

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

In the matter of:	:	
	:	
Jubilant Cadista Pharmaceuticals Inc.	:	U.S. EPA Docket RCRA-03-2017-0142
207 Kiley Drive	:	
Salisbury, MD 21808	:	
	:	
Respondent,	:	Proceeding under Section 3008(a) and (g)
	:	of the Resource Conservation and
	:	Recovery Act, as amended,
Jubilant Cadista Pharmaceuticals Inc.	:	42 U.S.C. § 6928(a) and (g)
207 Kiley Drive	:	
Salisbury, MD 21808	:	
	:	
Facility.	:	
	:	

RCRA-03-2017-0142
F112446

CONSENT AGREEMENT

I. PRELIMINARY STATEMENT

1. This Consent Agreement is entered into by the Director of the Land and Chemicals Division (“Complainant”), U.S. Environmental Protection Agency, Region III (“EPA” or the “Agency”), and Jubilant Cadista Pharmaceuticals Inc. (“Respondent”), pursuant to Section 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 Rules of Practice*”), 40 C.F.R. Part 22, including, specifically, 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3).

2. The *Consolidated Rules of Practice*, at 40 C.F.R. § 22.13(b), provide, in pertinent part, that where the parties agree to settlement of one or more causes of action before the filing of a complaint, a proceeding simultaneously may be commenced and concluded by the issuance of a consent agreement and final order pursuant to 40 C.F.R. § 22.18(b)(2) and (3). Pursuant thereto, this Consent Agreement and the accompanying Final Order simultaneously commence and conclude this administrative proceeding against the Respondent.

3. 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).
4. Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), authorizes EPA to initiate an enforcement action whenever it is determined 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 of a civil penalty against any person who violates any requirement of Subtitle C of RCRA.
5. This Consent Agreement (“CA”) and the accompanying Final Order (“FO”) (collectively, the “CAFO”) address alleged violations by Respondent of Subtitle C of RCRA, 42 U.S.C. §§ 6921–6939g, certain federally-authorized Maryland hazardous waste regulations, set forth at COMAR, Title 26, Subtitle 13 *et seq.*, and certain of the federal hazardous waste regulations, set forth at 40 C.F.R. Parts 260–266 and 273, for which the State of Maryland has not been granted authorization to administer in lieu of the federal hazardous waste management program under HSWA, in connection with Respondent’s facility. Respondent’s facility is located at 207 Kiley Drive Salisbury, MD 21808 (“Facility”) and is further described below.
6. Factual allegations or legal conclusions in this CA that are based on provisions of federally-authorized MdHWMR cite those respective provisions as the authority for such allegations or conclusions.
7. In accordance with Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2), and by written letter dated December 20, 2016, EPA notified the Maryland Department of the Environment (“MDE”) of EPA’s intent to commence this administrative action against Respondent in response to the violations of RCRA Subtitle C that are alleged herein.

II. GENERAL PROVISIONS

8. For purposes of this proceeding only, Respondent admits the jurisdictional allegations set forth in this CAFO.

9. Respondent neither admits nor denies the specific factual allegations or the conclusions of law contained in the CAFO, except as provided in Paragraph 8, above.
10. Respondent agrees not to contest EPA's jurisdiction with respect to the execution of this Consent Agreement, the issuance of the attached Final Order, or the enforcement of this CAFO.
11. For purposes of this proceeding only, Respondent hereby expressly waives its right to contest the allegations set forth in this Consent Agreement and any right to appeal the accompanying Final Order.
12. Respondent consents to the issuance of this CAFO and agrees to comply with its terms and conditions.
13. Respondent shall bear its own costs and attorney's fees.
14. This CAFO shall not relieve Respondent of its obligations to comply with all applicable provisions of federal, state or local law, nor shall it be construed to be a ruling on, or determination of, any issue related to any federal, state or local permit; nor does this CAFO constitute a waiver, suspension or modification of the requirements of RCRA Subtitle C, 42 U.S.C. §§ 6921-6939g, or any regulations promulgated and/or authorized thereunder.

