ethyl benzene, ethyl ether, methyl isobutyl ketone, n-butyl alcohol, cyclohexanone, and methanol; all spent solvent mixtures/blends containing, before use, only the above spent non-halogenated solvents; and all spent solvent mixtures/blends containing, before use, one or more of the above non-halogenated solvents, and, a total of ten percent or more (by volume) of one or more of those solvents listed in F001, F002, F004, and F005; and still bottoms from the recovery of these spent solvents and spent solvent mixtures, are identified with the EPA Hazardous Waste Number F003.
22. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. § 261.31], the following spent non-halogenated solvents: Toluene, methyl ethyl ketone, carbon disulfide, isobutanol, pyridine, benzene, 2-ethoxyethanol, and 2-nitropropane; all spent solvent mixtures/blends containing, before use, a total of ten percent or more (by volume) of one or more of the above non-halogenated solvents or those solvents listed in F001, F002, or F004; and still bottoms from the

recovery of these spent solvents and spent solvent mixtures, are identified with the EPA Hazardous Waste Number F005.

23. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.02 [40 C.F.R. § 260.10], a “generator” is defined as any person, by site, whose act or process produces hazardous waste identified or listed in Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. Part 261], or whose act first causes a hazardous waste to become subject to regulation.
24. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.02 [40 C.F.R. § 260.10], a “facility” includes “all contiguous land, and structures, other appurtenances, and improvements on the land, used for treating, storing, or disposing of hazardous waste.”
25. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.02 [40 C.F.R. § 260.10], a “person” includes a corporation.
26. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.02 [40 C.F.R. § 260.10], an “owner” is “the person who owns a facility or part of a facility” and an “operator” is “the person responsible for the overall operation of a facility.”
27. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.02 [40 C.F.R. § 260.10], a “container” is defined as “any portable device in which a material is stored, transported, treated, disposed of, or otherwise handled.”
28. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.02 [40 C.F.R. § 260.10], “disposal” is defined as “the discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharged into any waters, including ground waters.”
29. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.02 [40 C.F.R. § 260.10], “storage” means the containment or holding of hazardous waste, either on a temporary basis or for a period of years, in such a manner as not to constitute disposal of such hazardous waste.
30. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.02 [40 C.F.R. § 260.10], a “Large Quantity Generator” (LQG) is a generator who generates greater than or equal to 1,000 kilograms (2200 pounds (lbs)) of non-acute hazardous waste in a calendar month.
31. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.02 [40 C.F.R. § 260.10], a “hazardous secondary material” (HSM) is “a secondary material (e.g., spent material, by-product, or sludge) that, when discarded, would be identified as hazardous waste.”
32. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.11], a person who generates a solid waste, as defined in Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. § 261.2], must make an accurate determination as to whether that waste is a hazardous waste.
33. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.15(a)], a generator may accumulate as much as 55 gallons of non-acute hazardous waste in containers at or near the

point of generation where wastes initially accumulate, which is under the control of the operator of the process generating the waste, without a permit or without having interim status, as required by Ga. Code Ann. § 12-8-66 [Section 3005 of RCRA, 42 U.S.C. § 6925], and without complying with Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.17(a)], except as required by Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.15(a)(7) and (8)], provided that the generator complies with the satellite accumulation area (SAA) conditions listed in Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.15(a)] (hereinafter referred to as the “SAA Permit Exemption”).

34. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.15(a)(4)], which is a condition of the SAA Permit Exemption, a generator is required to keep containers of hazardous waste closed at all times during accumulation, except when adding, removing, or consolidating waste; or when temporary venting of a container is necessary for the proper operation of equipment, or to prevent dangerous situations, such as build-up of extreme pressure.
35. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.17], a LQG may accumulate hazardous waste on-site for 90 days or less without a permit or without having interim status, as required by Ga. Code Ann. § 12-8-66 [Section 3005 of RCRA, 42 U.S.C. § 6925], provided that the generator complies with the conditions listed in Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.17] (hereinafter referred to as the “LQG Permit Exemption”).
36. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.17(a)(6)], which incorporates Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.251] and is a condition of the LQG Permit Exemption, a generator is required to maintain and operate its facility to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water which could threaten human health or the environment.
37. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.17(a)(6)], which incorporates Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.261(a) and (f)] and is a condition of the LQG Permit Exemption, a generator must have a contingency plan that describes the actions facility personnel must take in response to fires and includes an evacuation plan for generator personnel where there is a possibility that evacuation could be necessary.
38. Pursuant to Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.17(a)(6)], which incorporates Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.262(b)] and is a condition of the LQG Permit Exemption, a LQG that is amending its contingency plan must at that time submit a quick reference guide (QRG) of the contingency plan to the local emergency responders.

