

**BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 3
Philadelphia, Pennsylvania 19103**

FILED

Apr 21, 2025

1:44 pm

**U.S. EPA REGION 3
HEARING CLERK**

IN THE MATTER OF:

**Frontida BioPharm, LLC
7722 Dungan Road
Philadelphia, PA 19111**

Respondent,

**Frontida BioPharm, LLC
7722 Dungan Road
Philadelphia, PA 19111,**

Facility

) **DOCKET NO.: RCRA-03-2025-0065**
)
)
)
) **EXPEDITED SETTLEMENT AGREEMENT AND**
) **FINAL ORDER**
)
) **Proceeding under Section**
) **3008(a) and (g) of the Resource**
) **Conservation and Recovery Act, as**
) **amended, 42 U.S.C. § 6928(a) and (g)**
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EXPEDITED SETTLEMENT AGREEMENT

1. Frontida BioPharm, LLC ("Respondent"), and the Director, Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency, Region 3 ("Complainant") enter into this Expedited Settlement Agreement ("Agreement") pursuant to Section 3008(a) and (g) of the Resource Conservation and Recovery Act ("RCRA"), as amended, 42 U.S.C. § 6928(a) and (g), and the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits* ("Consolidated Rules of Practice"), 40 C.F.R. Part 22 (with specific reference to 40 C.F.R. §§ 22.13(b), 22.18(b)(2), and (3)). The Administrator has delegated the authority to enter into this Agreement to the Regional Administrator who, in turn, has delegated it to the Complainant.
2. The U.S. Environmental Protection Agency, Region 3 ("EPA") has jurisdiction over this matter pursuant to Section 3008(g) of RCRA, 42 U.S.C. § 6928(g), and 40 C.F.R. §§ 22.1(a)(4) and 22.4 of the Consolidated Rules of Practice.
3. Pursuant to Section 3006(b) of RCRA, 42 U.S.C. § 6926(b), EPA has authorized Pennsylvania to administer a hazardous waste management program in lieu of the federal hazardous waste management program established under RCRA Subtitle C, 42 U.S.C. §§ 6921-6939g. The provisions of the current authorized Pennsylvania Hazardous Waste Management Regulations ("PaHWMR") codified at 25 Pa. Code Ch. 260a-266a, 266b, and 268a-270a, have thereby become requirements of RCRA Subtitle C and are enforceable by EPA pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a). EPA last authorized revisions to the PaHWMR on June 29, 2009, including incorporation by reference of the federal

regulations which were in effect as of October 12, 2005. The Code of Federal Regulation citations used herein are to the 2005 Federal regulations in place as of October 12, 2005, when referring to the Federal regulations incorporated by the Pennsylvania regulations.

4. On October 24, 2024, EPA sent a letter to Pennsylvania, through the Pennsylvania Department of Environmental Protection (“PADEP”), giving prior notice of this enforcement action in accordance with Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2).
5. At its facility, located at 7722 Dungan Road, Philadelphia, PA 19111 (“Facility”), Respondent is a contract packager of prescription pharmaceutical solids. On September 28, 1989, Respondent submitted a notification to PADEP that the Facility was a small quantity generator (“SQG”) of hazardous waste (“HW”) at the Facility, and PADEP assigned RCRA ID No. PAD002277150 to the Facility. Respondent does not have a permit for the treatment, storage or disposal of hazardous waste at the Facility.
6. Complainant alleges that, at all times relevant to the allegations described in this Agreement, Respondent was and continues to be a corporation and is therefore a “person,” as defined in Section 1004(15) of RCRA, 42 U.S.C. § 6903(15), and PaHWMR, and at all times relevant to the allegations in this Agreement was the “operator” and the “owner” of a “facility,” described in Paragraph 5, as the terms “facility”, “owner” and “operator” are defined in 40 C.F.R. § 260.10, as incorporated by reference in 25 Pa. Code § 260a.10.
7. At all times relevant to the allegations described in this Agreement, Respondent “stored” “hazardous waste” at the Facility including, but not limited to Rejected Powders Waste, Waste Aerosol Cans, Waste Lamps, Waste Batteries, and Isopropyl Alcohol (“IPA”)-Contaminated Wipes with EPA HW numbers D001, D002, and F003 at the Facility, as the terms “stored” and “hazardous waste” are defined in 40 C.F.R. § 260.10, as incorporated by reference in 25 Pa. Code § 260a.10.
8. On March 1, 2023, EPA representatives conducted a Compliance Evaluation Inspection at the Facility to determine compliance with the applicable hazardous waste regulations. On September 1, 2023, Respondent provided a response to EPA’s Inspection.
9. Based on the observations made during the Inspection, Complainant alleges and finds that Respondent failed to comply with specific requirements of Subtitle C of RCRA, 42 U.S.C. §§ 6921 et seq., its implementing regulations at 40 C.F.R. Parts 262, 264, 265, and the federally-authorized Pennsylvania hazardous waste management regulations set forth in the Pennsylvania Hazardous Waste Management Regulations (“PaHWR”), 25 Pa. Code Ch. 260a-266a, 266b, and 268a-270a.
10. Complainant has identified the following violations at the Facility:
 - a. Respondent violated 42 U.S.C. § 6925(a) and 25 Pa. Code § 270a.1, which