III. EPA FINDINGS OF FACT AND CONCLUSIONS OF LAW

15. In accordance with the *Consolidated Rules of Practice* at 40 C.F.R. §§22.13(b) and 22.18(b)(2) and (3), Complainant makes the following findings of fact and conclusions of law:
16. EPA has jurisdiction over this matter pursuant to RCRA Section 3008(a) and (g), 42 U.S.C. § 6928(a) and (g).
17. Respondent is a corporation incorporated in the State of Maryland. Respondent is now, and was at the time of the violations alleged herein, a "person" as that term is defined in Section 1004(15) of RCRA, 42 U.S.C. Section 6903(15), and COMAR 26.13.01.03B(61).
18. The Facility is located in a building of approximately 200,000 square feet, and has been in operation for approximately 14 years. The Facility manufactures generic pharmaceuticals in a tablet or capsule form.
19. On October 23, 2007, Respondent submitted a Notification of Hazardous Waste Activity ("Notification") for the Facility to the Maryland Department of the Environment ("MDE"), pursuant to Section 3010 of RCRA, 42 U.S.C. § 6930, to EPA, Region III, identifying the Facility as a generator of hazardous waste. Subsequently, the Facility was

- assigned EPA I.D. Number MDR000518225. The Facility does not have a permit for the treatment, storage or disposal of hazardous wastes.
20. At all times relevant to the allegations set forth in this CA, Respondent is, and has been, the “operator” and the “owner” of the Facility, as those terms are defined in COMAR 26.13.01.03.B(58) and (59).
 21. As described below, at all times relevant to the allegations set forth in this CA, Respondent is, and has been, a “generator” of “solid waste” and “hazardous waste” at the Facility, as these terms are defined in COMAR 26.13.01.03.B(29), (73) and (31). Respondent generates lab solvent waste (EPA Hazardous Waste Nos. D001, D035, F002, F003, F005), corrosive cleaner waste (EPA Hazardous Waste No. D002), and rags and other waste from small-scale cleanups (EPA Hazardous Waste No. D001).
 22. At all times relevant to the allegations set forth in this CA, and as described below, Respondent is, and has been, engaged in the temporary “storage” of “solid waste” and “hazardous waste” in “containers” at the Facility, as those terms are defined in COMAR 26.13.01.03.B(9), (31), (73), and (76).
 23. On March 22 and 23, 2016, three duly-authorized representatives of EPA (“EPA Inspectors”) conducted a Compliance Evaluation Inspection (the “CEI” or “Inspection”) at the Facility, to examine the Respondent’s compliance with the federally-authorized MdHWMR and applicable federal hazardous waste regulations.
 24. On February 8, 2017, EPA sent a Request to Show Cause (“Show Cause 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 as it believed the Agency should review and consider before reaching any final conclusions as to the Respondent’s compliance with the MdHWMR and federal hazardous waste regulations at the Facility.
 25. On the basis of EPA’s findings during the Inspection and Respondent’s response to EPA’s Show Cause letter, 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.
 26. At all times relevant to the allegations set forth in this CA, Respondent’s Facility is, and has been, a hazardous waste storage “facility” as that term is defined in COMAR 26.13.01.03.B(23).

COUNT I

(Operating a Treatment, Storage, and Disposal Facility without a Permit or Interim Status)

27. The information in the preceding Paragraphs is incorporated herein by reference, as though fully set forth at length.

28. Pursuant to Section 3005(a) and (e) of RCRA, 42 U.S.C. § 6925(a) and (e), and COMAR 26.13.07.01A, with exceptions not relevant to this matter, no person may own or operate a facility for the treatment, storage or disposal of hazardous waste without first obtaining a permit or interim status for such facility.
29. Respondent has never had a permit or interim status, pursuant to COMAR 26.13.07.01 or Section 3005(a) of RCRA, 42 U.S.C. § 6925(a), for the storage of hazardous waste at the Facility.

Generator Accumulation of Hazardous Waste (the "Generator Permit Exemption")

30. COMAR 26.13.03.05E(1) provides:
 - E. Accumulation Time.
 - (1) A generator may accumulate hazardous waste on-site without a permit or without holding interim status for 90 days or less if:
 - (a) The waste is shipped off-site within 90 days to a permitted facility or placed in an on-site permitted facility;
 - (b) The generator accumulates the waste:
 - (i) In containers,
 - (ii) In tanks, or
 - (iii) On drip pads, if the waste is drippage from a wood-preserving process, precipitation, or surface water run-on;
 - (iv) In a containment building;
 - (c) Containers used to accumulate the waste meet the standards of §A of this regulation;
 - (d) The generator accumulates the waste in containers in accordance with COMAR 26.13.05.09;
 - (e) The date upon which each period of accumulation begins is clearly marked and visible for inspection on each container;
 - (f) Each container is:
 - (i) Properly labeled according to §§B and C of this regulation; and
 - (ii) Labeled or marked clearly with the words "Hazardous Waste", while being accumulated on site.

