RCRA Inspection Report

1) Inspector and Author of Report

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U.S. Environmental Protection Agency, Region 4
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2) Facility Information

Aveva Drug Delivery Systems, Inc.
3280 Executive Way
Miramar, Florida 33025
EPA ID No: FLR000153304

3) Responsible Officials

Scott Schneider, Sr. Manager Environmental Health & Safety
sschneid@apotex.com

4) Inspection Participants

Kayla Acosta, US Environmental Protection Agency, Region 4
Tarin Tischler, FL Department of Environmental Protection (FDEP)
Romina Lancellotti, FDEP
Michele De Freitas, FDEP
Scott Schneider, Aveva Drug Delivery Systems, Inc.
Michael Cichon, Aveva Drug Delivery Systems, Inc.

5) Date of Inspection

January 26, 2022

6) Applicable Regulations

Resource Conservation and Recovery Act (RCRA) Sections 3002, 3005 and 3007 (42 U.S.C. §§ 6922, 6925 and 6927), and the regulations promulgated pursuant thereto at 40 Code of Federal Regulations (C.F.R.) Parts 260-270, 273 and 279.

Florida Statutes (F.S.) Chapter 403.702 et seq., and the regulations promulgated pursuant thereto and set forth at the Florida Administrative Code (Fla. Admin. Code Ann. r.), Chapters 62-

710, 62-730 and 62-750.

As the State's authorized hazardous waste program operates in lieu of the federal RCRA program, the citations of those authorized provisions alleged herein will be to the authorized State program; however, for ease of reference, the federal citations will follow in brackets.

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.17], a LQG may accumulate hazardous waste on-site for 90 days or less without a permit or without having interim status, as required by Section 403.722 of the Florida Statutes, Fla. Stat. § 403.722 [Section 3005 of RCRA, 42 U.S.C. § 6925], provided that the generator complies with the conditions listed in Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.17] (hereinafter referred to as the "LQG Permit Exemption").

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.15(a)], a generator may accumulate as much as 55 gallons of non-acute hazardous waste in containers at or near the point of generation where wastes initially accumulate, which is under the control of the operator of the process generating the waste, without a permit or without having interim status, as required by Section 403.722 of the Florida Statutes, Fla. Stat. § 403.722 [Section 3005 of RCRA, 42 U.S.C. § 6925], and without complying with Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.16(b) or §262.17(a)], except as required in Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.15(a)(7) and (8)], provided that the generator complies with the satellite accumulation area conditions listed in Fla. Admin. Code Ann. r. 62-730.160(1) [40 C.F.R. § 262.15(a)] (hereinafter referred to as the "SAA Permit Exemption").

7) Purpose of Inspection

The purpose of this inspection was to conduct a compliance evaluation inspection to determine Aveva's compliance with the applicable requirements of RCRA and the corresponding FDEP regulations.

8) Previous Inspection History

The last RCRA CEI was conducted by FDEP on 12/15/2016. No violations were identified.

9) Facility Description

Aveva Drug Delivery Systems, Inc. (known hereinafter as ADDS or the facility), began operations in this location in 2012. The company itself has been in operation for approximately 25 years. The ADDS property is roughly 25,000 sq ft. The facility operates two shifts that run from 7:00am-3:30pm and 3:00pm-11:30pm, Monday through Friday. ADDS employs 10-15 workers when in operating the process packaging lines.

ADDS first notified as a Large Quantity Generator (LQG) of hazardous waste on 12/21/2010. The facility submitted their most recent notification along with their biennial report on February 14, 2020. The EPA hazardous waste codes identified in the report include: D001 and P075. The facility does not appear to generate universal wastes such as spent mercury lamps since a third-party contractor manages building maintenance and ships them offsite for proper disposal. ADDS operates under the NAICS Code: 325412 – Pharmaceutical Preparation Manufacturing.

ADDS manufactures a variety of transdermal pharmaceutical patches which includes nicotine patches. Nicotine patches are manufactured at 7 mg, 14 mg, and 21 mg. ADDS produces 1 – 1.25 batches a week with over half a million transdermal patches per batch. The nicotine patches are manufactured in a separate ADDS facility in an adjacent building on 3250 Commerce Pkwy., which operates as a separate LQG (EPA ID FLD982143315). At the ADDS manufacturing facility (FLD982143315) active nicotine pharmaceuticals, adhesives, solvents, and excipients are blended in a 12-hour to 5-day process. The mix is then pumped to coating lines and scraped onto very thin liners and cooked in an industrial oven where solvents are volatized. Next, the laminated nicotine product is trimmed and lined with a sheet of backing material to prevent the layer of nicotine-containing adhesive from sticking to itself. The sheets of laminated nicotine adhesive are then rolled and packaged before being transferred to this ADDS facility (EPA ID FLR000153304) at 3280 Executive Way.