incorporates by reference 40 C.F.R. § 270.1(b), by operating a hazardous waste storage facility without a permit.

(1) On March 1, 2023, Respondent operated the Facility without a permit by accepting HW from its Orthodox facility, which is a Large Quantity Generator ("LQG") of HW. Consolidation of HW by mutually owned facilities is only allowable, with certain exceptions and requirements, by Very Small Quantity Generators to LQGs. Respondent is an SQG that accepted and stored HW from an LQG without a permit.

Additionally, the following act or omission prevented Respondent from meeting the regulatory permit exemption conditions set forth at 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(d)(2) and 40 C.F.R. § 265.174.

(2) From March 1, 2020 to at least March 1, 2023, Respondent failed to conduct weekly inspections of its HW accumulation area as required by 25 Pa. Code § 262a.10

b. On March 1, 2023, Respondent failed to make waste determinations in violation of 25 Pa. Code § 262a.10 which incorporates by reference 40 C.F.R. § 262.11, which requires a waste determination be made at the point of generation, on the following waste streams:

i. Reject Cage Material – Facility representatives stated that rejected material is accumulated in the Reject Cage for an unspecified period of time before a HW determination is made. The Inspector observed approximately 200 rejected material containers in the Reject Cage at the time of the Inspection for which a HW determination had not been made.

ii. Waste Aerosol Cans – the Inspector observed in-use aerosol cans at the Facility at the time of the Inspection. The Facility representatives indicated they were unsure how waste aerosol cans are managed by the Facility and unsure how previously generated waste aerosol cans had been disposed.

iii. IPA-contaminated Wipes – At the time of the Inspection, Facility representatives stated that IPA-contaminated wipes are disposed as nonhazardous waste and did not provide any HW determination documentation for the waste stream.

c. On July 2, 2023, Respondent failed to file an exception report in violation of 25 Pa Code § 262a.10, which incorporates by reference 40. C.F.R. § 262.42(a)(2). Respondent sent one (1) manifest (Manifest #024947115JJK) to EPA via email on September 1, 2023. The manifest documented a shipment of D001 HW on May 17, 2023 and was observed to not be signed by the designated facility. There is no

record of an exception report being filed after 45 days had passed from the time of shipment.

- d. From March 1, 2020 to at least March 1, 2023, Respondent failed to document HW shipments on Uniform Hazardous Waste Manifests in violation of 25 Pa Code § 262a.10 which incorporates by reference 40 C.F.R. § 262.20(a)(1). Facility representatives stated that during this time period, HW was shipped from the Facility to the Respondent's Orthodox facility without documentation on HW manifests.
 - e. On March 1, 2023, Respondent failed to manage universal waste ("UW") lamps and UW batteries according to the regulations in violation of 25 Pa. Code § 266b in the following ways:
 - i. At the time of the Inspection, the Inspector observed six (6) open containers of UW lamps in violation of 25 Pa. Code § 266b, which incorporates by reference 40 C.F.R. § 273.13(d)(1).
 - ii. At the time of the Inspection, the Inspector observed six (6) unlabeled containers of UW lamps in violation of 25 Pa. Code § 266b, which incorporates by reference 40 C.F.R. § 273.14(e).
 - iii. At the time of the Inspection, the Inspector observed six (6) containers of UW lamps and two (2) containers of UW batteries that were not marked with start accumulation dates and the Facility did not have another method to track accumulation time, in violation of 25 Pa. Code § 266b, which incorporates by reference 40 C.F.R. § 273.15(c).
 - iv. At the time of the Inspection, the Inspector observed two (2) unlabeled containers of UW batteries in violation of 25 Pa. Code § 266b, which incorporates by reference 40 C.F.R. § 273.14(a).
11. Complainant and Respondent agree that settlement of this matter for a total penalty of **THIRTEEN THOUSAND SEVEN HUNDRED AND FIFTY DOLLARS (\$13,750.00)** is in the public interest. In calculating this amount, Complainant considered the statutory factors set forth in Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), and with specific reference to EPA's October 1990 RCRA Civil Penalty Policy, as revised in June 2003 ("RCRA Penalty Policy"), and the 2021 RCRA Expedited Settlement Agreement Pilot.
12. Respondent agrees that, within 30 days of the effective date of this Agreement, Respondent shall make a payment of **THIRTEEN THOUSAND SEVEN HUNDRED AND FIFTY DOLLARS (\$13,750.00)** to "United States Treasury" with the case name, address and docket number of this Agreement (RCRA-03-2025-0065), for the amount specified above. Respondent shall pay the assessed penalty and any interest, fees, and other charges due