- (g) The generator complies with the requirements for owners or operators in COMAR 26.13.0S.02G [personnel training], .03 [preparedness and prevention], and .04 [contingency plan and emergency procedures];

Generator Permit Exemption: Satellite Accumulation

31. COMAR 26.13.03.05(E)(3), provides, “A generator may accumulate as much as 55 gallons of hazardous waste or 1 quart of acutely hazardous waste listed in COMAR 26.13.02.19E in containers at or near any point of generation where wastes initially accumulate, which is under the control of the operator of the process generating the waste, without a permit and without complying with §E(1) provided the generator:
 - (a) Complies with COMAR 26.13.05.09B—D; and
 - (b) Marks his containers either with the words "Hazardous Waste" or with other words that identify the contents of the containers.
32. Although the provisions of COMAR 26.13.03.05E(1) provide hazardous waste generators with an exemption from the permitting requirements for the temporary accumulation (90 days or less) of hazardous waste generated by a facility (referred to here as the “90-day accumulation exemption”), Respondent failed to meet the conditions necessary to qualify for the exemption set forth in COMAR 26.13.03.05E(1).
33. At the time of the Inspection on March 22 and 23, 2016, the following acts or omissions prevented Respondent from meeting the regulatory permit exemption conditions in COMAR 26.13.03.05(E)(1):
 - a. Respondent was storing one drum of hazardous waste on-site at the Facility for a time period in excess of the 90-day storage limitation set forth at COMAR 26.13.03.05E(1). One 55-gallon drum full of “Lab Solvent Vial Waste” (EPA Hazardous Waste Nos. D001, D035, F002, F003, F005) was located in the primary hazardous waste accumulation area at the Facility, and dated December 3, 2015. This drum was sent offsite, under Manifest #015278566 JJK, on March 28, 2016. Respondent had stored this drum of hazardous waste at the Facility for a total of 115 days, which was 25 days beyond the 90-day storage limitation.
 - b. Respondent was storing two containers of expired corrosive CIP 200 cleaner (EPA Hazardous Waste No. D002), and a red 10-gallon container of rags and other waste from small-scale cleanups (EPA Hazardous Waste No. D001), near the entrance of Warehouse 2021. These containers were not clearly marked with the date upon which each period of hazardous waste accumulation began, as required by the applicable permit exemption condition set forth at COMAR 26.13.03.05E(1)(e). In addition, the two containers of expired corrosive CIP 200 cleaner were not labelled or marked clearly with the words “Hazardous Waste,” as required by the applicable permit exemption condition set forth at of COMAR 26.13.03.05E(1)(f)(ii).

- c. Respondent failed to keep eight containers of spent High-Performance Liquid Chromatography (“HPLC”) solvent (EPA Hazardous Waste Nos. D001, D035, F005 ignitable and listed wastes) and a box of hazardous waste lamps closed except as needed to add or remove waste, as further described in Count II, below, as required by COMAR 26.13.05.09D, and the applicable permit exemption condition set forth at COMAR 26.13.03.05E(1)(d).
 - d. Respondent failed to prepare and maintain adequate personnel records with job titles and descriptions, as further described in Count III, below, as required by COMAR 26.13.05.02G(4)(a) and (b), and the applicable permit exemption condition set forth at COMAR 26.13.03.05E(1)(g).
 - e. Respondent failed to maintain at the Facility an adequate Contingency Plan for the Facility, as further described in Count IV, below, as required by COMAR 26.13.05.04B and C, and the applicable permit exemption condition set forth at COMAR 26.13.03.05E(1)(g).
34. For each of the reasons and during each of the dates and time periods identified in Paragraph 33, above, Respondent failed to comply with the permit exemption conditions set forth in COMAR 26.13.03.05E(1), as identified in Paragraphs 30 and 31, above, for temporary (*i.e.*, 90 days or less) and satellite accumulation of hazardous waste by a generator at the Facility, and therefore failed to qualify for an exemption from the permitting/interim status requirements provided by such sections.
 35. From March 3, 2016 through March 28, 2016, for each of the reasons identified in Paragraph 33, above, Respondent engaged in the operation of a hazardous waste storage facility (*i.e.*, the Facility) without having interim status or obtaining a permit for the Facility pursuant to Section 3005(a) and (e) of RCRA, 42 U.S.C. § 6925(a) and (e), or COMAR 26.13.07.01A.