ADDS at 3280 Executive Way, operates as the packaging and shipping facility for the transdermal pharmaceutical patches, including the 14 mg and 21 mg strength nicotine patches. The 7 mg nicotine patches are packaged and shipped in the ADDS manufacturing facility at 3250 Commerce Pkwy. The laminated rolls arrive in sealed bags from the manufacturing facility and are placed in the material staging area. The laminate rolls are then placed onto the shaft in the packaging machine where a portion of the material is unwound and spliced with the previous laminate roll. The packaging machine is then restarted to resume punching individual square units or "patches" which are then packaged and shipped offsite. The remaining punched out rolls or "skeleton" is rewound at the opposite end of the packaging machine. The skeleton roll is removed from the rewind shaft along with rejected splice material which is inserted into the core of the skeleton roll. The skeleton roll is then placed into a bag which is sealed and labeled as hazardous waste and later transported to the facility's second central accumulation area (CAA).

The facility is comprised of administrative offices, a material staging area, three packaging lines (HH1, HH2, and the Delta Packaging Room), a secondary packaging area, two CAAs, and a warehouse. Hazardous wastes generated at the facility include the skeleton waste of the nicotine laminate roll (P075), 70%-99% Isopropyl Alcohol and solvent-contaminated wipes used for cleaning surfaces (D001) and spent aerosol cans which are managed as (D001) hazardous waste.

10) Opening Conference

On January 26, 2022, EPA inspector Kayla Acosta accompanied by FDEP inspectors Tarin Tischler, Romina Lancellotti, and Michele De Freitas arrived at ADDS at approximately 10:15 a.m. Mr. Scott Schneider, Sr. Manager EH&S and Mr. Michael Cichon, EH&S Specialist received the inspectors. The inspectors introduced themselves, showed their credentials, and explained the purpose of the visit. The inspectors described the anticipated use of a digital camera during the inspection, and discussed the company's ability, pursuant to 40 C.F.R. §2.203, to assert a business confidentiality claim for information submitted to the EPA. The company did not assert a business confidentiality claim.

Facility representatives provided an overview of the facility's history and current operations during the opening conference. The company does not appear to meet the Small Business Regulatory Enforcement Fairness Act's classification of a "small business," which is generally

set by the Small Business Administration using the business' SIC/NAICS code and annual receipts or number of employees. Therefore, the EPA inspectors did not provide a copy of the agency's information sheet for small businesses, which can be found at https://www.epa.gov/sites/production/files/2017-06/documents/smallbusinessinfo.pdf.

The inspection participants also discussed health and safety protocols and required personal protective equipment (PPE) before Mr. Schneider and Mr. Cichon led the inspectors on a tour of the Facility operations.

11) Findings

Administrative Offices:
The administrative offices are located near the entrance of the facility on the east side of the building. Facility permits and licenses along with emergency coordinator contact information are displayed on the wall near the entrance of the facility. No hazardous waste was observed in this area.

HH2:
HH2 is located to the west of the administrative offices. It is a packaging line for 14 mg strength nicotine patches. Each packaging line is in a separate enclosed room equipped with packaging machines that unwind the laminated rolls and punch out the nicotine patches. 45 rolls of laminated nicotine adhesives are processed and packaged per batch. In front of each packaging line room is a small gowning room. Full laboratory gowning is required to enter the packaging lines. The inspectors did not enter the packaging line rooms and instead observed activities through the large windows of the rooms. HH2 was currently in use at the time of inspection. Each gowning room also contains a satellite accumulation area (SAA) for Isopropyl Alcohol (IPA) Wipes. The SAA contained one (1) 5-gallon closed container labeled "Hazardous Waste—Waste Isopropyl Alcohol Wipers". The container was also marked with an indication of hazard for flammable solid (Photo 1).

