

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 Arch Street
Philadelphia, Pennsylvania 19103**

In the Matter of:	:	
	:	
Aphena Pharma Solutions - Maryland, LLC	:	U.S. EPA Docket No. RCRA-03-2021-0016
7978 Industrial Park Road	:	
Easton, Maryland 21601	:	
	:	
Respondent.	:	Proceeding under Sections 3008(a) and
	:	(g) of the Resource Conservation and
	:	Recovery Act, as amended, 42 U.S.C.
	:	Sections 6928(a) and (g)
	:	

CONSENT AGREEMENT

PRELIMINARY STATEMENT

1. This Consent Agreement is entered into by the Director of the Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency, Region III (“Complainant”) and Aphena Pharma Solutions - Maryland, LLC (“Respondent”) (collectively the “Parties”), pursuant to Sections 3008(a) and (g) of the Solid Waste Disposal Act, commonly known as the Resource Conservation and Recovery Act of 1976, as amended by *inter alia*, the Hazardous and Solid Waste Amendments of 1984 (collectively referred to hereinafter as “RCRA”), 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 Rule of Practice”), 40 C.F.R. Part 22. 42 U.S.C. § 6928(a)(2), RCRA § 3008(a)(1), 42 U.S.C. § 6928(a)(1), authorizes the Administrator of the U.S. Environmental Protection Agency to assess penalties and undertake other actions required by this Consent Agreement. The Administrator has delegated this authority to the Regional Administrator, who, in turn, has delegated it to the Complainant. This Consent Agreement and the attached Final Order resolve Complainant’s civil penalty claims against Respondent under RCRA (or the “Act”) for the violations alleged herein.
2. In accordance with 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3) of the Consolidated Rules of Practice, Complainant hereby simultaneously commences and resolves this administrative proceeding.

JURISDICTION

3. The U.S. Environmental Protection Agency (“EPA” or “the Agency”) has jurisdiction over the above-captioned matter, as described in Paragraph 1, above.

4. Pursuant to Section 3006(b) of RCRA, 42 U.S.C. § 6926(b), and 40 C.F.R. Part 271, Subpart A, the State of Maryland has been granted final authorization to administer its hazardous waste management program, set forth at the Code of Maryland Regulations (“COMAR”), Title 10, Subtitle 51 et seq., in lieu of the federal hazardous waste management program established under RCRA Subtitle C, 42 U.S.C. §§ 6921-6939e. The State of Maryland Hazardous Waste Management Regulations (“MdHWMR”) originally were authorized by EPA on February 11, 1985, pursuant to Section 3006(b) of RCRA, 42 U.S.C. § 6926(b). Revisions to the MdHWMR set forth at COMAR, Title 26, Subtitle 13, were authorized by EPA effective July 31, 2001 and September 24, 2004. The provisions of the revised federally-authorized program 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).
5. Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), authorizes EPA to initiate an enforcement action whenever EPA determines that a person is in violation of any requirement of RCRA Subtitle C, EPA’s regulations thereunder, or any regulation of a state hazardous waste program which has been authorized by EPA. Section 3008(g) of RCRA, 42 U.S.C. § 6928(g), authorizes the assessment if a civil penalty against any person who violates any requirement of Subtitle C of RCRA.
6. The Consolidated Rules of Practice govern this administrative adjudicatory proceeding pursuant to 40 C.F.R. § 22.1(a)(4).
7. EPA has given the State of Maryland, through the Maryland Department of the Environment (“MDE”), prior notice as of April 16, 2019 concerning the initiation of this action in accordance with Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2).

GENERAL PROVISIONS

8. For purposes of this proceeding only, Respondent admits the jurisdictional allegations set forth in this Consent Agreement and Final Order.
9. Except as provided in Paragraph 8, above, Respondent neither admits nor denies the specific factual allegations set forth in this Consent Agreement.
10. Respondent agrees not to contest the jurisdiction of EPA with respect to the execution of this Consent Agreement, the issuance of the attached Final Order, or the enforcement of this Consent Agreement and Final Order.
11. For purposes of this proceeding only, Respondent hereby expressly waives its right to contest the allegations set forth in this Consent Agreement and waives its right to appeal the accompanying Final Order.
12. Respondent consents to the assessment of the civil penalty stated herein, to the issuance of any specified compliance order herein, and to any conditions specified herein.
13. Respondent shall bear its own costs and attorney’s fees in connection with this proceeding.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

14. In accordance with 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3) of the Consolidated Rules of Practice, Complainant alleges and adopts the Findings of Fact and Conclusions of Law set

forth immediately below.