IV. FINDINGS OF FACTS

39. The Respondent’s Facility is located at 1440 Olympic Drive in Athens, Georgia 30601-1645.

40. The Respondent is a manufacturer of ingredients used in pharmaceutical manufacturing facilities.
41. The Respondent generates 1,000 kilograms or more of hazardous waste in a calendar month and is a LQG.
42. The Respondent has notified of its LQG status since May 17, 2016.
43. The Respondent often manages toluene distillate as a HSM.
44. The Respondent generates hazardous waste sludge, which is identified with the EPA Hazardous Waste Numbers F003 and F005, and hazardous waste toluene distillate, which is identified with the EPA Hazardous Waste Numbers D001, D035, D038, F003, and F005, when not managed as a HSM.
45. On April 18, 2023, the EPA and the Georgia Environmental Protection Division (GAEPD) conducted a joint RCRA Compliance Evaluation Inspection (CEI) at the Facility.
46. On August 8, 2023, the EPA emailed the Respondent an Opportunity to Show Cause Letter and a CEI Report documenting its findings from the CEI.
47. At the time of the CEI, the Respondent was attempting to identify a recycler to accept the toluene distillate accumulating in Tank T-80.
48. At the time of the CEI, the Respondent had not made an accurate hazardous waste determination on the toluene distillate in Tank T-80 at the Facility as it believed the material was a HSM.
49. On May 4, 2023, and June 20, 2023, the Respondent shipped the toluene distillate in Tank T-80, identified with the EPA Hazardous Waste Numbers D001, D035, D038, F003, and F005, to Geocycle, LLC and Giant Cement Company for disposal.
50. At the time of the CEI, inspectors observed a four (4) liter container of D001 laboratory waste in the SAA of the Quality Control (QC) Laboratory. The container had a hose inserted into the lid that prevented the lid from closing.
51. At the time of the CEI, inspectors observed a sudden or non-sudden spill of F-listed hazardous waste sludge generated from the rotary fan press on the concrete floor underneath the hopper container inside of Building 3.
52. At the time of the CEI, the Respondent's contingency plan did not include a description of the actions Facility personnel must take in response to fires and did not include an evacuation plan for generator personnel. The description of the actions Facility personnel must take in response to fires and the evacuation plan were in the Emergency Procedures Manual, a document separate to the contingency plan.

53. At the time of the CEI, the Respondent could not demonstrate it had submitted a QRG of the Contingency Plan to local emergency responders after it had amended its contingency plan in 2021.

