

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

IN THE MATTER OF:

Merck Sharp & Dohme Corp.

Respondent,

**Merck Sharp & Dohme Corp. – Elkton
Facility
2778 South East Side Highway
Elkton, VA 22827**

Facility

DOCKET NO.: RCRA-03-2023-0098

**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)**

EXPEDITED SETTLEMENT AGREEMENT

1. Merck Sharp & Dohme Corp. (“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 Virginia 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 Virginia Hazardous Waste Management Program, 9 VAC-20-60-12 et seq., 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 Commonwealth of Virginia Hazardous Waste Management Program on November 4, 2013, including incorporation by reference of the federal regulations which were in effect as of July 1, 2010. The Code of Federal Regulation citations used herein are to the 2010 Federal regulations in

place as of November 4, 2013, when referring to the Federal regulations incorporated by the Virginia regulations.

4. On April 19, 2023, EPA sent a letter to the Commonwealth of Virginia, through the Virginia Department of Environmental Quality (“VADEQ”), 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 2778 South East Side Highway, Elkton, Virginia (“Facility”), Respondent owns and operates a pharmaceutical manufacturing facility. On February 22, 2022, Respondent submitted a notification to VADEQ that the Facility was a Large Quantity Generator (“LQG”) of hazardous waste at the Facility, and VADEQ assigned RCRA ID No. VAD001705110 to 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 Virginia and is therefore a “person,” as defined in Section 1004(15) of RCRA, 42 U.S.C. § 6903(15), and Commonwealth of Virginia Hazardous Waste Management Program, 9 VAC-20-60-12 et seq. Respondent was, at all times relevant to the allegations in this Agreement, the “operator” and the “owner” of a “facility,” described in Paragraph 5, as the terms “owner” and “operator” and “facility” are defined in 9 VAC-20-60-12.
7. At all times relevant to the allegations described in this Agreement, Respondent “stored” “hazardous waste” at the Facility, including but not limited to waste methanol and acetone, with EPA Hazardous Waste Number(s) D001 and F003, as the terms “storage” and “hazardous waste” are defined in 9 VAC-20-60-12.
8. On September 27, 2022 to September 29, 2022, EPA representatives conducted a Compliance Evaluation Inspection (“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 Virginia hazardous waste management regulations set forth in the Commonwealth of Virginia Hazardous Waste Management Program, 9 VAC-20-60-12 et seq.
10. Complainant has identified the following violations at the Facility: Respondent violated 42 U.S.C. § 6925(a) and 9 VAC 20-60-270, 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:
 - a. On September 29, 2022, Respondent failed to meet a condition of the generator permit exemption in 9 VAC 20-60-262, which incorporates by reference 40 C.F.R. 262.34(a)(2), when it failed to mark each container of hazardous waste with the start

accumulation date. EPA Inspectors observed, inside of the middle bay of Building 87, two pallets containing boxes (containers) of hazardous waste ("Vesta-syde", EPA waste code: D001). The pallets contained nine and twelve boxes, respectively. The boxes on the pallets were collectively wrapped with plastic wrap. A single hazardous waste label with a start accumulation date was affixed to the plastic wrap on each pallet. The pallet with the twelve boxes had a start accumulation date of 8/29/2022. The pallet with the nine boxes had a start accumulation date of 9/26/2022. No start accumulation date was observed on the individual containers on either pallet.

- b. On September 29, 2022, Respondent failed to meet a condition of the generator permit exemption in 9 VAC 20-60-262, which incorporates by reference 40 C.F.R. 262.34(a)(3), when it failed to mark each container of hazardous waste with the words "Hazardous Waste". EPA Inspectors observed, inside of the middle bay of Building 87, two pallets containing boxes (containers) of hazardous waste ("Vesta-syde", EPA waste code: D001). The pallets contained nine and twelve boxes, respectively. The boxes on the pallets were collectively wrapped with plastic wrap. A single label with the words "Hazardous Waste" was affixed to the plastic wrap on each pallet. The words "Hazardous Waste" were not observed on the individual containers.