15. At all times relevant to this Consent Agreement, Respondent is, and has been, a limited liability corporation and, therefore, Respondent is and has been a ‘person’ as that term is defined in Section 1004(15) of RCRA, 42 U.S.C. § 6903(15), 40 C.F.R. § 260.10 and COMAR § 26.13.01.03.B(61) and subject to the assessment of civil penalties for the violations alleged herein.
16. At all times relevant to this Consent Agreement, Respondent is, and has been, the “owner” and “operator” of a facility located at 7978 Industrial Park Road, Easton, Maryland 21601 (hereinafter “the Facility”), as those terms are defined in COMAR §§ 26.13.01.03.B(58) and (59).
17. At all times relevant to the allegations set forth in this Consent Agreement, Respondent was a large quantity generator of hazardous waste and has been assigned EPA ID Number MDD985384759 for the generation of hazardous waste at the Facility and Respondent did not have a permit for the treatment, storage or disposal of hazardous wastes.
18. At all times relevant to the allegations set forth in this Consent Agreement, Respondent’s operations included chemical mixing, blending and packaging of various types of liquids, creams, gels, suspensions, foams and lotions. Respondent manufactured, among other products, hand sanitizers, vitamin B12 and nasal inhalers. Respondent provided turnkey contract packaging, repackaging and manufacturing solutions for the pharmaceutical, dietary supplements, animal health, consumer health and medical device markets.
19. At all times relevant to the allegations set forth in this Consent Agreement, and as described below, Respondent was a “generator” of “solid waste” and “hazardous waste” at the Facility and engaged in the temporary “storage” of certain such waste in “containers” at the Facility, as those terms are defined in COMAR §§ 26.13.01.03.B(9), (29), (31), (73) and (76).
20. At all times relevant to the allegations set forth in this Consent Agreement, the Facility was a “facility” as that term is defined in COMAR § 26.13.01.03.B(23).
21. On April 25, 2018, inspectors from EPA conducted a Compliance Evaluation Inspection (“the Inspection”) of the Facility.
22. On December 4, 2019, EPA sent a Request to Show Cause and Request for Information letter to Respondent advising it of EPA’s preliminary findings of violations at the Facility and offering the Respondent an opportunity to provide such additional information relating to Respondent’s compliance with applicable hazardous waste regulations at the Facility.
23. Subsequent to December 4, 2019, Respondent provided EPA with information relating to Respondent’s compliance with applicable hazardous waste regulations at the Facility.
24. On the basis of information available to EPA and as specified below, EPA concludes that Respondent has violated certain requirements and provisions of RCRA Subtitle C, 42 U.S.C. §§ 6921-6939g, certain federally-authorized MdHWMR requirements promulgated thereunder, and certain applicable federal hazardous waste regulations.

Count I
Operating a Treatment, Storage or Disposal Facility Without a Permit or Interim Status

25. The allegations of Paragraphs 1 through 24 of this Consent Agreement are incorporated herein by reference.
26. Sections 3005(a) and (e) of RCRA, 42 U.S.C. §§ 6925(a) and (e), and 40 C.F.R. Parts 262 and 270 require, with certain exceptions not relevant here, that no person who owns or operates a facility for the treatment, storage or disposal of hazardous waste may do so without first obtaining a permit or interim status for the facility. COMAR § 26.13.07.01.A also requires a permit or interim status for the treatment, storage or disposal of hazardous waste.
27. Section 3005(e)(1) of RCRA (Interim Status), 42 U.S.C. § 6925(e)(1), provides, in pertinent part, that: “Any person who —
- (A) owns or operates a facility required to have a permit under this section which facility—
 - (i) was in existence on November 19, 1980, or
 - (ii) is in existence on the effective date of statutory or regulatory changes under this chapter that render the facility subject to the requirement to have a permit under this section,
 - (B) has complied with the requirements of section 6930(a) of this title, and
 - (C) has made an application for a permit under this section,
- shall be treated as having been issued such permit until such time as final administrative disposition of such application is made, unless the Administrator or other plaintiff proves that final administrative disposition of such application has not been made because of the failure of the applicant to furnish information reasonably required or requested in order to process the application...”
28. Respondent has never met the requirements for “interim status” pursuant to RCRA Section 3005(e) and has never been issued a permit pursuant to RCRA Section 3005(a) for the treatment, storage, or disposal of hazardous waste at the Facility.
29. Pursuant to COMAR § 26.13.03.05.E, large quantity generators of hazardous waste who accumulate hazardous waste on-site for less than 90 days are exempt from the requirement to obtain a permit for such accumulation, so long as the hazardous waste is stored in accordance with a number of conditions set forth in that section (hereinafter referred to as “Conditions for Exemption from the Hazardous Waste Storage Permit Requirement”), including, *inter alia*:
- a. Pursuant to COMAR § 26.13.03.05.E(1)(d), the generator must comply with the requirements of COMAR § 26.13.05.09, including the requirement to keep containers holding hazardous waste always closed during storage, except when necessary to add or remove waste, in accordance with COMAR § 26.13.05.09.D;
 - b. Pursuant to COMAR § 26.13.03.05.E(1)(g), the generator must comply with the

