

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

**IN THE MATTER OF:**

**Sigmapharm Laboratories LLC**

**Respondent,**

**Sigmapharm Laboratories LLC  
3375 Progress Drive  
Bensalem, PA 19020,**

**Facility**

) **DOCKET NO.: RCRA-03-2023-0044**  
)  
)  
) **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. Sigmapharm Laboratories LLC (“Respondent”), and the Director, Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency, Region III (“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 III (“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 the Commonwealth of 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 Commonwealth of Pennsylvania Hazardous Waste Management Regulations, codified at 25 Pa. Code Chapters 260a-266a, 266b, and 268a-270a (“PAHMWR”), 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).
4. On December 6, 2022, EPA sent a letter to the Commonwealth of 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 3375 Progress Drive, Bensalem, PA (“Facility”), Respondent manufactures generic pharmaceuticals and performs research and development. There is also an analytical laboratory where final products are tested to ensure they meet specifications. On April 4, 2015, Respondent submitted a notification to PADEP that the Facility was a large quantity generator (“LQG”) of hazardous waste at the Facility, and PADEP assigned RCRA ID No. PAR000518530 to the Facility. Respondent does not have a RCRA permit or interim status 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 organized under the laws of the Commonwealth of Pennsylvania and is therefore a “person,” as defined in Section 1004(15) of RCRA, 42 U.S.C. § 6903(15), and 25 Pa. Code § 260a.10, 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.1 and 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 solvents and lab packs with EPA Hazardous Waste Number(s) D001, D002, D018, D022, D040, F002, F003, and F005, 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.1 and 260a.10.
8. On June 7, 2022, EPA representatives conducted a Compliance Evaluation Inspection at the Facility to determine compliance with the applicable hazardous waste regulations.
9. Based on the observations 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 (“PaHWMR”), set forth in the 25 Pa. Code Ch. 260a-266a, 266b, 268a and 270a et seq.
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 or valid exemption to the permitting requirement. Respondent failed to meet the following conditions of the generator permit exemption:
    - i. On June 7, 2022, Respondent failed to meet a condition of the generator permit exemption in 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(3), when it failed to label a container holding hazardous waste. In the R&D Building, a 300-gallon tote used to collect methanol waste (EPA Hazardous Waste No. D001) from the laboratory sink

was not labeled with the words “Hazardous Waste.”

- ii. On June 7, 2022, Respondent failed to meet a condition of the generator permit exemption in 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(c)(1)(ii), when it failed to mark two containers in the satellite accumulation area of the Wash Area Room 020 with the words “Hazardous Waste” or with other words that identify the contents of the containers. The two containers were accumulating waste isopropyl alcohol (EPA Hazardous Waste No. D001).
  - iii. On June 7, 2022, Respondent failed to meet a condition of the generator permit exemption in 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(1)(i), which in turn references reference 40 C.F.R. § 265.173(a), when it failed to keep a container of hazardous waste closed, except when it is necessary to add or remove waste. The container, which was located in the Facility’s hazardous waste accumulation area, was labeled with the words “Hazardous Waste” and contained mixed solid waste of analytical lab tested drugs (EPA Hazardous Waste No. U058).
  - iv. On June 7, 2022, Respondent failed to meet a condition of the generator permit exemption in 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(c)(1)(i), which in turn references 40 C.F.R. § 265.173(a), when it failed to keep three containers of hazardous waste closed, except when it is necessary to add or remove waste. The three containers were located in the satellite accumulation areas of the AD Laboratory and were being used to collect solvent waste (EPA Hazardous Waste No. D001) from the Ultra Performance Liquid Chromatography (“UPLC”) machines. The containers had holes with tubes entering them from the UPLC machines which were not operating at the time of the inspection.
- b. On June 7, 2022, Respondent failed to ensure that at the point of being transported for disposal, solvent-contaminated wipes must contain no “free liquids”, as defined in 25 Pa. Code §260a.10, which incorporates by reference 40 C.F.R. § 260.10, in violation of 25 Pa. Code § 261a.4, which incorporates by reference 40 C.F.R. § 261.4(b)(18)(iii). In the satellite accumulation area of the Wash Area Room 020, a container labeled “Excluded Solvent-Contaminated Wipes” contained a rag sitting in waste isopropyl alcohol with no method to readily separate it from the free liquid in the container.
  - c. On June 7, 2022, Respondent failed to maintain a copy of the manifest signed by the designated facility in violation of 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.40(a). On June 7, 2022, the facility had a copy of the Uniform Hazardous Waste Manifest (“UHW”) Number 00206353VES that had a shipment date of October 15, 2021. The UHW form copy was not signed by the designated facility. The Facility, at the close of the inspection, received the completed signed copy from the designated facility via electronic mail.
  - d. On June 7, 2022, during review of Respondent’s training records for employees