11. Complainant also identified the following violations at the Facility:

- a. On September 28, 2022, Respondent failed to make a hazardous waste determination for one container of solid waste, in violation of 9 VAC 20-60-262 which incorporates by reference 40 C.F.R. § 262.11. During the inspection, the EPA Inspectors found the following solid wastes in Building 24:

(1) "DECON-AHOL® AEROSOL" aerosol can

The aerosol can was observed in a metal step container that had a label that read "AEROSOL CANS, EMPTY FOR RECYCLE". No other labels were observed on the metal step container. The observed aerosol can was not punctured and drained. Respondent had not determined whether the solid waste was a hazardous waste.

- b. For multiple time periods in 2019 and 2020, Respondent failed to either conduct or document daily inspections of a hazardous waste accumulation tank, as required by 9 VAC-20-60-264, which incorporates by reference 40 C.F.R. § 264.195(b) and (h). With respect to the hazardous waste accumulation tank TA-9752, located in the IPA shed, the Respondent did not conduct a daily inspection of TA-9752 on 6/09/2019, 6/16/2019, and 11/26/2020. Documentation for daily inspections in 2019 were not observed for the following dates: 2/08, 2/23, 3/02, 3/03, 3/10, 3/14, 3/17, 4/28, 5/24, 5/25, 5/27, 6/01, 6/02, 6/08, 6/09, 6/16, 6/22, 6/23, 6/29, 7/04, 8/10, and 8/11. Documentation for daily inspections was not observed for the time period of 10/05/2020 – 12/13/2020.

- c. Respondent failed to submit a 2019 biennial report by March 1, 2020, as required by 9 VAC-20-60-262, which incorporates by reference 40 C.F.R. 262.41(a). Respondent submitted the 2019 biennial report on June 9, 2020, 100 days after the March 1, 2020 deadline.
 - d. Respondent failed to include required content in the contingency plan, as required by 9 VAC 20-60-264, which incorporates by reference 40 C.F.R. 264.52(d) and (f). The primary emergency coordinator in the contingency plan was listed as “Varies” and did not include the name of the qualified person who would be the primary emergency coordinator. A single phone number was listed for all three levels of emergency coordinators (primary, secondary, and tertiary). No addresses were included for the emergency coordinators. The contingency plan did not include an evacuation plan for facility personnel where there is a possibility that evacuation could be necessary.
12. Complainant and Respondent agree that settlement of this matter for a total penalty of **SIX THOUSAND, TWO HUNDRED AND FIFTY DOLLARS (\$6,250.00)** 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.
 13. Respondent agrees that, within 30 days of the effective date of this Agreement, Respondent shall make a payment of **SIX THOUSAND, TWO HUNDRED AND FIFTY DOLLARS (\$6,250.00)** 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-03-2023-0098), 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 username 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 regular mail to:

U.S. Environmental Protection Agency
P.O. Box - Cincinnati Finance Center Box 979078
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 979078
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>.

14. 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:

Jeremy Dearden, Enforcement Officer (3ED22)
U.S. EPA, Region III

Dearden.jeremy@epa.gov

and

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

15. 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.
16. 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.
17. 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.
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 Merck Sharp & Dohme Corp.
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: dearden.jeremy@epa.gov (EPA), and Jonathan_gass@merck.com (Merck Sharp & Dohme Corp).

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: Merck Sharp & Dohme Corp.

Date: 21 Jun 2023

By: Jonathan Gass
Jonathan Gass
Associate Vice President – Plant 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.

By: _____
[Digital Signature and Date]
Karen Melvin, Director
Enforcement & Compliance Assurance Division

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FINAL ORDER

Complainant, the Director of the Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency - Region III, and Respondent, Merck Sharp & Dohme Corp., 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 **SIX THOUSAND, TWO HUNDRED AND FIFTY DOLLARS (\$6,250.00)**, 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: _____

[Digital Signature and Date]

Joseph J. Lisa

Regional Judicial and Presiding Officer

U.S. EPA Region III