HH1:
The HH1packaging line is designated for 21 mg strength nicotine patches and is located adjacent to the HH2 packaging line. The HH1 packaging line was in the process of being set up for an incoming batch and was not currently in operation. Set up takes approximately three to four days. The inspectors observed one SAA for IPA Wipes in the HH1 gowning room. The SAA contained one (1) 5-gallon closed container labeled "Hazardous Waste—Waste Isopropyl Alcohol Wipers". The container was missing an indication of hazard (Photo 2).

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 CFR 262.15(a)(5)(ii)], a generator must mark or label its container with the following: an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National

Fire Protection Association code 704).

CORRECTED ONSITE: During the inspection, this was corrected, and facility representatives immediately placed a DOT Flammable Solids placard on the container to demonstrate an indication of hazard.

CAA1:
CAA1 is a 90-day CAA for flammable waste and located across from HH1 and HH2. CAA1 is equipped with an eyewash station, fire extinguisher, and a No Smoking sign. Emergency contacts and an evacuation map were also posted on a wall next to the CAA. The inspectors observed the following hazardous wastes:

- In a flammable cabinet: One (1) 55-gallon closed drum labeled "Hazardous Waste—Isopropyl Alcohol Wipes", dated 01/11/2022. The drum had a DOT flammable solids placard to indicate the hazard. (Photo 3).
- In the same flammable cabinet: One (1) 55-gallon closed drum of expired IPA labeled "Hazardous Waste—Isopropyl Alcohol", dated 11/12/2021. The drum had a DOT flammable liquids placard to indicate the hazard. (Photo 4).
- Next to the flammable cabinet: One (1) 3-gallon closed container labeled "Hazardous Waste—Aerosol Cans", dated 11/08/2021. The drum had a DOT flammable placard to indicate the hazard (Photo 5).

Warehouse:
The warehouse is located on the north side of the facility and stores nicotine finished products before they are shipped offsite. There is a section of the warehouse that also stores raw materials and expired products that are managed by the Research and Development (R&D) department. Once the R&D department decides the expired products are no longer of use, it is declared a waste, and managed appropriately after a waste determination is conducted. No hazardous waste was observed in the warehouse.

Materials Staging Area:
The materials staging area is located on the west side of the facility and consists of four loading docks where materials are received and shipped off. This area is also the location of CAA2 and non-hazardous pharmaceutical waste storage.

CAA2:
The second 90-day CAA is located on the west side of the facility and is primarily used to store nicotine waste. Caution signs that read "Hazardous Waste Storage Area" are displayed by the CAA (Photo 6). Emergency contact numbers and a telephone are posted near the CAA along with an evacuation map, fire extinguisher, and fire alarm. The inspectors observed the following wastes:

- One (1) cubic yard box (CYB) with a liner, enclosed in a glass case with a latch that contained closed bags of waste nicotine material from the process packaging lines. The CYB was labeled "Hazardous Waste—Waste Nicotine Material Solid" and dated 1/21/2022. The CYB also had a DOT Toxic placard displayed as an indication of hazard (Photo 7).

- One (1) CYB with a liner was empty and stored in an enclosed glass case with a latch next to the other accumulating CYB. In preparation for use, it also has a label for "Hazardous Waste—Waste Nicotine Material Solid".
- One (1) CYB with a liner that was full and with a marked weight of 439.6 kg. The CYB was tied closed on a pallet ready for shipment offsite. The CYB was labeled "Hazardous Waste—Waste Nicotine Material Solid" and dated 01/19/2022. The CYB also had a DOT Toxic placard displayed as an indication of hazard (Photo 8).

Non-hazardous Pharmaceutical Waste:
PPE used in the process packaging lines is managed as non-hazardous pharmaceutical waste. During the 2012 FDEP inspection, PPE was previously being managed as hazardous waste with an EPA waste code of P075 for nicotine waste. In the 2016 FDEP inspection report, it was noted that this PPE was being managed as non-hazardous pharmaceutical waste. To verify that the PPE was being managed appropriately when disposed of the inspectors asked to observe the process in the packaging lines to determine if PPE is or is not coming into contact with the nicotine adhesive on the laminated rolls. Since the next laminated roll would not be processed for another three hours, the inspectors asked Mr. Schneider to submit a written waste determination and a step-by-step description of their process in the packaging lines. The inspectors also asked Mr. Schneider to include photos showing employee handling the laminated rolls of nicotine adhesives.

