

RCRA Inspection Report

1) Inspector and Author of Report

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U.S. Environmental Protection Agency,
Region 4
Enforcement and Compliance Assurance
Division
Chemical Safety and Land Enforcement
Branch
61 Forsyth Street, S.W.
Atlanta, Georgia 30303

2) Facility Information

Noven Pharmaceuticals
11960 SW 144th St
Miami, FL 33186

EPA ID # FL0000545921
NAICS # 325412 –
Pharmaceutical Preparation
Manufacturing

3) Responsible Officials

Juan C. Fernandez
Associate Director-Facility &
Security
Noven Pharmaceuticals, Inc.
JFernandez@noven.com

4) Inspection Participants

Clement Aikens
Noven Pharmaceuticals, Inc.
Senior Manager DEA Compliance

Juan C. Fernandez
Noven Pharmaceuticals, Inc.

Jeff Gregg Florida Department of
Environmental Protection (FDEP)

Kaitlyn A. Taylor, FDEP
Breanna Moore, FDEP

Nereida Hernandez, USEPA Region 4

5) Date of Inspection

January 25, 2024

6) **Applicable Regulations¹**

Resource Conservation and Recovery Act (RCRA) Sections 3002 (42 U.S. Code – Annotated U.S.C.A. 6925 and 6927), and 40 Code of Federal Regulation (C.F.R.) Parts 260 - 270, 273, 278, & 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.

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 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 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] (hereinafter referred to as the “SAA Permit Exemption”).

7) **Purpose of Inspection**

The purpose of this inspection was to conduct an unannounced compliance evaluation inspection to determine Noven Pharmaceuticals, Inc. compliance with the applicable requirements of RCRA and the corresponding Florida regulations. This was an EPA lead inspection supported by FDEP.

8) **Facility Description**

Noven Pharmaceuticals, Inc. (hereinafter referred as Noven or the facility) is in Miami, Florida. Noven has been operating since 1980s, occupies, approximately 14 acres, and employs approximately 250 employees. The facility consists of several buildings (office building, warehouses and manufacturing buildings for controlled substances and non-controlled substances). Noven operates two shifts from Monday to Friday. Access to the facility is restricted. The facility is connected to the public water system. Visitors must register at the

¹ As the State’s authorized hazardous waste program operates in lieu of the federal RCRA program, the citations of those authorized provisions will be to the authorized State program. However, for ease of reference, the federal citations will follow in brackets.

main office and must always be escorted by facility personnel. Noven is a subsidiary of Hisamitsu Pharmaceutical Co. Inc. and is engaged in the research, development, manufacture, and sale of prescription products. At their current location they manufacture products whose active ingredients are delivered through absorption, such as transdermal patch.

The general process consists of the following: a pharmaceutical active ingredient is mixed according to weight. The product used in the controlled substance building is pre-weighed by the manufacturer. Once the product is weighed it is added to blending kettles, then the blended mixture is transferred to the coating room where an automated machine, using heat and pressure, applies the adhesive to a roll of polymer webbing. Then the roll reverses back through the system to apply the blend to the same side of the roll. A second roll of protective webbing is applied over the side where the blend took place to protect it until it is peeled before use. The roll goes to a controlled ambient storage temperature area to allow for proper drying and solidification. When the roll is hardened and ready, it is taken to the slitting room. The roll is automatically slit and then sent to packaging for punching to manufacture a properly sized patch. The patches come right out of the punching machine and down a conveyor belt where they fall into their individual wrapped pouches. At this stage of the process, the pouches are inserted automatically or manually into small boxes, which are then shipped by the case from the facility. The whole process can take several hours or even a full day.

Hazardous waste streams generated during the process include acetonitrile, methanol, isopropanol, waste resin, toluene, ethyl acetate and HPLC vials (methanol, acetonitrile), non-hazardous pharmaceuticals waste and universal waste batteries. Other main waste streams are off-spec non-hazardous pharmaceutical waste, that they handle as hazardous waste because shipping it back to their providers is not cost effective.

