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.
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2) Facility Information

PharmaLink, Inc.
8285 Bryan Dairy Road
Largo, Pinellas County, Florida 33777

EPA ID#: FLR000221135
NAICS #: 446110 - Pharmacies and Drug Stores

3) Responsible Official

John Mahoney
Sr. Environmental Waste & Safety Specialist

(800) 257-3527, ext 267
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4) Inspection Participants

John Mahoney, PharmaLink, Inc.
Sean Haskins, PharmaLink, Inc.
Ray Bodamer, PharmaLink, Inc.
Robert Faulcomer, PharmaLink, Inc.
Timothy Brightbill, PharmaLink, Inc.
Thierry Beckers, PharmaLink, Inc.
Warren McNelley, Florida Department of Environmental Protection
Mollie Enck, Florida Department of Environmental Protection
Leslie Pedigo, Florida Department of Environmental Protection
M. Brandon Miller, Florida Department of Environmental Protection
William Kappler, U. S. Environmental Protection Agency, Region 4

5) Date of Inspection

March 22, 2023

6) Applicable Regulations[1]

Resource Conservation and Recovery Act (RCRA) Sections 3002 (42 U.S. Code – Annotated

[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.

U.S.C.A. §§ 6925 and 6927), Chapter 403 of the Florida Statutes, Fla. Stat. § 403.702 *et seq.*, and rules 62.710.210 -.901, and 62-730 *et seq.* of the Florida Administrative Code Annotated (Fla. Admin. Code Ann.) [40 Code of Federal Regulation (C.F.R.) Parts 260 - 270, 273, 278, & 279].

Pursuant to F.A.C. Chapter 62-730.185(1), [40 C.F.R. § 273.9], a small quantity handler of universal waste (SQHUW) is a universal waste handler who accumulates less than 5,000 kilograms total of universal waste (batteries, pesticides, mercury-containing equipment, lamps, or aerosol cans, calculated collectively) at any time.

7) Purpose of Inspection

The purpose of this inspection was for the U.S. Environmental Protection Agency, Region 4, and the Florida Department of Environmental Protection to conduct a joint unannounced compliance evaluation inspection (CEI) at PharmaLink, Inc., (hereinafter, "PharmaLink" or the "facility") to determine compliance with the applicable requirements of the Resource Conservation and Recovery Act (RCRA) and the corresponding Florida Department of Environmental Protection (FDEP) regulations. This was an EPA lead inspection.

8) Facility Description

PharmaLink is in the Bardmoor Palms Business Center at 8285 Bryan Dairy Road, Largo, Pinellas County, Florida, Latitude 28.872346, and Longitude -82.753912. The facility has been at its present location since December 2016. The facility employs approximately 250 people and operates Monday through Friday from 7:00 a.m. to 12:00 a.m. and sometimes on weekends. The facility is in a large building comprised of numerous suites. PharmaLink occupies Suites 160 and 200, in the building. The City of Largo provides potable water and sanitary sewer services. The primary NAICS code for the facility is 446110, Pharmacies and Drug Stores.

PharmaLink is a reverse distributor licensed in Florida. The facility provides a service for healthcare facilities reverse distributing pharmaceuticals for credit. Pharmaceuticals are received from common carriers (UPS and USPS). Pharmaceuticals arrive in various size cardboard boxes (containers) and are staged in the receiving area prior to processing. There are three receiving bays in this area. The facility scans the customer's bar code on each container label to generate a unique customer identification number. The containers with Schedule II DEA controlled substances are tagged with a yellow sticker and managed under DEA regulation. Common pharmaceuticals are loaded onto a conveyer system and are flowed through to the Pre-Processing Area. In pre-processing the containers are opened and the customer's inventory sheet is reviewed for customer number, address, wholesaler, manufacturer information, class of pharmaceutical to validate the pharmaceuticals in each container. The customer, prior to shipping, creates an inventory sheet and shipping label using the facility's MedFlats Program, a web-based customer portal. The customer places the inventory sheet in each container and can only create the shipping label after the inventory sheet is completed. Pre-processing matches the pharmaceuticals in each container to the inventory sheet and a customer account number is assigned by PharmaLink using their unique "Prophet software system" (software). The containers are next placed on first in/first out shelves where the oldest dated containers are processed first.