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 CFR 262.11(f)], a small or large quantity generator must maintain records supporting its hazardous waste determinations, including records that identify whether a solid waste is a hazardous waste, as defined by 40 CFR 261.3. Records must be maintained for at least three years from the date that the waste was last sent to on-site or off-site treatment, storage, or disposal. These records must comprise the generator's knowledge of the waste and support the generator's determination, as described at paragraphs (c) and (d) of this section. The records must include, but are not limited to, the following types of information: The results of any tests, sampling, waste analyses, or other determinations made in accordance with this section; records documenting the tests, sampling, and analytical methods used to demonstrate the validity and relevance of such tests; records consulted in order to determine the process by which the waste was generated, the composition of the waste, and the properties of the waste; and records which explain the knowledge basis for the generator's determination, as described at paragraph (d)(1) of this section. The periods of record retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the Administrator.

CORRECTED: On 02/09/2022, Mr. Schneider submitted a step-by-step description with photos of the laminated nicotine rolls and skeleton waste being handled by employees to demonstrate that PPE (including gloves and lab coats) are not coming into contact with the nicotine adhesive and hazardous waste. It was further explained that the nicotine adhesive is brought to the facility already contained between a liner and the backing of the laminate material in rolls, which prevents the nicotine adhesive from sticking to itself when rolled. The nicotine adhesive is also not coated to the edge of the laminate rolls. The step-by-step description with photos and

generator knowledge was sufficient to demonstrate that the PPE does not come into direct contact with the nicotine adhesive and therefore can be managed as non-hazardous pharmaceutical waste.

Delta Packaging Room and Secondary Packaging Room:
The Delta Packaging Room and Secondary Packaging Room are side by side and share a small gowning room with an SAA. Both rooms are for a new process packaging line for transdermal patches that contain controlled substances such as Buprenorphine. The Delta Packaging room will be used for packaging of the individual units. The Secondary Packaging Room is used for bulk packaging of the pouched units. Both rooms were not in operation at the time of the inspection. In the shared gowning room, the SAA contained one (1) 5-gallon closed container labeled "Hazardous Waste—Waste Isopropyl Alcohol Wipers". The container was also marked with an indication of hazard for flammable solid (Photo 9).

PPE in the Delta Packaging Room and Secondary Packaging Room are also managed as non-hazardous pharmaceutical waste similarly to HH1 and HH2, they also do not come into direct contact with controlled substances.

Records Review

Disposal Records:
Hazardous waste manifests were available for review going back to 2019. Original generator signed copy and final signed copy of manifests along with Land Disposal Restriction notifications were available for review.

Contingency Plan:
The actions that facility personnel should take in response to an emergency are described in the facility's Hazardous Waste Contingency Plan. The plan included a Quick Reference Guide (QRG) which included a list of emergency coordinators and contact information. Equipment list and capabilities addressed include fire response, spill response, and communication. The location of fire control equipment was included in the plan. The facility had maps with evacuation routes posted throughout the facility; however, a map with evacuation routes and alternative routes was not included in the contingency plan.

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 CFR 262.261(f)], the plan must include an evacuation plan for generator personnel where there is a possibility that evacuation could be necessary. This plan must describe signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes (in cases where the primary routes could be blocked by releases of hazardous waste or fires).

CORRECTED: On 02/04/2022, Mr. Schneider submitted an updated contingency plan that included evacuation routes and an updated QRG with a new emergency coordinator who became effective shortly after the inspection. Copies of the newly updated contingency plan were also submitted to local responders pursuant to 40 CFR 262.262(a). FDEP, City of Miramar Utilities, and Triumvirate Environmental received it on 02/04/2022 via email. Miramar Police Department, Miramar Fire Department, and Memorial Hospital West received their copies on

02/08/2022 via FedEx.

Employee training / annual training and position descriptions:
Training records for online hazardous waste training and employee position descriptions were available for review. Training records are current for employees handling hazardous waste, including Mr. Michael Cichon and Mr. Scott Schneider who completed their DOT Hazardous Materials training on 1/22/2022 and annual RCRA training in 12/06/2021 and 12/09/2021 respectively.

Weekly Inspections:
Weekly container inspections were reviewed for the past three years. Container inspections appeared to be conducted on a weekly basis and all required inspection elements were documented.