The most recent Hazardous Waste Generator Notification (EPA Form 8700-12) dated February 24, 2022 characterized the facility as a large quantity generator (LQG) of hazardous waste. Waste codes from the EPA Form 8700-12 include D001 (ignitable waste), D002 (corrosive), D003 (reactive), D008 (lead), D011 (silver), D018 (benzene), F003 (spent non-halogenated solvents), F038 (petroleum refinery-emulsified), P012 (arsenic oxide), P098 (potassium cyanide), U019 (benzene), U056 (cyclohexane or hexahydro-benzene), U112 (acetic acid, ethyl ester or ethyl acetate), U113 (2-Propenoic acid, ethyl ester or ethyl acrylate), U134 (hydrofluoric acid or hydrogen fluoride), U144 (acetic acid, lead(2+) salt or lead acetate), U151 (mercury), U154 (methanol or methyl alcohol), U162 (methyl methacrylate or 2-Propenoic acid, 2-methyl-, methyl ester), U196 (pyridine), U218 (ethanethioamide or thioacetamide), U220 (methyl-benzene or toluene), and U239 (dimethyl-benzene or xylene). The facility generates universal waste batteries.

The facility operates under a General Air Permit 001426-2023/2024 and the Industrial Waste Pre-Treatment-IWP – 000356 2023/2024.

9) Previous Inspection History

Noven has been inspected by FDEP since 1998. The most recent inspection was conducted by the FDEP on May 31, 2018. The inspector found one apparent violation for not providing a returned signed copy of more than 3 manifests reviewed during the inspection. The violation was resolved on June 1, 2018. Based on the documentation provided, the facility did not fail to submit any exception report because all the signatures described in the manifest were complying within the 45 days.

10) Opening Conference

On January 25, 2024, EPA inspector, Nereida Hernandez Morales, accompanied by FDEP inspectors, Jeff Gregg, Kaitlyn A. Taylor, and Breanna Moore, arrived at Noven at approximately 10:00 a.m. After checking-in in the main office, Juan C. Fernandez and Clement Aikens, from Noven Pharmaceuticals, received the inspectors. The inspectors introduced themselves, showed their credentials and explained the purpose of the visit.

The inspectors described the anticipated use of equipment (digital camera) during the inspection and provided a list of records to be reviewed as part of the recordkeeping. The EPA inspector also discussed the company's ability, pursuant to 40 C.F.R. §2.203, to assert a business confidentiality claim for information submitted to EPA. The facility asserted business confidentiality claim due to the manufacture of controlled substances.

Mr. Fernandez provided an overview of the facility's history and current operations during the opening conference. Mr. Fernandez also discussed health and safety protocols and the required personal protective equipment required for the inspection.

11) Inspection Observations

Noven manages one central accumulation area (CAA) and several satellite accumulation areas (SAAs) across the facility. All the waste in the SAAs is moved to a CAAs prior to shipment. The facility's main processes consist of preparation and manufacturing of transdermal patches.

Emergency showers, eye wash stations, and spill kits were observed around the SAAs and CAA at time of the inspection.

The following areas were inspected:

Building #2 (East) - Non-controlled substances:

Building #2 consists of the following areas: warehouses, manufacturing, and quality control laboratory (QC Lab). The manufacturing area consists of blending, coating, cleaning, slitting, and packing rooms. The building is also equipped with a QC Lab on the second floor.

Blending Room – is used to blend the active ingredients. At the time of the inspection, Edwardo Cuevas was cleaning the blending machine, using isopropyl alcohol (IPA). The spent solvent was collected in a 5-gallon container labeled as "hazardous waste" and transferred to a 55-gallon container located in the Cleaning Room 105. The 5-gallon container was not labeled with the

indication of the hazard of the content. Photo #1. One 25-gallon container for solvent contaminated materials generated from the cleaning process was also observed in this room. The container was labeled as "Non-hazardous waste". However, an alcohol like odor came out from the container. Copy of the waste profile was received by email on February 9, 2024, therefore the waste qualifies for the excluded solvent contaminated wipes and the facility should label all corresponding waste containers with the words "Excluded solvent contaminated wipes". Photo #2.

Pursuant to Fla. Admin. Code Ann. R. 62-730.160(1) [40 C.F.R. §262.15(a)(5)(ii)], which is a condition of the SAA permit exemption, a generator must mark or label its container with the following: (ii) 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).