COUNT II
(Failure to Keep Hazardous Containers Closed
Except as Needed to Add or Remove Waste)

36. The allegations in the preceding Paragraphs are incorporated herein by reference, as though fully set forth at length.
37. The provisions of COMAR 26.13.05.09D, pertaining to the “Management of Containers,” require that “[a] container holding hazardous waste shall always be kept closed during storage, except when it is necessary to add or remove waste, and the container may not be opened, handled, or stored in any manner which may rupture the container or cause it to leak.”
38. At the time of the March 22 and 23, 2016 Inspection, eight containers of spent High-Performance Liquid Chromatography (“HPLC”) solvent (EPA Hazardous Waste Nos.

D001, D035, F005 ignitable and listed wastes) were open at a time when waste was not being added or removed.

39. At the time of the Inspection, Respondent was also storing an open box containing more than 60 mercury-containing waste lamps (EPA Characteristic Hazardous Waste D009) in the RM 3015: Plant Central Utility (main room).
40. On March 22 and 23, 2016, Respondent violated the requirements of COMAR 26.13.05.09D by failing to keep containers holding hazardous waste closed except when it is necessary to add or remove waste.

COUNT III

(Failure to Maintain Records Which Document Job Titles and Descriptions)

41. The allegations in the preceding Paragraphs are incorporated herein by reference, as though fully set forth at length.
42. COMAR 26.13.05.02G(1) – (5), pertaining to “Personnel Training,” requires the owner or operator of a hazardous waste facility to provide initial hazardous waste training and an annual refresher training to each person employed in a position related to hazardous waste management. The program may consist of classroom instruction or on-the-job training that teaches employees to perform their duties in a way that ensures the facility’s compliance with the applicable hazardous waste regulations. Records documenting the training completed by current facility personnel must be kept until closure of the facility.
43. COMAR 26.13.05.02G(4) further requires the owner and operator of a hazardous waste facility to maintain records, which document (a) the job title for each position at the facility related to hazardous waste management and the name of the employee filling each job, (b) a written job description of each such position, (c) a written description of the type and amount of introductory and continuing training that will be given to each person filling such position, and (d) records that document the training and job experience given to and completed by facility personnel who perform hazardous waste management.
44. At the time of the Inspection on March 22 and 23, 2016, Respondent’s Facility records did not document a written job description for the Backup Emergency Coordinator, and did not document a written description of the type and amount of introductory and continuing training that would be given to the person filling this position.
45. On March 22 and 23, 2016, Respondent violated the requirements of COMAR 26.13.05.02G(4)(b) by failing to have Facility records that document a written job description for the Backup Emergency Coordinator at the Facility.

- 46. On March 22 and 23, 2016, Respondent violated the requirements of COMAR 26.13.05.02G(4)(c) by failing to have Facility records that document a written description of the type and amount of both introductory and continuing training to be given to the person serving as Backup Emergency Coordinator at the Facility.

COUNT IV
(Failure to Maintain Adequate Contingency Plan)

- 47. The allegations in the preceding Paragraphs are incorporated herein by reference, as though fully set forth at length.
- 48. The provisions of COMAR 26.13.05.04, pertaining to the “Contingency and Emergency Procedures,” provide as follows:

- A. Applicability. This regulation applies to owners and operators of all hazardous waste facilities [with an exception not herein applicable].

- B. Purpose and Implementation of Contingency Plan.

- (1) Every owner or operator shall have a contingency plan for his facility . . . designed to minimize hazards to human health and the environment from fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water. . . .

- C. Content of Contingency Plan.

- (1) The contingency plan shall describe the actions facility personnel shall take . . . in response to fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water at the facility[;]

* * *

- (3) The plan shall describe the arrangements agreed to by local police departments, fire departments, hospitals, contractors, and State and local emergency response teams to coordinate emergency services[;]

- (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[;]

- (5) The plan shall include a list of emergency equipment at the facility [; and]

(6) The plan shall include an evacuation plan for facility personnel . . .” .