The containers are then transferred to the Processing Room where the software is used to process the pharmaceuticals in approximately 40 active process stations. PharmaLink representatives indicated the process station is the beginning of the 30-day evaluation time. The bar code for each solid and liquid pharmaceutical is scanned and the information is shown in the process station's computer screen. The pharmaceutical expiration date is typically one week to several months but can arrive one year prior to expiration. The station processor enters additional pharmaceutical data and the software evaluates the pharmaceutical as creditable, non-creditable, a non-hazardous waste or a hazardous waste pharmaceutical for storage in a process station bin. The software generates a bin number (one, two, three, four) designating the bin destination. A pharmaceutical evaluated with a number one is stored in Bin One (general batch credit), a pharmaceutical with a number two is stored in Bin Two (packaging-future creditable), a pharmaceutical with a number three is stored in Bin Three (non-hazardous waste) and a pharmaceutical with a number four is stored in Bin Four (hazardous waste). Once the processing is completed by the station processor, the pharmaceutical is transferred to either the Packaging Area for shipment as a creditable pharmaceutical to the manufacturer, the Hand Packaging Area for credit as a non-batch pharmaceutical, or the to the central accumulation area for the storage of non-hazardous waste and hazardous waste pharmaceuticals. Creditable pharmaceuticals are next packaged with a debit memo that lists the pharmaceuticals packaged for credit. The packaged pharmaceuticals are transferred to the Shipping Area for pending shipment by PharmaLink upon receipt of a return authorization from the manufacturer. Pharmaceuticals that are determined creditable to the customer, but the manufacturer does not want returned and authorizes for destruction is documented with a "Proof of Destruction" authorization by the manufacturer.

The facility manages the received pharmaceuticals in accordance with the manufacturer or wholesaler's instructions. PharmLink has agreements with several manufacturers to dispose of their non-hazardous and hazardous creditable pharmaceuticals, rather than being returned to the manufacturers. PharmaLink arranges for the shipment of the waste pharmaceuticals to a destination facility.

Hazardous waste pharmaceuticals are transported by Freehold Cartage (NJD084126164), A.R. Parquette and Company (FLD982105884), Heritage Transport, LLC (IND085484114), Trilogy Medwaste Southeast, LLC (FLR000230839) and Clean Harbors Environmental Services, Inc (MAD039322250).

Hazardous waste pharmaceuticals are shipped to Clean Earth of Alabama, Inc. (ALD981020894), Heritage Thermal Services. Inc (OHD980613541), Triumvirate Environmental Services, Inc (FLR980559728), Clean Harbors Florida, LLC (FLD980728610) and Clean Harbors Deer Park, LLC (TXD055141378)

PharmaLink initially operated at 771 Coachman Plaza Drive, Suite 3, Clearwater, Florida 33759. The facility submitted a RCRA Subtitle C Site Identification Form, 8700-12FL, to the FDEP on or about March 1, 2002, notifying as an LQG (FLR000085274).

PharmaLink moved in 2002 until 2011 to 12345 Starkey Road Suite L, Largo, Florida 33773 and notified the FDEP (Form 8700-12FL) as an LQG (FLR000089714).

PharmaLink moved in 2011 until 2016 to 11211 69th Street, Largo, Florida 33773, and notified the FDEP (Form 8700-12FL) as an SQG (FLR000047464).

Pharmalink moved in 2016 to 8285 Bryan Dairy Road #200, Largo, Florida and notified the FDEP on December 2, 2016, (Form 8700-12FL) as an SQG, a large quantity handler of universal waste (batteries, lamps, mercury containing devices, mercury containing equipment) and a large quantity handler of universal waste pharmaceuticals (FLR000221135).

On October 9, 2019, PharmaLink notified FDEP as an SQG and a reverse distributor under 40 C.F.R. Part 266 Subpart P. On April 27, 2020, PharmaLink notified FDEP as an LQG and a reverse distributor under 40 C.F.R. Part 266 Subpart P.

Pharmalink recently notified FDEP on January 14, 2022, as an SQG and a reverse distributor under 40 C.F.R. Part 266 Subpart P for hazardous waste pharmaceuticals with the following waste codes. D00l, D002, D003, D004, D005, D007, D009, D010, D011 D013, D022, D024, D034, D035, U026, U039, U044 U058, U059, U089, U075, U089, U112, U117, U121, U122, U123, U129, U132, U150, U154, U159, U162, U163, U182, U188, U200, U201, U202, U205, U206, U220, U236, U237, U238, U239, U248, U328, U395, U403, P023 and P050.

9) Previous Inspection History

PharmaLink has not previously been inspected by the EPA, Region 4 or the FDEP at its current location for compliance with federal and state RCRA regulations.