using any method, or combination of appropriate methods, as provided on the EPA website: <https://www.epa.gov/financial/makepayment>. For additional instructions see: <https://www.epa.gov/financial/additional-instructions-making-payments-epa>.

13. Within 24 hours of payment, Respondent shall also send proof of payment (a copy of the check, confirmation of credit card or debit card payment, confirmation of wire or automated clearinghouse transfer), by electronic mail to:

Rebecca Serfass, Sr. Inspector / Enforcement Officer (3ED22)
U.S. EPA, Region 3
Serfass.Rebecca@epa.gov

and

Regional Hearing Clerk (3RC00)
U.S. EPA, Region 3
R3_Hearing_Clerk@epa.gov

14. In signing this Agreement, Respondent: admits the jurisdictional allegations in this Agreement; neither admits nor denies the specific factual allegations in this Agreement, except as provided in the jurisdictional admission above; agrees not to contest EPA's jurisdiction with respect to the execution of this Agreement, the issuance of the attached Final Order, or the enforcement the Agreement; expressly waives its right to a hearing on any issue of law or fact in this Agreement and any right to appeal the accompanying Final Order; consents to the issuance of the Agreement and agrees to comply with its terms; agrees to bear its own costs and attorney's fees; and agrees not to deduct for federal tax purposes the civil penalty assessed in this Consent Agreement and Final Order.
15. By its signature below, Respondent certifies, subject to civil and criminal penalties for making a false submission to the United States Government, that (1) the alleged violations have been corrected, and (2) any documentation or information provided to EPA was true and accurate.
16. This Agreement and the attached Final Order constitute a settlement by EPA of its claims for civil penalties for the violations alleged in this Agreement.
17. By signing this Agreement, Respondent waives any rights or defenses that Respondent has or may have for this matter to be resolved in federal court, including but not limited to any right to a jury trial, and waives any right to challenge the lawfulness of the final order accompanying the Agreement.
18. EPA reserves the right to commence action against any person, including Respondent, in response to any condition which EPA determines may present an imminent and substantial endangerment to the public health, public welfare, or the environment. In addition, this

settlement is subject to all limitations on the scope of resolution and to the reservation of rights set forth in Sections 22.18(c) and 22.31(a) of the Consolidated Rules of Practice. Further, EPA reserves any rights and remedies available to it under the RCRA, the RCRA regulations promulgated, and any other federal laws or regulations for which EPA has jurisdiction, to enforce the provisions of this Agreement, following its filing with the Regional Hearing Clerk.

19. Late payment of the agreed upon penalty may subject Respondent to interest, administrative costs and late payment penalties in accordance with 40 C.F.R. § 13.11.
20. This Agreement is effective upon filing, in accordance with 40 C.F.R. § 22.31(b).
21. The undersigned representative certifies that she/he is fully authorized to execute this Agreement and to legally bind Frontida BioPharm, LLC.
22. As permitted under 40 CFR § 22.6, the Regional Hearing Clerk will serve copies of this Agreement and Final Order by e-mail to the parties at the following valid e-mail addresses: Serfass.Rebecca@epa.gov (for Complainant), and Joseph.Jefferson@adareps.com (for Respondent).
23. By signing this Agreement, Respondent acknowledges that this Agreement and Final Order will be available to the public and represents that, to the best of Respondent's knowledge and belief, this Agreement and Final Order does not contain any confidential business information or personally identifiable information from Respondent.