D. Copies of Contingency Plan. A copy of the contingency plan and all revisions to the plan shall be:

(1) Maintained at the facility

49. At the time of the March 22 and 23, 2016 Inspection, Respondent’s Facility Emergency Evacuation/Spill Response/Fire Protection Guide, which serves as Respondent’s Contingency Plan, with an effective date of September 10, 2010, failed to include any emergency contact information for the emergency coordinators, and did not list any spill equipment or the location of such equipment. Furthermore, the document did not describe the arrangements agreed to by local police departments, fire departments, hospitals, contractors, and State and local emergency response teams to coordinate emergency services.

50. From September 10, 2010 to March 23, 2016, Respondent violated the requirements of COMAR 26.13.05.04C(3), (4) and (5), by then failing to have a contingency plan that included arrangements by local response organizations to coordinate emergency services, contact information for the emergency coordinators, or a list of spill equipment and its location.

COUNT V

(Failure to Submit Timely and Complete Biennial Report)

51. The allegations in the preceding Paragraphs are incorporated herein by reference, as though fully set forth at length.

52. The provisions of COMAR 26.13.03.06.B(1), pertaining to “Record Keeping and Reporting, Annual or Biennial Reporting” requires:

“(1) A person who generates hazardous waste and ships it off-site to a facility within the United States shall:

(a) Periodically submit reports to the [MDE] Secretary concerning the hazardous waste generated during the preceding calendar year on EPA or State Form 8700-13A, or on an alternate form provided by the Secretary;

(b) Submit the reports required by § B(1)(a) of this regulation with the following frequency:

. . .

(ii) Biennially for reporting periods beginning January 1, 1997.

. . . and

(c) Submit the reports required by § B(1)(a) of this regulation not later than:

...

(ii) March 1 of each even numbered year for the preceding calendar year for reporting periods beginning January 1, 1997; and

(d) Assure that the reports required by § B(1)(a) of this regulation contain, at a minimum, the following information:

...

(v) For shipments of hazardous waste to a treatment storage or disposal facility within the United States, the description, the EPA or State hazardous waste number from COMAR 26.13.02, the DOT hazard class, and the quantity of each hazardous waste listed by the EPA identification number of each off-site facility to which the waste was shipped.

53. Respondent failed to submit its Biennial Report for the calendar year 2013 in a complete and timely manner. The Biennial Report for 2013 was due by March 1, 2014. While Respondent first submitted this Report on February 6, 2014, the Report was incomplete because Respondent had failed to include the quantity of each hazardous waste shipped to each off-site facility on a form known as the "GM Form." Respondent revised its Biennial Report to include the missing information, and resubmitted its Biennial Report for the year 2013 on October 10, 2014.
54. From March 1, 2014 to October 10, 2014, Respondent violated COMAR 26.13.03.06.B(1) by failing to timely submit a complete Biennial Report to MDE for calendar year 2013.

IV. CIVIL PENALTIES

55. Respondent agrees to pay a civil penalty in the amount of **\$35,000.00 (THIRTY-FIVE THOUSAND DOLLARS)** in full and final settlement and satisfaction of all civil claims for penalties which Complainant may have concerning the violations and facts alleged and set forth in Section III ("EPA Findings of Fact and Conclusions of Law") of this Consent Agreement. Such civil penalty shall become due and payable immediately upon Respondent's receipt of a true and correct copy of this CAFO. In order to avoid the assessment of interest, administrative costs and late payment penalties in connection with such civil penalty, Respondent must pay such civil penalty no later than thirty (30) calendar days after the date on which a copy of this CAFO is mailed or hand-delivered to Respondent.
56. The civil penalty settlement amount set forth in Paragraph 55, immediately above, was determined after consideration of the statutory factors set forth in Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), which include 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 Section 3008(a)(3) and (g) of RCRA, 42 U.S.C. §§ 6928(a)(3) and (g). Complainant has also considered the Adjustment of Civil Monetary Penalties for Inflation, 40 C.F.R. Part 19, and the July 27, 2016 Memorandum by EPA Assistant Administrator, Cynthia Giles, entitled, "Amendments to the U.S. Environmental Protection Agency's Civil Penalty Policies to Account for Inflation," (effective August 1, 2016). The settlement in this proceeding is consistent with the provisions and objectives of Section 3008 of RCRA, and its implementing regulations.