Cleaning Room - The parts from the blending and coating machines are cleaned/washed in a stainless-steel sink with isopropyl alcohol. The spent solvent from the sink is drained in a 5-gallon bucket that is kept under the sink. The content of the bucket is totally drained through a funnel into 55-gallon satellite container. It is recommended to label the sink with the words "hazardous waste" and with the indication of the hazard of the content.

The following containers were observed at time of the inspection:

One closed (5)-gallon container (under the sink) with IPA waste, labeled as hazardous waste. The container was not marked with the indication of the hazards of the contents. Photo #3.

One closed (55)-gallon container with oleic acid (from the blending machine), labeled as hazardous waste. The container was not marked with the indication of the hazards of the contents. Photo #4.

One (55)-gallon container with IPA waste, opened funnel, labeled as "hazardous waste". The container was not marked with the indication of the hazards of the contents. The container was closed at the time of the inspection. Photo #5.

Two 55-gallon containers of solvent contaminated material labeled "Non-hazardous waste".

Pursuant to Fla. Admin. Code Ann. R. 62-730.160(1) [40 C.F.R. §262.15(a)(5)(ii)], which is a condition of the SAA permit exemption, a generator must mark or label its container with the following: (ii) 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 C.F.R. § 262.15(a)(4)], which is a condition of the SAA permit exemption, a container holding hazardous waste must be closed at all times during accumulation, except: (i) When adding, removing, or consolidating waste; or (ii) when temporary venting of a container is necessary.

Coating Room – generates baking and laminates that are not contaminated waste and are disposed as regular trash.

Room 123-Seal/Packing Station – The machine uses a laser to put the lab number and date. Machines are cleaned with IPA which generates alcohol contaminated wipes. One closed (15)-gallon container labeled with the words “Used Alcohol Wipes” was observed at the time of the inspection. The container was empty. Photo #6.

QC Laboratory - The laboratory is located on the second floor and the following was observed in this area.

Two (55)-gallon containers (one for liquid and one for solid) were observed closed, labeled as “hazardous waste”, and with the indication of the hazard of the content (flammable). Photo #7.

Expired Reagents – The inspectors observed various containers of expired reagents separated by “oxidizers, bases, acids, and other”. Some of the containers were properly labeled and dated; however, 10 containers were not labeled with the words “hazardous waste, and with the indication of the hazard of the content. Photo #8.

Four 1-3-gallon containers connected to HPLC machines labeled as “hazardous waste - IPA, ethyl acetate, methanol, acetone, acetonitrile”, and with no indication of the hazards of the contents. (Photo #9).

Several 1-3-gallon containers connected to HPLC machines were labeled “hazardous waste” and with indication of the hazards of the contents (flammable). (Photo #9)

One 1-gallon container under the fume hood labeled “hazardous waste – organic waste” with no indication of the hazards of the contents. (Photo #9).

In different areas around the lab, six (5)-gallon (red) containers were observed closed and marked as flammable; however, these containers were not labeled with the words “hazardous waste”. Photo #10.

Pursuant to Fla. Admin. Code Ann. R. 62-730.160(1) [40 C.F.R. §262.15(a)(5)(i)(ii)], which is a condition of the SAA permit exemption, a generator must mark or label its container with the following: (i) the words “Hazardous Waste”, and (ii) 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).

Building #3 (West) - Controlled Substances:

Building #3 consists of the following areas: warehouses, manufacturing, and quality control laboratory (QC Lab). The manufacturing area consists of blending, coating, cleaning, slitting, and packing rooms. The building is also equipped with a QC Lab on the second floor.

Blending Rooms – There are three blending rooms that follow the same process as Building #2 but for controlled substances. One closed (20)-gallon container with gloves/IPA waste was observed without label. Photo #11.

Cleaning Room - The parts from the blending and coating machines are cleaned/washed in a stainless-steel sink with isopropyl alcohol. The spent solvent from the sink is drained in a 5-gallon bucket that is kept under the sink. The content of the bucket is totally drained through a funnel into 55-gallon satellite container. It is recommended that the sink be labeled with the words “hazardous waste” and with the indication of the hazard of the content.