- requirements of COMAR § 26.13.05.02.G., including the requirements that facility personnel shall take part in an annual review of the initial hazardous waste management training required by COMAR § 26.13.05.02.G(1)(a), as set forth at COMAR § 26.13.05.02.G(3);
- c. Pursuant to COMAR § 26.13.03.05.E(1)(g), the generator must comply with the requirements of COMAR § 26.13.05.04, which requires that the owner or operator maintain a written contingency plan that includes *inter alia*:
1. In accordance with COMAR § 26.13.05.04.C(4), the plan shall list names, addresses, and phone numbers (office and home) of all persons qualified to act as emergency coordinator, and this list shall be kept up to date. When more than one person is listed, one shall be named as primary emergency coordinator and others shall be listed in the order in which they will assume responsibility as alternates.
 2. In accordance with COMAR § 26.13.05.04.C(5), the plan shall include a list of all emergency equipment at the facility (such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment), where this equipment is required. This list shall be kept up to date. In addition, the plan shall include the location and a physical description of each item on the list, and a brief outline of its capabilities.
- d. Pursuant to COMAR § 26.13.03.05.E(1)(k), the generator must maintain an inspection log or summary that includes the date and time of each weekly inspection performed in accordance with COMAR §§ 26.13.03.05.E(1)(d) and (h), the name of the inspector, a notation of the observations made, and the date and nature of any repairs made or other remedial actions taken.
30. Based upon information obtained by EPA, during and subsequent to the Inspection, EPA has determined that, on April 25, 2018, Respondent stored hazardous waste in an open and unsealed 55- gallon metal container, during a period of time when it was not necessary to add or remove waste from such container, in noncompliance with the Condition for Exemption from the Hazardous Waste Storage Permit Requirement set forth at COMAR § 26.13.03.05.E(1)(d).
31. Based upon information obtained by EPA, during and subsequent to the Inspection, EPA has determined that, during January 2016 through December 2017, Respondent accumulated hazardous waste at the Facility without a permit or without holding interim status for 90 days or less and failed to ensure that Facility personnel took part in an annual review of the hazardous waste management procedures training in noncompliance with the Condition for Exemption from the Hazardous Waste Storage Permit Requirement set forth at COMAR § 26.13.03.05.E(1)(g).
32. Based upon information obtained by EPA, during and subsequent to the Inspection, EPA has determined that, on April 25, 2018, Respondent accumulated hazardous waste at the Facility without a permit or without holding interim status for 90 days or less and failed to have a Contingency Plan that included the following information, as required pursuant to COMAR § 26.13.03.04.C(4) and (5): a) a listing of the name, address, office and home

phone numbers of each emergency coordinator, b) a listing of the emergency equipment located at the Facility and c) a listing of the location, physical description and brief outline of capabilities of each emergency equipment item at the Facility.