57. Payment of the civil penalty set forth in Paragraph 55, above, plus any interest, administrative fees, and late payment penalties owed, in accordance with Paragraphs 59 through 62, below, shall be made by either cashier's check, certified check, or electronic wire transfer, in the following manner:
- a. All payments by Respondent shall reference Respondent's name and address, and the EPA Docket Number of this Consent Agreement, i.e., RCRA03-2017-0142;
 - b. All checks shall be made payable to "**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
 - Fine and Penalties
 - Cincinnati Finance Center
 - P.O. Box 979077
 - St. Louis, MO 63197-9000Customer service contact: 513-487-2091
 - d. All payments made by check and sent by overnight delivery service shall be addressed and mailed to:
 - U.S. Environmental Protection Agency
 - Cincinnati Finance Center
 - Government Lockbox 979077
 - 1005 Convention Plaza
 - Mail Station SL-MO-C2-GL
 - St. Louis, MO 63101Contact: 314-418-1818
 - e. All payments made by check in any currency drawn on banks with no USA branches shall be addressed for delivery to:

Cincinnati Finance
US EPA, MS-NWD
26 W. M.L. King Drive
Cincinnati, OH 45268-0001

- f. All payments made by electronic wire transfer shall be directed to:

Federal Reserve Bank of New York
ABA = 021030004
Account = 68010727
SWIFT address = FRNYUS33
33 Liberty Street
New York, NY 10045

Field Tag 4200 of the Fedwire message should read:
“D 68010727 Environmental Protection Agency”

- g. All electronic payments made through the Automated Clearinghouse (ACH), also known as Remittance Express (REX), shall be directed to:

US Treasury REX / Cashlink ACH Receiver
ABA = 051036706
Account No.: 310006, Environmental Protection Agency
CTX Format Transaction Code 22 - Checking

Physical location of U.S. Treasury facility:
5700 Rivertech Court
Riverdale, MD 20737

Contact: 866-234-5681

- h. On-Line Payment Option: WWW.PAY.GOV/paygov/

Enter **sfo 1.1** in the search field. Open and complete the form.

- i. Additional payment guidance is available at:

<http://www2.epa.gov/financial/makepayment>

or by contacting Craig Steffen at 513-487-2091

58. At the time of payment, Respondent shall send a notice of such payment, including a copy of the check or electronic fund transfer, as applicable, to:

Ms. Lydia Guy
Regional Hearing Clerk (3RC00)

U.S. EPA, Region III
1650 Arch Street
Philadelphia, PA 19103-2029;

and

Natalie Katz
Sr. Assistant Regional Counsel (3RC30)
U.S. EPA, Region III
1650 Arch Street
Philadelphia, PA 19103-2029.

59. Pursuant to 31 U.S.C. § 3717 and 40 C.F.R. § 13.11, EPA is entitled to assess interest, administrative costs 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 or to comply with the conditions in this CAFO shall result in the assessment of late payment charges including interest, penalties, and/or administrative costs of handling delinquent debts.
60. In accordance with 40 C.F.R. § 13.11(a), interest on any civil penalty assessed in a CAFO begins to accrue on the date that a copy of the CAFO is mailed or hand-delivered to the Respondent. However, EPA will not seek to recover interest on any amount of such civil penalty 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).
61. The costs of the Agency'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 - Cash 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.
62. A late payment penalty of six percent (6%) per year will be assessed monthly on any portion of a civil penalty which remains delinquent more than ninety (90) calendar days. 40 C.F.R. § 13.11(c). Should assessment of the penalty charge on a debt be required, it shall accrue from the first day payment is delinquent. 31 C.F.R. § 901.9(d).
63. The Respondent agrees not to deduct for federal tax purposes the civil monetary penalty specified in this Consent Agreement and the accompanying Final Order.

V. CERTIFICATIONS

64. Respondent certifies to Complainant by its signature hereto, to the best of Respondent's knowledge and belief, that Respondent is in compliance with all relevant provisions of the current, authorized revised MdHWMR and of RCRA Subtitle C, 42 U.S.C. §§ 6921-6939g, for which violations are alleged in this Consent Agreement.

VI. OTHER APPLICABLE LAWS

65. Nothing in this CAFO shall relieve Respondent of any duties otherwise imposed upon it by applicable federal, state, or local law and/or regulation.

VII. RESERVATION OF RIGHTS

66. This CAFO resolves only EPA's claims for civil penalties for the specific violations and facts which are alleged in this Consent Agreement. Nothing in this CAFO shall be construed as limiting the authority of EPA to undertake action against any person, including the 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 Section 22.18(c) of the Consolidated Rules of Practice. Further, EPA reserves any rights and remedies available to it under RCRA, the regulations promulgated thereunder, and any other federal laws or regulations for which EPA has jurisdiction, to enforce the provisions of this CAFO following its filing with the Regional Hearing Clerk.