The following containers were observed at the time of the inspection:

Two closed (15)-gallon containers labeled as “Used Alcohol Wipes”. Photo #12.

Two (5)-gallon containers with IPA ethyl acetate waste, labeled as “hazardous waste”. The container was not labeled with the indication of the hazards of the contents. Photo #13.

One (55)-gallon container with IPA ethyl acetate waste, with funnel, labeled as “hazardous waste”. The container was not labeled with the indications of the hazard of the contents. The container was dated January 22, 2024. Inspectors were informed that the drum was being relocated to the CAA by the end of the day. Photo #14.

One closed (5)-gallon empty container used to store alcohol wipes. The container was not labeled with the words “hazardous waste” and not marked with the indication of the hazard of the content. Photo #15.

One 20-gallon container inside of a flammable cabinet with no hazardous waste label.

Pursuant to Fla. Admin. Code Ann. R. 62-730.160(1) [40 C.F.R. §262.15(a)(5)(i)(ii)], which is a condition of the SAA permit exemption, a generator must mark or label its container with the following: (i) the words “Hazardous Waste”, and (ii) 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).

Coating Room – The coating room generates baking and laminates that are not contaminated waste and are disposed of as regular trash.

Seal/Packing Station – The machine uses a laser to put the lab number and date. Machines are cleaned with IPA and generates alcohol contaminated wipes. One closed (10)-gallon container labeled with the words “Used Alcohol Wipes” was observed at the time of the inspection.

QC Laboratory - The laboratory is located on the second floor and the following was observed in this area:

One (35)-gallon container with a funnel, used to store vials/tubes, was observed closed, labeled as “hazardous waste”, and with the indication of the hazards of the contents (flammable). Photo #16.

Several containers or bottles of different sizes (ranging from one liter to three gallons) were observed connected to the HPLC machines. Except for one container, these containers were closed, labeled with the words “hazardous waste” and with the indication of the hazards of the contents (flammable). Photo #17.

One (3)-gallon container labeled as methanol/acetone/ethyl acetate, etc. was not marked with the indication of the hazards of the contents. Photo #18.

In different areas around the lab, three (5)-gallon (red) containers were observed closed and marked as flammable; however, these containers were not labeled with the words “hazardous waste”.

Pursuant to Fla. Admin. Code Ann. R. 62-730.160(1) [40 C.F.R. §262.15(a)(5)(i)(ii)], which is a condition of the SAA permit exemption, a generator must mark or label its container with the following: (i) the words “Hazardous Waste”, and (ii) 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).

90 Day Central Accumulation Area (CAA):

The inspectors visited the 90 day CAA that is located behind Building #3. Christian Jinete, Inventory Control Analyst of Noven, joined the inspection team during the inspection. The area was identified with the words “Hazardous Waste Storage Area”, “Restricted Entry”, “No Smoking Sign”, land line phone, list of phone numbers, and the National Fire Protection Association code 704 at the entrance. The “No Smoking” label was faded, but it was replaced by a new one. There was adequate aisle space between sections. Eight (8) containers with hazardous waste material were observed in this area. The containers were observed closed, labeled with the words “hazardous waste”, and dated. The oldest accumulation start date was December 2023. However, these containers were not marked with the indication of the hazards of the contents. Photos #19 and #20.

Pursuant to Fla. Admin. Code Ann. R. 62-730.160(1) [40 C.F.R. §262.15(a)(5)(ii)], which is a

condition of the SAA permit exemption, a generator must mark or label its container with the following: (ii) 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).

Lab Pack - Small bottles of different sizes were observed in separate bins, labeled with the words "hazardous waste", dated, and with the indication of the hazards of the contents. The oldest date accumulation start date was March 6, 2023. An email with a manifest (Lab Pack disposal) was received on February 13, 2024. Photos #21 and #22.