33. On April 25, 2018, Respondent accumulated hazardous waste at the Facility without a permit or without holding interim status for 90 days or less and failed to have a Contingency Plan that included the information required by the Condition for Exemption from the Hazardous Waste Storage Permit Requirement set forth at COMAR § 26.13.03.05.E(1)(g).
34. Based upon information obtained by EPA, during and subsequent to the Inspection, EPA has determined that, during February 2018 through April 2018, Respondent accumulated hazardous waste on-site without a permit or without holding interim status for 90 days or less and failed to record the time for each weekly inspection performed in accordance with COMAR §§ 26.13.03.05.E(1)(d) and (h) and, thereby, failed to comply with the Condition for Exemption from the Hazardous Waste Storage Permit Requirement set forth at COMAR § 26.13.03.05.E(1)(k).
35. Based upon information obtained by EPA, during and subsequent to the Inspection, EPA has determined that Respondent accumulated hazardous waste at the Facility for greater than 90-days during the following time periods: August 15, 2017 through December 6, 2017 and January 17, 2018 through at least August 22, 2018.
36. Respondent accumulated hazardous waste at the Facility for greater than 90-days and failed to meet the 90-day limitation for accumulating hazardous waste on-site without a permit as set forth at COMAR § 26.13.03.05.E during the following time periods: August 15, 2017 through December 6, 2017 and January 17, 2018 through at least August 22, 2018.
37. For the reasons and during the times set forth above, at the Facility, Respondent accumulated hazardous waste at the Facility and failed to comply with the Conditions for Exemption from the Hazardous Waste Storage Permit Requirement that are set forth at COMAR § 26.13.03.05.E, and, therefore, failed to qualify for an exemption from the permitting requirements set forth at Sections 3005(a) and (e) of RCRA, 42 U.S.C. §§ 6925(a) and (e), and COMAR § 26.13.07.01.A.
38. During the times set forth above, Respondent engaged in the storage of hazardous waste without a permit in violation of Sections 3005(a) and (e) of RCRA, 42 U.S.C. §§ 6925(a) and (e), and COMAR § 26.13.07.01.A.
39. In failing to comply with Sections 3005(a) and (e) of RCRA, 42 U.S.C. § 6925(a) and (e), and COMAR § 26.13.07.01A, Respondent is subject to the assessment of penalties under Sections 3008(a) and (g) of RCRA, 42 U.S.C. §§ 6928(a) and (g).

Count II
Failure to Keep Container of Hazardous Waste Closed

40. The allegations of Paragraphs 1 through 39 of this Consent Agreement are incorporated herein by reference.
41. Pursuant to COMAR § 26.13.05.09.D, a container holding hazardous waste shall always

be closed during storage, except when it is necessary to add or remove waste.

42. Based upon information obtained by EPA, during and subsequent to the Inspection, EPA has determined that, on April 25, 2018, Respondent stored hazardous waste in an open and unsealed fifty-five (55) gallon metal container at the Facility, during a period of time when it was not necessary to add or remove waste from such container.
43. On or about April 25, 2018, at the Facility, Respondent failed to comply with the hazardous waste container management requirement set forth at COMAR § 26.13.05.09.D.
44. In failing to comply with COMAR § 26.13.05.09.D, Respondent is subject to the assessment of penalties under Sections 3008(a) and (g) of RCRA, 42 U.S.C. §§ 6928(a) and (g).

Count III
Failure to Provide Annual Hazardous Waste Training

45. The allegations of Paragraphs 1 through 44 of this Consent Agreement are incorporated herein by reference.
46. Pursuant to COMAR § 26.13.05.02.G(3), facility personnel shall take part in an annual review of the initial training required in COMAR § 26.13.05.02.G(1).
47. During January 2016 through December 2017, Respondent Aphenia stored hazardous waste at the Facility and failed to ensure that Facility personnel took part in an annual review of the hazardous waste management procedures training.
48. During January 2016 through December 2017, Respondent Aphenia failed to comply with the annual review of initial training requirement set forth at COMAR § 26.13.05.02.G(3).
49. In failing to comply with COMAR § 26.13.05.02.G(3), Respondent is subject to the assessment of penalties under Sections 3008(a) and (g) of RCRA, 42 U.S.C. §§ 6928(a) and (g).

Count IV
Failure to Maintain an Adequate Contingency Plan

50. The allegations of Paragraphs 1 through 49 of this Consent Agreement are incorporated herein by reference.
51. Pursuant to COMAR § 26.13.05.04.C(4), the owner or operator of a hazardous waste facility is required to maintain a Contingency Plan that includes, *inter alia*, the following information: 1) a list of names, addresses, and phone numbers (office and home) of all persons qualified to act as emergency coordinator, and this list shall be kept up to date and 2) when more than one person is listed, one shall be named as primary emergency coordinator and others shall be listed in the order in which they will assume responsibility as alternates.
52. Pursuant to COMAR § 26.13.05.04.C(5), the owner or operator of a hazardous waste facility is required to maintain a Contingency Plan that includes, *inter alia*, the following information: a) a list of all emergency equipment at the facility (such as fire extinguishing

systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment), where this equipment is required, b) this list shall be kept up to date and c) the location and a physical description of each item on the list and a brief outline of its capabilities.