V. ALLEGED VIOLATIONS

54. The Respondent is a “person,” as defined in Ga. Comp. R. and Regs. 391-3-11-.02 [40 C.F.R. § 260.10].
55. The Respondent is the “owner” and/or “operator” of a “facility” located at 1440 Olympic Drive, Athens, Georgia, as those terms are defined in Ga. Comp. R. and Regs 391-3-11-.02 [40 C.F.R. § 260.10].
56. The Respondent generates wastes that are “solid wastes” as defined in Ga. Comp. R. & Regs. 391-3-11-.07(1) [40 C.F.R. § 261.2].
57. The Respondent is a “generator” of “hazardous waste” as those terms are defined in Ga. Comp. R. and Regs 391-3-11-.02 [40 C.F.R. § 260.10], and Ga. Comp. R. and Regs. 391-3-11-.07(1) [40 C.F.R. § 261.3].
58. The Respondent is a “LQG” of hazardous waste, as that term is defined in Ga. Comp. R. and Regs. 391-3-11-.02 [40 C.F.R. § 260.10].
59. The Respondent failed to make an accurate hazardous waste determination on the toluene distillate in Tank T-80 and as a result, failed to manage the material as hazardous waste during storage at the Facility prior to disposal. The EPA therefore alleges that the Respondent violated Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.11] by failing to make an accurate hazardous waste determination.
60. The Respondent failed to keep a four (4) liter container of hazardous waste closed at all times except when adding or removing waste in the SAA in the QC Laboratory because there was a hose inserted into the lid. The EPA therefore alleges that the Respondent violated Ga. Code Ann. § 12-8-66 [Section 3005 of RCRA, 42 U.S.C. § 6925], by storing hazardous waste without a permit or interim status, because the Respondent failed to keep containers of hazardous waste closed at all times during accumulation, except when adding, removing, or consolidating waste, as required by Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.15(a)(4)], which is a condition of the SAA Permit Exemption.
61. The Respondent failed to address the sudden or non-sudden spill of F-listed hazardous waste sludge underneath the hopper container inside Building 3. The EPA therefore alleges that the Respondent violated Ga. Code Ann. § 12-8-66 [Section 3005 of RCRA, 42 U.S.C. § 6925], by storing hazardous waste without a permit or interim status, because the Respondent failed to comply with a condition of the LQG Permit Exemption set forth in Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.17(a)(6)], by not complying with the operation and maintenance requirements in Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.251].

62. The Respondent failed to include, within the Facility's contingency plan, the emergency procedures in response to a fire or evacuation routes. The EPA therefore alleges that the Respondent violated Ga. Code Ann. § 12-8-66 [Section 3005 of RCRA, 42 U.S.C. § 6925], by storing hazardous waste without a permit or interim status, because the Respondent failed to comply with a condition of the LQG Permit Exemption set forth in Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.17(a)(6)], by not complying with the contingency plan requirements in Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.261(a) and (f)].
63. The Respondent failed to develop and submit a QRG to local emergency responders. The EPA therefore alleges that the Respondent violated Ga. Code Ann. § 12-8-66 [Section 3005 of RCRA, 42 U.S.C. § 6925] by storing hazardous waste without a permit or interim status, because the Respondent failed to comply with a condition of the LQG Permit Exemption set forth in Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.17(a)(6)], by failing to develop and submit a QRG to local emergency responders after amending its contingency plan in 2021, as required by Ga. Comp. R. and Regs. 391-3-11-.08(1) [40 C.F.R. § 262.262(b)].

VI. STIPULATIONS

64. The issuance of this CAFO simultaneously commences and concludes this proceeding. 40 C.F.R. § 22.13(b).
65. For the purpose of this proceeding, as required by 40 C.F.R. § 22.18(b)(2), the Respondent:
- a. admits that the EPA has jurisdiction over the subject matter alleged in this CAFO;
 - b. neither admits nor denies the factual allegations set forth in Section IV (Findings of Facts) of this CAFO;
 - c. consents to the assessment of a civil penalty as stated below;
 - d. consents to the conditions specified in this CAFO;
 - e. waives any right to contest the allegations set forth in Section V (Alleged Violations) of this CAFO; and
 - f. waives its rights to appeal the Final Order accompanying this CAFO.
66. For the purpose of this proceeding, the Respondent:
- a. agrees that this CAFO states a claim upon which relief may be granted against the Respondent;
 - b. acknowledges that this CAFO constitutes an enforcement action for purposes of considering the Respondent's compliance history in any subsequent enforcement actions;

- c. waives any and all remedies, claims for relief, and otherwise available rights to judicial or administrative review that the Respondent may have with respect to any issue of fact or law set forth in this CAFO, including any right of judicial review under Chapter 7 of the Administrative Procedure Act, 5 U.S.C. §§ 701-706;
 - d. waives any rights it may possess at law or in equity to challenge the authority of the EPA to bring a civil action in a United States District Court to compel compliance with the CAFO, and to seek an additional penalty for such noncompliance, and agrees that federal law shall govern in any such civil action;
 - e. waives any right it may have pursuant to 40 C.F.R. § 22.8 to be present during any discussions with, or to be served with and reply to, any memorandum or communication addressed to EPA officials where the purpose of such discussion, memorandum, or communication is to persuade such official to accept and issue this CAFO; and
 - f. agrees to comply with the terms of this CAFO.
67. By executing this CAFO, the Respondent certifies to the best of its knowledge that the Respondent is currently in compliance with all relevant requirements of the authorized State program found in the GHWMA and the GHWMR, and the Act and its implementing regulations, and that all violations alleged herein, which are neither admitted nor denied, have been corrected.
68. In accordance with 40 C.F.R. § 22.5, the individuals named in the Certificate of Service are authorized to receive service related to this proceeding and the Parties agree to receive service by electronic means.