Pursuant to F.A.C. Chapter 62-730.160(1) [40 C.F.R. § 262.17(a)], which is a condition of the LQG Permit Exemption, a large quantity generator may accumulate hazardous waste on site without a permit or interim status, and without complying with the requirements of parts 124, 264 through 267, and 270 of this chapter, or the notification requirements of section 3010 of RCRA, provided the following condition for exemption is met: A large quantity generator accumulates hazardous waste on site for no more than 90 days, unless in compliance with the accumulation time limit extension or F006 accumulation conditions for exemption in paragraphs (b) through (e) of this section.

In case of emergency, the personnel will activate a local fire alarm, use cell phones, landline Noven phone to immediate emergency instruction to facility personnel. The area is equipped with eye and shower stations, portable fire extinguishers (carbon dioxide or dry chemical), spill control equipment, and it is equipped with water to supply water hose streams. The fire alarm alerts to the onsite Fire Department.

Universal Waste:

The facility generates universal waste batteries that are stored in the CAA. One closed (5)-gallon container with "universal waste" (batteries), dated January 18, 2024 was also observed at the time of the inspection. Photo #23.

12) Records Review:

After the walkthrough, the inspectors reviewed the following records:

Contingency Plan and Quick Reference Guide (QRG):

The facility maintains a contingency plan (CP) that describes the actions that facility personnel must take in response to fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste. The Contingency Plan was last revised on November 7, 2023; the plan includes the quick reference guide.

The plan describes arrangements agreed to with the local police department, fire department,

other emergency response teams, emergency response contractors, equipment suppliers, local hospitals, or the Local Emergency Planning Committee. The generator provides evidence that a Copy of the Hazardous Waste Contingency Plan was submitted to the police department, fire department, hospital, State and local emergency response teams and the Local Emergency Planning Committee.

The quick reference guide lists the names and emergency telephone numbers for persons identified as emergency coordinators. The primary emergency response coordinator, and the other individuals are listed in the order in which they will assume responsibility as alternates.

The plan includes the emergency equipment (fire extinguishing systems, spill control equipment, and communications and alarm systems) at the facility. However, it does not include a list with the location and a physical description of each item included, and a brief of its capabilities.

Pursuant to Fla. Admin. Code Ann. R. 62-730.160(1) [40 C.F.R. §262.261(e)], the plan must 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 must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list, and a brief outline of its capabilities.

The plan includes an evacuation plan for personnel. This plan describes signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes.

The plan includes the quick reference guide; however, the identification of on-site notification systems (e.g. fire alarm that rings off site, smoke alarms) is not included.

Pursuant to Fla. Admin. Code Ann. R. 62-730.160(1) [40 C.F.R. §262.262(b)(7)], a large quantity generator that first becomes subject to these provisions after May 30, 2017 or a large quantity generator that is otherwise amending its contingency plan must at that time submit a quick reference guide of the contingency plan to the local emergency responders identified at paragraph (a) of this section or, as appropriate, the Local Emergency Planning Committee. The quick reference guide must include the following elements: (7) the identification of on-site notification systems (e.g., a fire alarm that rings off site, smoke alarms).

Spill Prevention, Control, and Countermeasures (SPCC) Plan:

Last revision on June 22, 2022.

Waste Manifest and Land Disposal Restriction (LDR) Records:

The inspectors reviewed available hazardous waste manifest records and land disposal restriction forms for shipments of hazardous waste sent from January 2021 to January 2024. The last shipment was on January 11, 2024, and the facility used Cliff Berry, Inc (FLR000083071)

and Clean Earth Specialty Waste Solutions (MNS000110924) as transporters and Cecily Bowers (ALD094476793) was used for the disposal of their hazardous waste.

Waste Profiles:

Waste profile documents were available for review at time of the inspection.

The waste profile for solvent contaminated materials (Used Alcohol Wipes) was received by email on February 9, 2024 and the waste was categorized as nonhazardous, therefore the waste qualifies for the excluded solvent contaminated wipes rule and the facility should label all corresponding waste containers with the words “Excluded solvent contaminated wipes”.