53. Based upon information obtained by EPA, during and subsequent to the Inspection, EPA has determined that, on April 25, 2018, Respondent stored hazardous waste at the Facility and failed to have a Contingency Plan that included the following information, as required pursuant to COMAR§ 26.13.05.04.C(4) and (5): a) a listing of the name, address, office and home phone numbers of each emergency coordinator, b) a listing of the emergency equipment located at the Facility and c) a listing of the location, physical description and brief outline of capabilities of each emergency equipment item at the Facility.
54. On or about April 25, 2018, Respondent failed to meet the Contingency Plan requirements set forth at COMAR §§ 26.13.05.04.C(4) and (5).
55. In failing to comply with COMAR §§ 26.13.05.04.C(4) and (5), Respondent is subject to the assessment of penalties under Sections 3008(a) and (g) of RCRA, 42 U.S.C. §§ 6928(a) and (g).

CIVIL PENALTY

56. In settlement of EPA’s claims for civil penalties for the violations alleged in this Consent Agreement, Respondent consents to the assessment of a civil penalty in the amount of EIGHTY-TWO THOUSAND ONE HUNDRED TWENTY DOLLARS (\$82,120), which Respondent shall be liable to pay in accordance with the terms set forth below.
57. The civil penalty is based upon EPA’s consideration of a number of factors, including the penalty criteria (“statutory factors”) set forth in Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), including, the following: the seriousness of the violation and any good faith efforts to comply with the applicable requirements. These factors were applied to the particular facts and circumstances of this case with specific reference to EPA’s October, 1990 RCRA Civil Penalty Policy, as revised in June, 2003 (“RCRA Penalty Policy”), which reflect the statutory penalty criteria and factors set forth at Sections 3008(a)(3) and (g) of RCRA, 42 U.S.C. §§ 6928(a)(3) and (g), the appropriate Adjustment of Civil Monetary Penalties for Inflation, pursuant to 40 C.F.R. Part 19, and the applicable EPA memoranda addressing EPA’s civil penalty policies to account for inflation.
58. Payment of the civil penalty amount, and any associated interest, administrative fees, and late payment penalties owed, shall be made by either cashier’s check, certified check or electronic wire transfer, in the following manner:
 - a. All payments by Respondent shall include reference to Respondent’s name and address, and the Docket Number of this action, *i.e.*, EPA Docket No. RCRA-03-2021-0016;
 - b. All checks shall be made payable to the “United States Treasury”;
 - c. All payments made by check and sent by regular mail shall be addressed and mailed to:

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

- d. For additional information concerning other acceptable methods of payment of the civil penalty amount see:

<https://www.epa.gov/financial/makepayment>.

- e. A copy of Respondent's check or other documentation of payment of the penalty using the method selected by Respondent for payment shall be sent simultaneously via email to:

Kathleen Root, Esq
Sr. Assistant Regional Counsel
U.S. EPA, Region III (3RC40)
1650 Arch Street
Philadelphia, PA 19103-2029
root.kathleen@epa.gov

59. Pursuant to 31 U.S.C. § 3717 and 40 C.F.R. § 13.11, EPA is entitled to assess interest and late payment penalties on outstanding debts owed to the United States and a charge to cover the costs of processing and handling a delinquent claim, as more fully described below. Accordingly, Respondent's failure to make timely payment of the penalty as specified herein shall result in the assessment of late payment charges including interest, penalties and/or administrative costs of handling delinquent debts.
60. Payment of the civil penalty is due and payable immediately upon receipt by Respondent of a true and correct copy of the fully executed and filed Consent Agreement and Final Order. Receipt by Respondent or Respondent's legal counsel of such copy of the fully executed Consent Agreement and Final Order, with a date stamp indicating the date on which the Consent Agreement and Final Order was filed with the Regional Hearing Clerk, shall constitute receipt of written initial notice that a debt is owed EPA by Respondent in accordance with 40 C.F.R. § 13.9(a).
61. INTEREST: In accordance with 40 C.F.R. § 13.11(a)(1), interest on the civil penalty assessed in this Consent Agreement and Final Order will begin to accrue on the date that a copy of the fully executed and filed Consent Agreement and Final Order is electronically transmitted, mailed or hand-delivered to Respondent. However, EPA will not seek to recover interest on any amount of the civil penalties that is paid within thirty (30) calendar days after the date on which such interest begins to accrue. Interest will be assessed at the rate of the United States Treasury tax and loan rate in accordance with 40 C.F.R. § 13.11(a).
62. ADMINISTRATIVE COSTS: The costs of the EPA's administrative handling of overdue debts will be charged and assessed monthly throughout the period a debt is overdue. 40 C.F.R. § 13.11(b). Pursuant to Appendix 2 of EPA's *Resources Management Directives – Case Management*, Chapter 9, EPA will assess a \$15.00 administrative handling charge for administrative costs on unpaid penalties for the first

