

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION 2

IN THE MATTER OF:)	Docket No. RCRA-02-2024-7201
)	
)	
Neolpharma, Inc.)	
99 Jardines Street)	
Caguas, Puerto Rico, 00725)	
EPA ID. No. PRD090378225)	EXPEDITED SETTLEMENT AGREEMENT
)	AND
)	FINAL ORDER
Respondent)	
_____)	

EXPEDITED SETTLEMENT AGREEMENT

1. The United States Environmental Protection Agency (“EPA”) is authorized to enter into this Expedited Settlement Agreement (herein alternatively referred to as “the Agreement”) pursuant to Section 3008 of the Resource Conservation and Recovery Act (“RCRA”) and 40 C.F.R. § 22.13(b).
2. By copy of this letter, EPA is providing the Commonwealth of Puerto Rico Department of Natural and Environmental Resources with notice of the referenced violations of Subtitle C of RCRA.
3. Neolpharma, Inc. (“Respondent”) is the owner or operator of the facility located at 99 Jardines Street in Caguas, Puerto Rico (“Facility”). EPA conducted a RCRA Compliance Evaluation Inspection on or about August 9, 2023. EPA alleges that Respondent violated the following requirements of the RCRA hazardous waste management program.
 - a. 40 C.F.R. § Part 262.215(a)(4) which requires a container holding hazardous waste to be closed at all times during accumulation, except: when adding, removing, or consolidating waste; or when temporary venting of a container is necessary. During EPA’s visual inspection, a hazardous waste container of acetonitrile was found open at the Analytical Laboratory #1 Satellite Accumulation Area.
 - b. 40 C.F.R. § Part 262.15(a)(6)(ii) which requires a generator to remove the hazardous waste excess from a satellite accumulation area within three consecutive calendar days after it is dated. The Raw Material Laboratory #4 Satellite Accumulation Area was accumulating pyridine in a container dated August 3, 2023. Thus, the container had to be removed on or before August 6, 2023, to either a central accumulation area, an on-

- site interim status or permitted treatment, storage, or disposal facility, or an off-site designated facility.
- c. 40 C.F.R. § Part 262.17(a)(7)(iii) which requires facility personnel to take part in an annual review of the initial training. On August 9, 2023, EPA requested RCRA personnel training records for calendar years 2020, 2021, and 2022. The Respondent provided training records for calendar year 2022 and stated that for calendar years 2020 and 2021, a RCRA annual review of the initial training was not conducted.
 - d. 40 C.F.R. § Part 262.17(a)(7)(iv)(C) which requires that a large quantity generator must maintain the following documents and records at the facility: a written description of the type and amount of both introductory and continuing training that will be given to each person. The job title and duty documents provided by Respondent for the “Environmental Support Services Technician,” the “Sr. Pharmaceutical Services Operator,” the “Quality Operations Clerk,” and the “Environmental, Health and Safety Manager” did not include a written description of the type and amount of both introductory and continuing training that needs to be given to each person in and/or filling the position.
 - e. 40 C.F.R. § Part 262.262(b) which requires a large quantity generator to prepare a quick reference guide of the contingency plan and submit it to local emergency responders. On August 9, 2023, EPA requested a copy of the Contingency Plan alongside its Quick Reference Guide. The Respondent was not able to provide a copy of the Quick Reference Guide.
4. EPA and Respondent agree that settlement of this matter for a civil penalty of **seven thousand and five hundred dollars (\$7,500.00)** is in the public interest.
 5. In signing this Agreement, Respondent: (1) admits that Respondent is subject to RCRA and its implementing regulations; (2) admits that EPA has jurisdiction over Respondent and Respondent’s conduct as alleged herein; (3) neither admits nor denies the factual allegations contained herein; (4) consents to the assessment of this penalty; (5) waives the opportunity for a hearing to contest any issue of fact or law set forth herein; (6) waives its right to appeal the Final Order accompanying this Agreement pursuant to Section 3008(b) of RCRA; and (7) consents to electronic service of the filed Expedited Settlement Agreement.
 6. By its signature below Respondent certifies, subject to civil and criminal penalties for making a false submission to the United States Government, that the alleged violations have been corrected and Respondent has submitted true and accurate documentation of such correction.

7. The undersigned representative of Respondent certifies that he or she is fully authorized to enter the terms and conditions of this Expedited Settlement Agreement and Final Order and to execute and legally bind Respondent to it. Payment of the civil penalty shall constitute full settlement of the civil claims alleged herein.
8. EPA reserves all its rights to take an enforcement action for any other past, present, or future violations by Respondent of RCRA, any other federal statute or regulation, or this Agreement.
9. Each party shall bear its own costs and fees, if any.
10. This Agreement is binding on the parties signing below, and in accordance with 40 C.F.R. § 22.31(b), shall be effective upon the filing of the Final Order with the Regional Hearing Clerk for EPA, Region 2.

Pursuant to the authority of Section 3008(a) of RCRA, 42 U.S.C. §6938(a), and according to the terms of this Expedited Settlement Agreement and Final Order, IT IS HEREBY ORDERED THAT:

11. Within thirty (30) calendar days of the effective date of this Agreement, Respondent must pay the civil penalty of \$7,500.00 using any method provided on the following website: <https://www.epa.gov/financial/makepayment>. Such payment shall identify Respondent by name and include the docket number assigned to this Agreement by the Regional Hearing Clerk.
12. Within 24 hours of payment, email proof of payment (e.g., a copy of the check or a statement of affirmation regarding electronic funds transfer), including Respondent's name, complete address, and docket number to the following:

Karen Maples, Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 2
maples.karen@epa.gov

Carlos J. Colombani, Enforcement Officer
U.S. Environmental Protection Agency, Region 2
colombani.carlos@epa.gov
13. No portion of the civil penalty or interest paid by Respondent pursuant to the requirements of this CAFO shall be claimed by Respondent as a deduction for federal, state or local income tax purposes.

IT IS SO AGREED,

Name of individual signing (type or print): _____

Octavio Rivera
Name (Signature)

Date: 12/29/23

Octavio Rivera - General Manager
Title (print)

**In the Matter of Neolpharma, Inc.
Docket Number RCRA-02-2024-7201**

COMPLAINANT:

**Carmen R. Guerrero Pérez, Director
Caribbean Environmental Protection Division**

Date: _____

**In the Matter of Neolpharma, Inc.
Docket Number RCRA-02-2024-7201**

FINAL ORDER

The Regional Judicial Officer of the U.S. Environmental Protection Agency, Region 2, ratifies the foregoing Expedited Settlement Agreement. This Agreement, entered into by the parties to this matter, is hereby approved, incorporated herein, and issued as an Order pursuant to Section 3008 of the Act and 40 C.F.R. § 22.18(b)(3). The Effective Date of this Order shall be the date of its filing with the Regional Hearing Clerk, U.S. Environmental Protection Agency, Region 2, New York, New York. 40 C.F.R. § 22.31 (b).

IT IS SO ORDERED:

**Helen Ferrara, Regional Judicial Officer
U.S. Environmental Protection Agency – Region 2
290 Broadway
New York, New York 10007-1866**

Date: _____