Pursuant to Fla. Admin. Code Ann. R. 62-730.160(1) [40 C.F.R. § 261.4(b)(18)], Solvent-contaminated wipes, except for wipes that are hazardous waste due to the presence of trichloroethylene, that are sent for disposal are not hazardous wastes from the point of generation provided that (i) The solvent-contaminated wipes, when accumulated, stored, and transported, are contained in non-leaking, closed containers that are labeled “Excluded Solvent-Contaminated Wipes.” The containers must be able to contain free liquids, should free liquids occur. During accumulation, a container is considered closed when there is complete contact between the fitted lid and the rim, except when it is necessary to add or remove solvent-contaminated wipes. When the container is full, or when the solvent-contaminated wipes are no longer being accumulated, or when the container is being transported, the container must be sealed with all lids properly and securely affixed to the container and all openings tightly bound or closed sufficiently to prevent leaks and emissions.

Training Records:

Training records were available for review at the time of the inspection. Job descriptions for each employee handling hazardous waste were available for review. Trainings are up to date.

Weekly and Daily Inspection Records:

Noven is conducting weekly inspections to the CAA. The inspectors reviewed the records of inspections of the CAA from January 8, 2021 to January 19, 2024. The container inspection log included the date and time of inspection, the name of the staff member conducting the inspection, any corrective actions taken, and the total number of containers.

Biennial/Annual Reports Record:

The biennial/annual reports for the facility’s hazardous waste activities in 2019, 2021 and 2023 were available to review on-site.

13) Closing Conference

After the inspection, the inspectors had their exit briefing with Juan C. Fernandez and Clement Aikens. During the meeting, the inspectors discussed the observations made during the inspection and the inspection was concluded.

14) List of Attachments

Attachment 1 – Photo Log:

Photos taken on: January 25, 2024

Photos taken by: Breanna Moore from FDEP

Photos taken with: Cell Phone

15) Signed

NEREIDA HERNANDEZ MORALES Digitally signed by NEREIDA HERNANDEZ MORALES
Date: 2024.02.28 16:42:19 -05'00'

Nereida Hernandez Morales
Life Scientist

16) Concurrence

ARACELI CHAVEZ Digitally signed
by ARACELI CHAVEZ
Date: 2024.03.01
09:02:03 -05'00'

Araceli B. Chavez
Chief
RCRA Enforcement Section

Appendix 1 – Photo Log

Photos taken on: January 25, 2024

Photos taken by: Breanna Moore

Photos taken with: Cell Phone



Photo #1 -Bldg #2: Blending Room: A 5-gallon container not labeled with the indication of the hazard of the content.



Photo #2 - Bldg #2: Blending Room: A 20-gallon container with solvent contaminated materials



Photo #3 – Bldg #2: Cleaning Room: A 5-gallon container (under the sink) not labeled with the indication of the hazard of the content.



Photo #4 – Bldg #2: Cleaning Room: A (55)-gallon container. The container was not marked with the indication of the hazard of the content.



Photo #5 – Bldg #2: Cleaning Room: A (55)-gallon container with IPA waste, opened funnel. The container was not marked with the indication of the hazard of the content.



Photo #6 – Bldg. #2 Cleaning Room: A (10)-gallon container used to store “alcohol wipes”.