responsible for the management of hazardous waste, documentation was not available to demonstrate two employees received annual refresher training in 2019. Respondent failed to maintain training records for two employees to indicate they took part in an annual review of the initial training in violation of 25 Pa. Code § 265a.1, which incorporates by reference 40 C.F.R. § 265.16(c).

- e. On June 7, 2022, Respondent failed to include the location of the spill equipment and descriptions of the evacuation routes in the Facility’s contingency plan in violation of 25 Pa. Code § 265a.1, which incorporates by reference 40 C.F.R. § 265.52(e) and 40 C.F.R. § 265.52(f), respectively.
  - f. On June 7, 2022, Respondent failed to manage universal waste as required by 25 Pa. Code § 266b which incorporates by reference 40 C.F.R. § 273.
    - i. In the Mechanical Room for MS1A and MS1B, there were two universal waste lamps that were not in containers or packages that are structurally sound, adequate to prevent breakage, and compatible with the contents of the lamps in violation of 25 Pa. Code § 266b which incorporates by reference 40 C.F.R. § 273.13(d)(1). Additionally, Respondent did not mark an accumulation date on the two universal waste lamps and did not keep track of the accumulation time in violation of 25 Pa. Code § 266b, which incorporates by reference 40 C.F.R. § 273.15(c).
    - ii. In the Mechanical Room for MS1A and MS1B, a container of universal waste batteries was not marked or labeled with any one of the following phrases: “Universal Waste – Battery(ies),” or “Waste Battery(ies),” or “Used Battery(ies)” 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 **ELEVEN THOUSAND TWO HUNDRED AND FIFTY DOLLARS (\$11,250.00)** 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 **ELEVEN THOUSAND TWO HUNDRED AND FIFTY DOLLARS (\$11,250.00)** by one of four methods: 1) electronic funds transfer (“EFT”), 2) Automated Clearinghouse, 3) Pay.gov, or 4) a cashier’s check or certified check made out to “**United States Treasury**” with the case name, address and docket number of this Agreement (RCRA-03-2023-0044), for the amount specified above:

a. Payment of the penalty amount by EFT:

Federal Reserve Bank of New York  
ABA 021030004  
Account 68010727  
SWIFT address FRNYUS33



33 Liberty Street  
New York, NY 10045  
Beneficiary: Environmental Protection Agency

b. Payment of the penalty amount by Automated Clearinghouse (“ACH”):

U.S. Treasury REX/Cashlink ACH Receiver

ABA: 051036706

Account Number: 310006, Environmental Protection Agency

CTX Format Transaction Code 22- Checking

Physical Location of the U.S. Treasury Facility  
5700 Rivertech Court  
Riverdale, MD 20737

Remittance Express (REX): 1-866-234-5681

c. Payments made through Pay.gov:

Payers can use their credit or debit cards (Visa, MasterCard, American Express & Discover) as well as checking account information to make payments. Follow these steps to make a payment:

- (1) You **DO NOT** need a user name and password or account.
- (2) Enter **SFO 1.1** in the form search box on the top left side of the screen.
- (3) Open the form and follow the on-screen instructions.
- (4) Select your method of payment from the “Type of Payment” drop down menu.
- (5) Based on your selection, the corresponding line will open and no longer be shaded grey.
- (6) Enter the docket number of this Agreement into the field.

d. Payment of the penalty amount by regular U.S. Postal Service shall be sent via **certified mail to:**

U.S. Environmental Protection Agency  
P.O. Box - Cincinnati Finance Center Box 979077  
St. Louis, MO 63197-9000

e. Payment of the penalty amount by overnight mail (FedEx or other non-U.S. Postal Service express mail) shall be sent to:

U.S. Environmental Protection Agency  
Government Lock Box - Cincinnati Finance Center Box 979077  
1005 Convention Plaza  
SL-MO-C2-GL