12) Closing Conference

An exit meeting was held at the end of the inspection with ADDS staff to discuss preliminary conclusions and to go over the findings.

13) Inspection Findings

Based on the observations made during the inspection, Aveva Drug Delivery Systems was apparently deficient with the following RCRA requirements:

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 CFR 262.11(f)], a small or large quantity generator must maintain records supporting its hazardous waste determinations, including records that identify whether a solid waste is a hazardous waste, as defined by 40 CFR 261.3. Records must be maintained for at least three years from the date that the waste was last sent to on-site or off-site treatment, storage, or disposal. These records must comprise the generator's knowledge of the waste and support the generator's determination, as described at paragraphs (c) and (d) of this section. The records must include, but are not limited to, the following types of information: The results of any tests, sampling, waste analyses, or other determinations made in accordance with this section; records documenting the tests, sampling, and analytical methods used to demonstrate the validity and relevance of such tests; records consulted in order to determine the process by which the waste was generated, the composition of the waste, and the properties of the waste; and records which explain the knowledge basis for the generator's determination, as described at paragraph (d)(1) of this section. The periods of record retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the Administrator.

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 CFR 262.15(a)(5)(ii)], a generator must mark or label its container with the following: an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172

subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704).

Pursuant to Fla. Admin. Code Ann. r. 62-730.160(1) [40 CFR 262.261(f)], the plan must include an evacuation plan for generator personnel where there is a possibility that evacuation could be necessary. This plan must describe signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes (in cases where the primary routes could be blocked by releases of hazardous waste or fires).

14) List of Appendices

Appendix 1 – Photo Log:
{09} Photos taken on: [01/26/2022]
Photos taken by: Kayla Acosta
Photos taken with: Olympus Tough Digital Camera
EPA Property Tag: S75903

15) Signed

KAYLA ACOSTA
Digitally signed by KAYLA ACOSTA
Date: 2022.03.21 09:11:14 -04'00'

Kayla Acosta — Date
Enforcement and Compliance Specialist

Concurrence

ARACELI CHAVEZ
Digitally signed by ARACELI CHAVEZ
Date: 2022.03.22 11:17:17 -04'00'

Araceli Chavez — Date
Chief
RCRA Enforcement Section

Photo 1: The SAA contained one (1) 5-gallon closed container labeled “Hazardous Waste—Waste Isopropyl Alcohol Wipers”. The container was also marked with an indication of hazard for flammable solid.

Photo 2: The SAA contained one (1) 5-gallon closed container labeled “Hazardous Waste—Waste Isopropyl Alcohol Wipers”. The container was missing an indication of hazard. This was corrected onsite.

Photo 3: One (1) 55-gallon closed drum labeled “Hazardous Waste—Isopropyl Alcohol Wipes”, dated 01/11/2022. The drum had a DOT flammable solids placard to indicate the hazard.

Photo 4: One (1) 55-gallon closed drum labeled “Hazardous Waste—Isopropyl Alcohol”, dated 11/12/2021. The drum had a DOT flammable liquids placard to indicate the hazard.

Photo 5: One (1) 3-gallon closed container labeled “Hazardous Waste—Aerosol Cans”, dated 11/08/2021. The drum had a DOT flammable placard to indicate the hazard.


CHECKLIST BEFORE EXITING!
CAUTION
HAZARDOUS
WASTE
STORAGE AREA
CAUTION
HAZARDOUS
WASTE
STORAGE AREA
2022/01/26

Photo 6: CAA2

Photo 7: One (1) cubic yard box (CYB) with a liner, enclosed in a glass case with a latch that contained closed bags of waste nicotine material from the process packaging lines. The CYB was labeled "Hazardous Waste—Waste Nicotine Material Solid" and dated 1/21/2022. The CYB also had a DOT Toxic placard displayed as an indication of hazard.

Photo 8: One (1) CYB with a liner that was full and with a marked weight of 439.6 kg. The CYB was tied closed on a pallet ready for shipment offsite. The CYB was labeled “Hazardous Waste—Waste Nicotine Material Solid” and dated 01/19/2022. The CYB also had a DOT Toxic placard displayed as an indication of hazard.

Photo 9: SAA for Delta Packaging and Secondary packaging contained one (1) 5-gallon closed container labeled “Hazardous Waste—Waste Isopropyl Alcohol Wipers”. The container was also marked with an indication of hazard for flammable solid.