Photo #7 – Bldg. #2 QC Laboratory

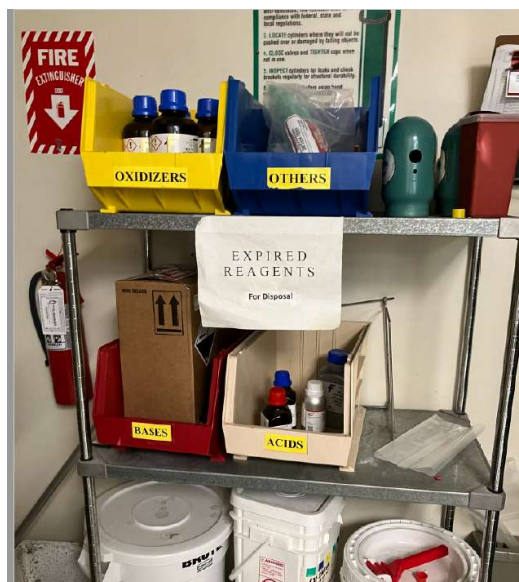


Photo #8 – Bldg. #2 QC Laboratory

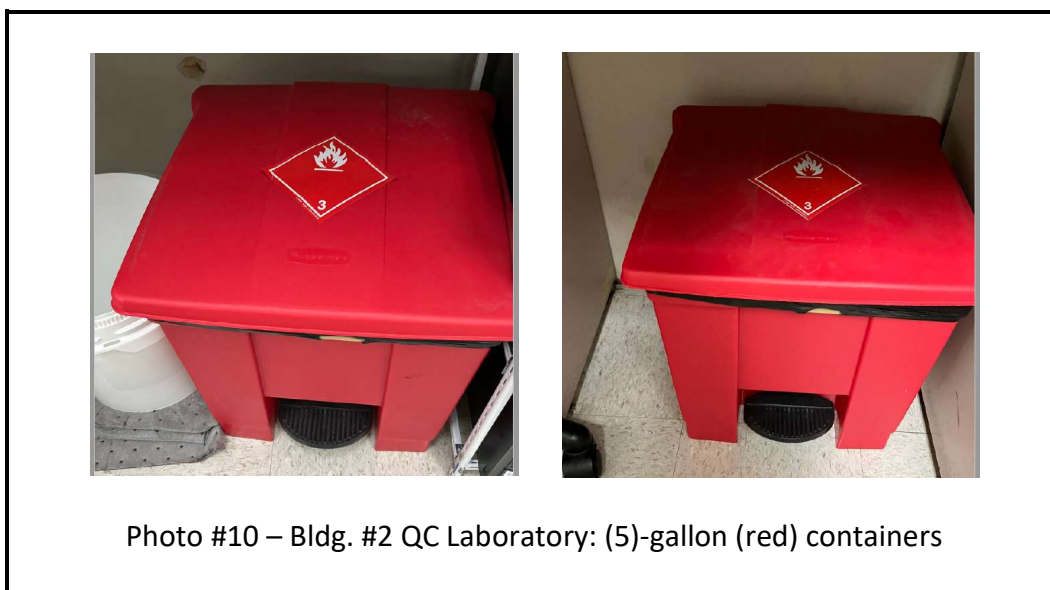
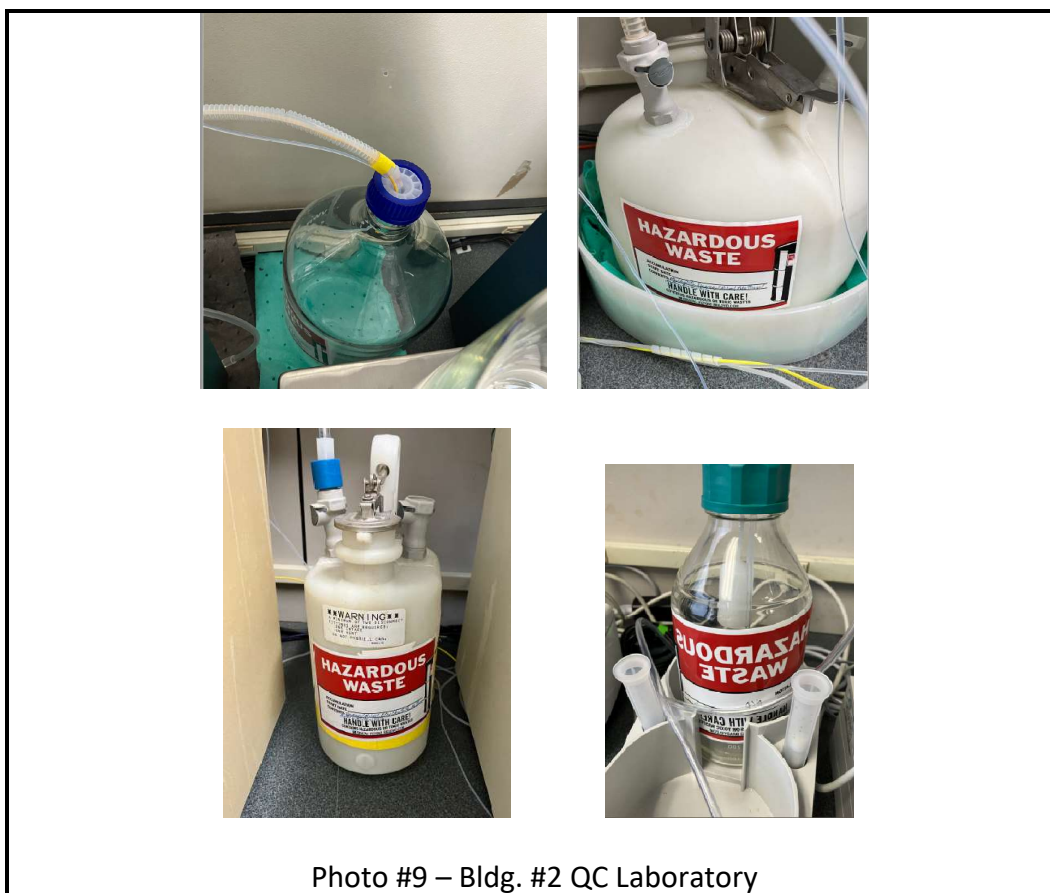