VII. TERMS OF PAYMENT

69. Respondent consents to the payment of a civil penalty, which was calculated in accordance with the Act, in the amount of **THIRTY-THOUSAND FOUR HUNDRED DOLLARS (\$30,400)**, which is to be paid within 30 days of the Effective Date of this CAFO.
70. Payment(s) shall be made by cashier's check, certified check, by electronic funds transfer (EFT), or by Automated Clearing House (ACH) (also known as REX or remittance express). If paying by check, the check shall be payable to: Treasurer, United States of America, and the Facility name and docket number for this matter shall be referenced on the face of the check.
- a. If the Respondent sends payment by standard U.S. Postal Service delivery, the payment shall be addressed to:

U.S. Environmental Protection Agency
P.O. Box 979078
St. Louis, MO 63197-9000

- b. If the Respondent sends payment by non-U.S. Postal express mail delivery, the payment shall be sent to:

U.S. Environmental Protection Agency
Government Lockbox 979078
3180 Rider Trail S.
Earth City, MO 63045

- c. If paying by EFT, the Respondent shall transfer the payment to:

Federal Reserve Bank of New York
ABA: 021030004
Account Number: 68010727
SWIFT address: FRNYUS33
33 Liberty Street
New York, NY 10045
Beneficiary: Environmental Protection Agency

- d. If paying by ACH, the Respondent shall remit payment to:

US Treasury REX / Cashlink ACH Receiver
ABA: 051036706
Account Number: 310006, Environmental Protection Agency
CTX Format Transaction Code 22 – checking
Physical location of US Treasury facility:
5700 Rivertech Court
Riverdale, MD 20737
Remittance Express (REX): 1-866-234-5681

71. The Respondent shall send proof of payment, within 24 hours of payment of the civil penalty, to:

Regional Hearing Clerk
R4_Regional_Hearing_Clerk@epa.gov

and

Tarin Tischler
Chemical Safety and Land Enforcement Branch
Enforcement and Compliance Assurance Division
tischler.tarin@epa.gov

72. "Proof of payment" means, as applicable, a copy of the check, confirmation of credit card or debit card payment, confirmation of wire or automated clearinghouse transfer, and any other information required to demonstrate that payment has been made according to EPA

requirements, in the amount due, and identified with the Facility name and Docket No. RCRA-04-2024-4003(b).

73. Pursuant to 31 U.S.C. § 3717, 31 C.F.R. § 901.9, and 40 C.F.R. § 13.11, if the Respondent fails to remit the civil penalty as agreed to herein, the EPA is entitled to assess interest and penalties on debts owed to the United States and a charge to cover the costs of processing and handling the delinquent claim. Accordingly, the EPA may require the Respondent to pay the following amounts on any amount overdue:

- a. Interest. Interest will begin to accrue on the civil penalty from the Effective Date of this CAFO. If the civil penalty is paid within 30 days of the Effective Date of this CAFO, interest is waived. However, if the civil penalty is not paid in full within 30 days, interest will continue to accrue on any unpaid portion until the unpaid portion of the civil penalty and accrued interest are paid. Interest will be assessed at the rate of the United States Treasury tax and loan rate, as established by the Secretary of the Treasury, in accordance with 31 U.S.C. § 3717(a)(1), 31 C.F.R. § 901.9(b)(2), and 40 C.F.R. § 13.11(a).
- b. Non-Payment Penalty. On any portion of a civil penalty or a stipulated penalty more than 90 days past due, the Respondent must pay a non-payment penalty of not more than six percent (6%) per annum, which will accrue from the date the penalty payment became due and is not paid, as provided in 31 U.S.C. § 3717(e)(2) and 31 C.F.R. § 901.9(d). This non-payment penalty is in addition to charges which accrue or may accrue under subparagraphs (a) and (c) and will be assessed monthly. 40 C.F.R. § 13.11(c).
- c. Monthly Handling Charge. The Respondent must pay a late payment handling charge to cover the administrative costs of processing and handling the delinquent claim, based on either actual or average cost incurred. 31 C.F.R. § 901.9(c) and 40 C.F.R. § 13.11(b). Administrative costs will be assessed monthly throughout the period the debt is overdue except as provided by 40 C.F.R. § 13.12.