St. Louis, MO 63101

- f. A list of the payment methods is also provided at this website <https://www.epa.gov/financial/makepayment>.
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:

Stephen Forostiak, Environmental Scientist (3ED22)  
U.S. EPA, Region III  
[forostiak.stephen@epa.gov](mailto:forostiak.stephen@epa.gov)

and

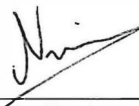
Regional Hearing Clerk (3RC00)  
U.S. EPA, Region III  
[R3\\_Hearing\\_Clerk@epa.gov](mailto:R3_Hearing_Clerk@epa.gov)

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. 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.

18. 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.
19. This Agreement is effective upon filing, in accordance with 40 C.F.R. § 22.31(b).
20. The undersigned representative certifies that she/he is fully authorized to execute this Agreement and to legally bind Sigmapharm Laboratories LLC.
21. 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: [Forostiak.stephen@epa.gov](mailto:Forostiak.stephen@epa.gov) (for Complainant), and [nkurien@sigmapharm.com](mailto:nkurien@sigmapharm.com) (for Respondent).

**For Respondent:** Sigmapharm Laboratories LLC

Date: 02/23/2023

By:   
\_\_\_\_\_  
Nimin C. Kurien  
Environmental Health and Safety Manager

**For Complainant: U.S. Environmental Protection Agency, Region III**

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 III, 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.

Date: \_\_\_\_\_

By: \_\_\_\_\_

Karen Melvin, Director  
Enforcement & Compliance Assurance Division



**BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION III  
Philadelphia, Pennsylvania 19103-2029**

<b>IN THE MATTER OF:</b>	)	<b>DOCKET NO.: RCRA-03-2023-0044</b>
	)	
<b>Sigmapharm Laboratories LLC</b>	)	
	)	
<b>Respondent,</b>	)	<b>EXPEDITED SETTLEMENT AGREEMENT AND FINAL ORDER</b>
	)	
<b>Sigmapharm Laboratories LLC</b>	)	
<b>3375 Progress Drive</b>	)	<b>Proceeding under Section</b>
<b>Bensalem, PA 19020,</b>	)	<b>3008(a) and (g) of the Resource</b>
	)	<b>Conservation and Recovery Act, as</b>
	)	<b>amended, 42 U.S.C. § 6928(a) and (g)</b>
	)	
<b>Facility</b>	)	
	)	
	)	

**FINAL ORDER**

Complainant, the Director of the Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency - Region III, and Respondent, Sigmapharm Laboratories 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 **ELEVEN THOUSAND TWO HUNDRED AND FIFTY DOLLARS (\$11,250.00)**, 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.

Date: \_\_\_\_\_

By: \_\_\_\_\_

Joseph J. Lisa  
Regional Judicial and Presiding Officer  
U.S. EPA Region III

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION III  
Philadelphia, Pennsylvania 19103-2029

<p>IN THE MATTER OF:</p> <p>Sigmapharm Laboratories LLC</p> <p style="padding-left: 40px;">Respondent,</p> <p>Sigmapharm Laboratories LLC 3375 Progress Drive Bensalem, PA 19020,</p> <p>Facility</p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	<p>DOCKET NO.: RCRA-03-2023-0044</p> <p>EXPEDITED SETTLEMENT AGREEMENT AND FINAL ORDER</p> <p>Proceeding under Section 3008(a) and (g) of the Resource Conservation and Recovery Act, as amended, 42 U.S.C. § 6928(a) and (g)</p>
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CERTIFICATE OF SERVICE

I certify that on \_\_\_\_\_, the foregoing *Consent Agreement and Final Order*, was filed with the EPA Region III Regional Hearing Clerk. 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:

Copies served via email to:

Nimin C. Kurien  
EHS Manager  
3375 Progress Drive  
Bensalem, PA 19020  
[nkurien@sigmapharm.com](mailto:nkurien@sigmapharm.com)

Stephen Forostiak  
Compliance Officer  
U.S. EPA Region III  
[forostiak.stephen@epa.gov](mailto:forostiak.stephen@epa.gov)

Date: \_\_\_\_\_

\_\_\_\_\_  
Regional Hearing Clerk  
U.S. Environmental Protection Agency, Region III