thirty (30) day period after the payment is due and an additional \$15.00 for each subsequent thirty (30) days the penalty remains unpaid.

63. LATE PAYMENT PENALTY: A late payment penalty of six percent per year will be assessed monthly on any portion of the civil penalty that remains delinquent more than ninety (90) calendar days. See 40 C.F.R. § 13.11(c). Should assessment of the penalty charge on the debt be required, it shall accrue from the first day payment is delinquent. See 31 C.F.R. § 901.9(d).
64. Respondent agrees not to deduct for federal tax purposes the civil penalty assessed in this Consent Agreement and Final Order.

GENERAL SETTLEMENT CONDITIONS

65. By signing this Consent Agreement, Respondent acknowledges that this Consent Agreement and Final Order will be available to the public and represents that, to the best of Respondent's knowledge and belief, this Consent Agreement and Final Order does not contain any confidential business information or personally identifiable information from Respondent.
66. Respondent certifies that any information or representation it has supplied or made to EPA concerning this matter was, at the time of submission true, accurate, and complete and that there has been no material change regarding the truthfulness, accuracy or completeness of such information or representation. EPA shall have the right to institute further actions to recover appropriate relief if EPA obtains evidence that any information provided and/or representations made by Respondent to the EPA regarding matters relevant to this Consent Agreement and Final Order, including information about respondent's ability to pay a penalty, are false or, in any material respect, inaccurate. This right shall be in addition to all other rights and causes of action that EPA may have, civil or criminal, under law or equity in such event. Respondent and its officers, directors and agents are aware that the submission of false or misleading information to the United States government may subject a person to separate civil and/or criminal liability.

CERTIFICATION OF COMPLIANCE

67. Respondent certifies to EPA, upon personal investigation and to the best of its knowledge and belief, that it currently is in compliance with regard to the violations alleged in this Consent Agreement.

OTHER APPLICABLE LAWS

68. Nothing in this Consent Agreement and Final Order shall relieve Respondent of its obligation to comply with all applicable federal, state, and local laws and regulations, nor shall it restrict EPA's authority to seek compliance with any applicable laws or regulations, nor shall it be construed to be a ruling on the validity of any federal, state or local permit. This Consent Agreement and Final Order does not constitute a waiver, suspension or modification of the requirements of the RCRA, or any regulations promulgated thereunder.

RESERVATION OF RIGHTS

69. This Consent Agreement and Final Order resolves only EPA’s claims for civil penalties for the specific violations alleged against Respondent in this Consent Agreement and Final Order. 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. This settlement is subject to all limitations on the scope of resolution and to the reservation of rights set forth in Section 22.18(c) of the Consolidated Rules of Practice, 40 C.F.R. § 22.18(c). EPA reserves any rights and remedies available to it under the RCRA, the regulations promulgated thereunder and any other federal law or regulation to enforce the terms of this Consent Agreement and Final Order after its effective date.

EXECUTION /PARTIES BOUND

70. This Consent Agreement and Final Order shall apply to and be binding upon the EPA, the Respondent and the officers, directors, employees, contractors, successors, agents and assigns of Respondent. By his or her signature below, the person who signs this Consent Agreement on behalf of Respondent is acknowledging that he or she is fully authorized by the Respondent to execute this Consent Agreement and to legally bind Respondent to the terms and conditions of this Consent Agreement and Final Order.

EFFECTIVE DATE

71. The effective date of this Consent Agreement and Final Order is the date on which the Final Order, signed by the Regional Administrator of EPA, Region III, or his/her designee, the Regional Judicial Officer, is filed along with the Consent Agreement with the Regional Hearing Clerk pursuant to the Consolidated Rules of Practice.