74. In addition to what is stated in the prior Paragraph, if the Respondent fails to timely pay any portion of the penalty assessed under this CAFO, the EPA may:

- a. refer the debt to a credit reporting agency or a collection agency (*see* 40 C.F.R. §§ 13.13 and 13.14);
- b. collect the debt by administrative offset (i.e., the withholding of money payable by the United States to, or held by the United States for, a person to satisfy the debt the person owes the Government), which includes, but is not limited to, referral to the Internal Revenue Service for offset against income tax refunds (*see* 40 C.F.R. Part 13, Subparts C and H);
- c. suspend or revoke the Respondent's licenses or other privileges, or suspend or disqualify the Respondent from doing business with the EPA or engaging in programs the EPA sponsors or funds (*see* 40 C.F.R. § 13.17); and/or

- d. refer the debt to the Department of Justice as provided in 40 C.F.R. § 13.33. In any such judicial action, the validity, amount, and appropriateness of the penalty and of this CAFO shall not be subject to review.

75. Penalties paid pursuant to this CAFO shall not be deductible for purposes of federal taxes.

VIII. EFFECT OF CAFO

76. In accordance with 40 C.F.R. § 22.18(c), the Respondent's full compliance with this CAFO shall only resolve the Respondent's liability for federal civil penalties for the violations and facts specifically alleged above.
77. Full payment of the civil penalty, as provided in Section VII (Terms of Payment) shall satisfy the requirements of this CAFO; but, shall not in any case affect the right of the EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law. 40 C.F.R. § 22.18(c).
78. Any violation of this CAFO may result in a civil penalty for each day of continued noncompliance with the CAFO and/or the suspension or revocation of any federal or state permit issued to the violator, as provided in Section 3008(c) of the Act, 42 U.S.C § 6928(c).
79. Nothing in this CAFO shall relieve the Respondent of the duty to comply with all applicable provisions of the Act and other federal, state, or local laws or statutes, nor shall it restrict the EPA's authority to seek compliance with any applicable laws or regulations, nor shall it be construed to be a ruling on, or determination of, any issue related to any federal, state, or local permit, except as expressly provided herein.
80. Nothing herein shall be construed to limit the power of the EPA to undertake any action against the Respondent or any person in response to conditions that may present an imminent and substantial endangerment as provided under the Act.
81. The terms, conditions, and compliance requirements of this CAFO may not be modified or amended except upon the written agreement of both Parties, and approval of the Regional Judicial Officer.
82. The provisions of this CAFO shall apply to and be binding upon the Respondent and its successors and assigns. The Respondent shall direct its officers, directors, employees, agents, trustees, and authorized representatives to comply with the provisions of this CAFO, as appropriate.
83. Any change in the legal status of the Respondent, or change in ownership, partnership, corporate or legal status relating to the Facility, will not in any way alter the Respondent's obligations and responsibilities under this CAFO.
84. By signing this Consent Agreement, the Respondent acknowledges that this CAFO will be available to the public and agrees that this CAFO does not contain any confidential business information or personally identifiable information.