For Respondent: Frontida BioPharm, LLC

Date: _____

By: _____

Joseph Jefferson

Electronically signed by: Joseph
Jefferson
Reason: I approve this document
Date: Apr 15, 2025 17:04 EDT

Joseph Jefferson
Sr. Director Packaging Operations

For Complainant: U.S. Environmental Protection Agency, Region 3

After reviewing the Agreement and other pertinent matters, I, the undersigned Director of the Enforcement and Compliance Assurance Division of the United States Environmental Protection Agency, Region 3, agree to the terms and conditions of this Agreement and recommend that the Regional Administrator, or his/her designee, the Regional Judicial Officer, issue the attached Final Order.

[Digital Signature and Date]

Karen Melvin, Director

Enforcement and Compliance Assurance Division

BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 3
Philadelphia, Pennsylvania 19103

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IN THE MATTER OF:

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DOCKET NO.: RCRA-03-2025-0065

EXPEDITED SETTLEMENT AGREEMENT AND
FINAL ORDER

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

FINAL ORDER

Complainant, the Director of the Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency - Region III, and Respondent, Frontida BioPharm, LLC, have executed a document entitled "Expedited Settlement Agreement," which I hereby ratify as a Consent Agreement in accordance with the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits* ("Consolidated Rules of Practice"), 40 C.F.R. Part 22, (with specific reference to Sections 22.13(b) and 22.18(b)(2) and (3)). The terms of the foregoing Expedited Settlement Agreement are accepted by the undersigned and incorporated herein as if set forth at length.

Based upon the representations of the parties in the attached Expedited Settlement Agreement, the penalty agreed to therein took into account the statutory factors set forth in Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), and with specific reference to EPA's October 1990 RCRA Civil Penalty Policy, as revised in June 2003 ("RCRA Penalty Policy"), and the 2021 RCRA Expedited Settlement Agreement Pilot.

NOW, THEREFORE, PURSUANT TO 3008(g) of the Resource Conservation and Recovery Act ("RCRA"), as amended, 42 U.S.C. Section 6991e, and Section 22.18(b)(3) of the Consolidated Rules of Practice, **IT IS HEREBY ORDERED** that Respondent pay a civil penalty in the amount of **THIRTEEN THOUSAND SEVEN HUNDRED AND FIFTY DOLLARS (\$13,750.00)**, in accordance with the payment provisions set forth in the Expedited Settlement Agreement, and comply with the terms and conditions of the Consent Agreement.

This Final Order constitutes the final Agency action in this proceeding. This Final Order shall not in any case affect the right of the Agency or the United States to pursue appropriate

injunctive or other equitable relief, or criminal sanctions for any violations of the law. This Final Order resolves only those causes of action alleged in the Expedited Settlement Agreement and does not waive, extinguish or otherwise affect Respondent's obligation to comply with all applicable provisions of Subtitle C of the Resource Conservation and Recovery Act, 42 U.S.C. §§ 6921 et seq., and the regulations promulgated thereunder.

The effective date of the foregoing Expedited Settlement Agreement and this Final Order is the date on which this Final Order is filed with the Regional Hearing Clerk.

[Digital Signature and Date]

Joseph J. Lisa

Regional Judicial Officer

U.S. EPA - Region 3

IN THE MATTER OF:)	DOCKET NO.: RCRA-03-2025-0065
)	
Frontida BioPharm, LLC)	
7722 Dungan Road)	
Philadelphia, PA 19111)	EXPEDITED SETTLEMENT AGREEMENT AND
)	FINAL ORDER
Respondent,)	
)	
)	Proceeding under Section
)	3008(a) and (g) of the Resource
Frontida BioPharm, LLC)	Conservation and Recovery Act, as
7722 Dungan Road)	amended, 42 U.S.C. § 6928(a) and (g)
Philadelphia, PA 19111,)	
)	
Facility)	

I certify that the foregoing ***Expedited Settlement Agreement and Final Order*** was filed with the EPA Region 3 Regional Hearing Clerk on the date that has been electronically stamped on the ***Expedited Settlement Agreement and Final Order***. I further certify that on the date set forth below, I caused to be served a true and correct copy of the foregoing to each of the following persons, in the manner specified below, at the following addresses:

Joseph Jefferson, Sr. Director Packaging Operations
Frontida BioPharm, LLC
Joseph.jefferson@adareps.com
7722 Dungan Road
Philadelphia, PA 19111

Rebecca Serfass
Sr. Inspector / Enforcement Officer
U.S. EPA, Region 3
Serfass.Rebecca@epa.gov

[Digital Signature and Date]

Regional Hearing Clerk

U.S. Environmental Protection Agency, Region 3