ENTIRE AGREEMENT

72. This Consent Agreement and Final Order constitutes the entire agreement and understanding between the Parties regarding settlement of all claims for civil penalties pertaining to the specific violations alleged herein and there are no representations, warranties, covenants, terms, or conditions agreed upon between the Parties other than those expressed in this Consent Agreement and Final Order.

In Re: Aphenia Pharma Solutions – Maryland, LLC
EPA Docket No. RCRA-03-2021-0016

For Respondent: Aphenia Pharma Solutions – Maryland, LLC

Date: 2/2/21

By: 
Name: Shawn R. Kelly
Title: CEO



For the Complainant:

After reviewing the Consent 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 Consent Agreement and recommend that the Regional Administrator, or his/her designee, the Regional Judicial Officer, issue the attached Final Order.

By: _____
Karen Melvin
Director, Enforcement and Compliance
Assurance Division
U.S. EPA – Region III
Complainant

Attorney for Complainant:

By: _____
Kathleen Root, Esq.
Sr. Assistant Regional Counsel
U.S. EPA – Region III

**BEFORE THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION III**

In the Matter of:	:	
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Aphena Pharma Solutions - Maryland, LLC	:	U.S. EPA Docket No. RCRA-03-2021-0016
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Easton, Maryland 21601	:	Proceeding under Sections 3008(a) and
	:	(g) of the Resource Conservation and
Respondent.	:	Recovery Act, as amended, 42 U.S.C.
	:	Sections 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, Aphena Pharma Solutions – Maryland, LLC, have executed a document entitled “Consent 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 Consent Agreement are accepted by the undersigned and incorporated into this Final Order as if fully set forth at length herein.

Based upon the representations of the parties in the attached Consent Agreement, the penalty agreed to therein is based upon consideration of, *inter alia*, EPA’s October 1990 RCRA Civil Penalty Policy, as revised in June, 2003 (“RCRA Penalty Policy”), which reflects the statutory penalty criteria and factors set forth at Sections 3008(a)(3) and (g) of the Resource Conservation and Recovery Act (“RCRA”), 42 U.S.C. §§ 6982(a)(3) and (g), the appropriate *Adjustment of Civil Monetary Penalties for Inflation*, pursuant to 40 C.F.R. Part 19, and the applicable EPA memoranda addressing EPA’s civil penalty policies to account for inflation.

NOW, THEREFORE, PURSUANT TO Sections 3008(a) and (g) of RCRA, as amended, 42 U.S.C. §§ 6928(a) and (g), 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 EIGHTY-TWO THOUSAND ONE HUNDRED TWENTY DOLLARS (\$82,120), in accordance with the payment provisions set forth in the Consent 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 Consent Agreement and does not waive, extinguish or otherwise affect Respondent’s obligation to comply with all applicable provisions of RCRA Subtitle C and the regulations promulgated thereunder.

In Re: Aphenia Pharma Solutions – Maryland, LLC
EPA Docket No. RCRA-03-2021-0016

The effective date of the attached Consent Agreement and this Final Order is the date on which this Final Order is filed with the Regional Hearing Clerk.

Date

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

**BEFORE THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION III**

In the Matter of: :

Aphena Pharma Solutions - Maryland, LLC : **U.S. EPA Docket No. RCRA-03-2021-0016**

7978 Industrial Park Road :

Easton, Maryland 21601 :

Respondent. : **Proceeding under Sections 3008(a) and**

: **(g) of the Resource Conservation and**

: **Recovery Act, as amended, 42 U.S.C.**

: **Sections 6928(a) and (g)**

:

CERTIFICATE OF SERVICE

I certify that on _____, the original and one (1) copy of the foregoing ***Consent Agreement and Final Order***, were 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:

Copy served via ELECTRONIC TRANSMITTAL to:

Mr. David Schrader, Esq.
Paykin Krieg & Adams, LLP
Email: dschrader@pka-law.com
Phone: (212) 725-4423

Copies served via ELECTRONIC TRANSMITTAL, or Hand Delivery or Inter-Office Mail to:

Kathleen J. Root, Esq.
Sr. Assistant Regional Counsel
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Compliance Officer
Enforcement and Compliance Assurance
Division (3ED22)
U.S. EPA, Region III
1650 Arch Street
Philadelphia, PA 19103
matlin.martin@epa.gov

Dated: _____

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