85. By signing this Consent Agreement, the Complainant and the undersigned representative of the Respondent each certify that one is fully authorized to execute and enter into the terms and conditions of this CAFO and has the legal capacity to bind the party one represents to this CAFO.
86. By signing this Consent Agreement, both Parties agree that each party's obligations under this CAFO constitute sufficient consideration for the other party's obligations.
87. By signing this Consent Agreement, the Respondent certifies that the information it has supplied concerning this matter was at the time of submission, and continues to be, true, accurate, and complete for each such submission, response, and statement. The Respondent acknowledges that there are significant penalties for submitting false or misleading information, including the possibility of fines and imprisonment for knowing submission of such information, under 18 U.S.C. § 1001.
88. The EPA also reserves the right to revoke this CAFO and settlement penalty if and to the extent that the EPA finds, after signing this CAFO, that any information provided by the Respondent was materially false or inaccurate at the time such information was provided to the EPA. If such false or inaccurate material was provided, the EPA reserves the right to assess and collect any and all civil penalties for any violation described herein. The EPA shall give Respondent notice of its intent to revoke, which shall not be effective until received by Respondent in writing.
89. Unless specifically stated otherwise in this CAFO, each party shall bear its own attorney's fees, costs, and disbursements incurred in this proceeding.
90. It is the intent of the Parties that the provisions of this CAFO are severable. If any provision or authority of this CAFO or the application of this CAFO to any party or circumstances is held by any judicial or administrative authority to be invalid or unenforceable, the application of such provisions to other parties or circumstances and the remainder of the CAFO shall remain in force and shall not be affected thereby.

IX. EFFECTIVE DATE

91. This CAFO shall become effective after execution of the Final Order by the Regional Judicial Officer, on the date of filing with the Regional Hearing Clerk.

[Remainder of Page Intentionally Left Blank

Complainant and Respondent will Each Sign on Separate Pages.]

The foregoing Consent Agreement In the Matter of Janssen Pharmaceuticals, Inc., Docket No. RCRA-04-2024-4003(b), is Hereby Stipulated, Agreed, and Approved for Entry.

FOR RESPONDENT:

Janssen Pharmaceuticals, Inc., a Pennsylvania corporation

By: *Jeff Thompson* *08/14/2024*
Signature Date

Printed Name: *Jeff Thompson*

Title: *General Manager*

Address: *1440 Olympic Dr. Athens, GA 30601*

The foregoing Consent Agreement In the Matter of Janssen Pharmaceuticals, Inc., Docket No. RCRA-04-2024-4003(b), is Hereby Stipulated, Agreed, and Approved for Entry.

FOR COMPLAINANT:

Araceli B. Chavez, Acting Chief
Chemical Safety and Land Enforcement Branch
Enforcement and Compliance Assurance Division
U.S. Environmental Protection Agency, Region 4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4

In the Matter of:

Janssen Pharmaceuticals, Inc.
1440 Olympic Drive Athens, GA 30601
EPA ID No.: GAD980726491

Respondent.

Docket No. RCRA-04-2024-4003(b)

Proceeding Under Section 3008(a) of the
Resource Conservation and Recovery Act,
42 U.S.C. § 6928(a)

The Regional Judicial Officer is authorized to ratify this Consent Agreement which memorializes a settlement between Complainant and Respondent. 40 C.F.R. §§ 22.4(b) and 22.18(b)(3). The foregoing Consent Agreement is, therefore, hereby approved, ratified, and incorporated by reference into this Final Order in accordance with the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits*, 40 C.F.R. Part 22.

The Respondent is hereby ORDERED to comply with all of the terms of the foregoing Consent Agreement effective immediately upon filing of this Consent Agreement and Final Order with the Regional Hearing Clerk. This Final Order disposes of this matter pursuant to 40 C.F.R. §§ 22.18 and 22.31.

BEING AGREED, IT IS SO ORDERED.

Regional Judicial Officer

CERTIFICATE OF SERVICE

I certify that the foregoing Consent Agreement and Final Order, In the Matter of Janssen Pharmaceuticals, Inc., Docket No. RCRA-04-2024-4003(b), was filed and copies of the same were emailed to the parties as indicated below.

Via email to all Parties at the following email addresses:

To Respondent: Cristina Stummer
Attorney
Johnson & Johnson
cstummer@its.jnj.com
(732) 524-0400

To EPA: Tarin Tischler
Life Scientist
tischler.tarin@epa.gov
(404) 562-9702

Ximena Vasquez
Attorney
vasquez.maria-ximena@epa.gov
(404) 562-9548

Shannon L. Richardson, Regional Hearing Clerk
R4_Regional_Hearing_Clerk@epa.gov