Photo #11 – Bldg. #3 Blending Room: A (20)-gallon



Photo #12 – Bldg. #3 Cleaning Room: Containers with alcohol wipes



Photo #13 – Bldg. #3 Cleaning Room: Two (5)-gallon containers with IPA ethyl acetate waste



Photo #14 – Bldg. #3 Cleaning Room: One (55)-gallon container with IPA ethyl acetate waste



Photo #15 – Bldg. #3 Cleaning Room: Containers with alcohol wipes



Photo #16 – Bldg. #3 QC Laboratory: A (35)-gallon container



Photo #17 – Bldg. #3 QC Laboratory:



Photo #18 – Bldg. #3 QC Laboratory: – A (3)-Gallon container



Photo #19 – Central Accumulation Area



Photo #20 – Central Accumulation Area



Photo #21 – Central Accumulation Area (Lab Pack)

USE ONLY IF APPLICABLE		Form Approved, U.S. GPO: 2002-400-000-000	
1. Generator ID Number FL0000545921		4. National Tracking Number 022034216 JJK	
2. Page 1 of 1		3. Emergency Response Phone	
5. Generator's Name and Mailing Address Noven Pharmaceuticals 11960 SW 144th St Miami FL 33186		6. Generator's Site Address (if different from mailing address) Noven Pharmaceuticals Inc 14500 SW 14th Ave Miami FL 33186	
7. Shipper's Name Clean Earth Specialty Waste Solutions		8. Shipper's ID Number MUS000110924	
9. Shipper's Name and Mailing Address Clean Earth Inc Allworth Rd Birmingham AL 35217		10. U.S. EPA ID Number FLR000083071	
11. U.S. DOT Description (including Proper Shipping Name, Hazard Class, ID Number, and Packing Group (if any)) UN1993, Waste Flammable Liquid N.O.S. (Tetrahydrofuran) 3 DSG II		12. Waste Codes P 000 4001 4117 4108 4213	
13. Containers 1 Dr 9B		14. Special Handling Instructions and Additional Information	
15. GENERATOR'S CERTIFICATION: I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled in accordance with the requirements of the U.S. Department of Transportation, and are in full compliance with the requirements of the U.S. Environmental Protection Agency. I certify that the contents of this consignment conform to the terms of the applicable EPA Acknowledgment of Receipt. I certify that the waste identification statement identified in 40 CFR 261.27(a) (2) is a large quantity, as defined in 40 CFR 261.27(a) (1).			
16. Signature of Generator Representative D. Williams		17. Signature of Shipper Representative D. Williams	
18. Date of Shipment 12/12/24		19. Date of Receipt 12/12/24	
20. Signature of Facility Representative A. Trejo		21. Signature of Facility Representative A. Trejo	
22. Date of Receipt 12/12/24		23. Date of Receipt 12/12/24	
24. Discrepancy The Discrepancy Indication Space		25. Discrepancy Indication Space	
26. Facility Name (or Generator)		27. Facility Name (or Generator)	
28. Facility Phone		29. Facility Phone	

Photo #22 – Lab Pack Disposal



Photo #23– Universal Waste Batteries