VIII. FULL AND FINAL SATISFACTION

67. This settlement shall constitute full and final satisfaction of all civil claims for penalties which Complainant has under RCRA Section 3008(a) and (g), 42 U.S.C. § 6928(a) and (g), for the violations alleged in this Consent Agreement.

IX. PARTIES BOUND

68. This CAFO shall apply to and be binding upon the EPA, the Respondent, Respondent's officers and directors (in their official capacity) and Respondent's successors and assigns. By his or her signature below, the person signing this Consent Agreement on behalf of Respondent acknowledges that he or she is fully authorized to enter into this Consent Agreement and to bind the Respondent to the terms and conditions of this CAFO.

X. EFFECTIVE DATE

69. The effective date of this CAFO is the date on which the Final Order is filed with the Regional Hearing Clerk after signature by the Regional Administrator or his designee, the Regional Judicial Officer.

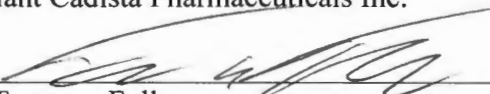
XI. ENTIRE AGREEMENT

70. This CAFO constitutes the entire agreement and understanding of the parties concerning settlement of the above-captioned action and there are no representations, warranties, covenants, terms or conditions agreed upon between the parties other than those expressed in this CAFO.

For Respondent:

Jubilant Cadista Pharmaceuticals Inc.

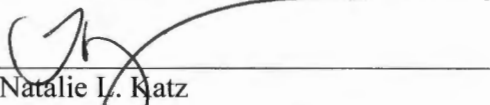
Date: 5/26/17

By: 
Terrence Fullem
President

For the Complainant:

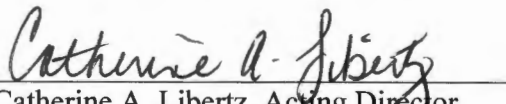
U.S. Environmental Protection Agency, Region III

Date: 5/30/2017

By: 
Natalie L. Katz
Sr. Assistant Regional Counsel

After reviewing the EPA Findings of Fact and Conclusions of Law and other pertinent matters, the Land and Chemicals Division of the United States Environmental Protection Agency, Region III, recommends that the Regional Administrator, or his designee, the Regional Judicial Officer, issue the attached Final Order.

Date: 6-2-17

By: 
Catherine A. Libertz, Acting Director
Land and Chemicals Division

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

In the matter of:	:	
	:	
Jubilant Cadista Pharmaceuticals Inc. 207 Kiley Drive Salisbury, MD 21808	:	U.S. EPA Docket RCRA-03-2017-0142
	:	
Respondent,	:	Proceeding under Section 3008(a) and (g)
	:	of the Resource Conservation and
	:	Recovery Act, as amended,
Jubilant Cadista Pharmaceuticals Inc. 207 Kiley Drive Salisbury, MD 21808	:	42 U.S.C. § 6928(a) and (g)
	:	
	:	
Facility.	:	
	:	

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FINAL ORDER

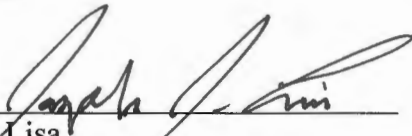
Complainant, the Director, Land and Chemical Division, U.S. Environmental Protection Agency, Region III, and Jubilant Cadista Pharmaceuticals Inc. (“Respondent”), have executed a document entitled “Consent Agreement,” which I hereby ratify as a Consent Agreement in accordance with the Consolidated Rules 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. § 22.18(b)(2) and (3). The terms of the foregoing Consent Agreement are accepted by the undersigned and incorporated herein as if 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”), and the statutory factors set forth in Section 3008(a) of RCRA, 42 U.S.C. § 6928(a).

NOW, THEREFORE, PURSUANT TO Section 3008(a) and (g) of the Resource Conservation and Recovery Act, 42 U.S.C. § 6928(a) and (g) (“RCRA”), and Section 22.18(b)(3) of the Consolidated Rules of Practice, **IT IS HEREBY ORDERED** that Respondents pay a civil penalty payment **\$35,000.00 (THIRTY-FIVE THOUSAND DOLLARS)**, in accordance with the payment provisions set forth in of the Consent Agreement, and comply with the terms and conditions of the Consent Agreement.

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

June 7, 2017
Date:



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