10) Opening Conference

On March 22, 2023, the EPA inspector William Kappler, accompanied by FDEP inspectors Warren McNelly, Mollie Enck, Leslie Pedigo and M. Brandon Miller, arrived at the facility at approximately 9:55 a.m. The inspectors were received by John Mahoney, Sr. Environmental Waste & Safety Specialist. The inspectors signed a visitor's log and received a visitor's badge. The inspectors were escorted by John Mahoney to a conference room and were joined by Sean Haskins, Ray Bodamer, Robert Faulcomer, Timothy Brightbill, and Thierry Beckers (PharmaLink representatives) for an opening conference. 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 provided a written list of the records needed for review. The EPA inspector explained that the Small Business Regulatory Enforcement Fairness Act's classification of a "small business" is generally set by the Small Business Administration using the business' SIC/NAICS code and annual receipts or number of employees. A copy of the EPA's information sheet for small businesses can be found at https://www.epa.gov/sites/production/files/2017-06/documents/smallbusinessinfo.pdf. 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 provided to the EPA. PharmaLink did not assert a business confidentiality claim.

PharmaLink provided an overview of the facility's history and current operations during the opening conference. The inspection participants also discussed health and safety protocols and

the required personal protective equipment before PharmaLink representatives escorted the inspectors on a tour of the facility operations.

11) Inspection Observations

Shipping and Receiving
Pharmaceutical containers are received in three bays. Pharmaceuticals arrive in various sized containers and are initially staged in the receiving area. Hazardous waste was not observed in this area at the time of the inspection.

Pre-Processing Area
In pre-processing the containers are opened and the inventory sheet is reviewed. Hazardous waste was not observed in this area at the time of the inspection (Photograph 1).

Creditable Batch Area
Containers of creditable pharmaceuticals are consolidated on pallets for return processing to wholesalers. Hazardous waste was not observed in this area at the time of the inspection.

Processing Room
Henry Johnson is the processing manager in this area. Inspectors observed processor, Jarvis Race, evaluating solid pharmaceuticals in process station three. The inspectors observed a processor was evaluating liquid pharmaceuticals in process station six. Each vial is scanned to evaluate the pharmaceutical ingredients and bin designation. PharmaLink representatives indicated that it takes on average approximately five days to evaluate the pharmaceuticals.

Process Room Accumulation Area
PharmaLink manages three accumulation areas (AA) in the Process Room accumulating different types of pharmaceuticals. The inspectors observed a one cubic yard container accumulating evaluated (waste) pharmaceuticals in the first AA, a one cubic yard container accumulating waste pharmaceuticals in the second AA and a one cubic yard container accumulating waste pharmaceuticals in the third AA. Each pharmaceutical package in each cubic yard container was closed and in good condition. The cubic yard containers were labeled with the words “hazardous waste pharmaceuticals”, labeled with a hazard indicator and marked with the date March 15, 2023, or March 16, 2023. PharmaLink representatives indicated that all containers accumulating hazardous waste pharmaceuticals were required to be marked with a date regardless of container size.

Process Accumulation Area
The accumulation area (AA) is located outside the entrance to the Process Room. PharmaLink manages four AAs in this area. The inspectors observed one 55-gallon container accumulating waste pharmaceutical aerosols in the first AA and one 55-gallon container accumulating waste pharmaceutical corrosives in a second AA. The containers were closed, in good condition, labeled with the words “hazardous waste pharmaceuticals”, marked with a hazard indicator and each marked with the date February 23, 2023 (Photograph 2). The inspectors observed a one cubic yard container accumulating more than 55-gallons of waste pharmaceutical flammable and toxic solids in a third AA (Photograph 4). The inspectors observed a sign next to the container with the words “satellite accumulation area, hazardous pharmaceutical waste, flammable and

toxic" (Photograph 5). The inspectors observed the container was labeled with the words "hazardous waste pharmaceuticals". A pallet of cardboard boxes next to the one cubic yard container limited the inspectors from observing a hazard indicator and a date on the container (Photograph 3). The inspectors asked the facility to move the boxes so that the container could be inspected. After the facility moved the boxes for aisle space, the inspectors observed the container was labeled with a hazard indicator and marked with the date March 21, 2023.

Pursuant to F.A.C. Chapter 62-730.181(1) which references F.A.C. Chapter 62-730.160(4), generators required to inspect containers under 40 C.F.R. 262.16(b)(2)(iv) and 262.17 (a)(1)(v), [as adopted in subsection 62-730.160(1), F.A.C.] shall maintain adequate aisle space between containers of hazardous waste to allow for inspection of the condition and labels of the individual containers.

The inspectors observed a 20 to 30-pound cardboard container on a metal shelf next to the wall was accumulating waste pharmaceuticals in a fourth AA. The container was closed, in good condition, labeled with the words "hazardous waste pharmaceuticals" and marked with the date March 21, 2023. The inspectors observed the container was not marked or labeled with a hazard indicator (Photograph 6). PharmaLink representatives marked the container with a hazard indicator during the inspection (Photograph 7).

Pursuant to F.A.C. Chapter 62-730.181(1) [40 C.F.R. § 266.508(a)(1)(i-ii], a healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with the following pre-transport requirements, before transporting or offering for transport off-site.

The inspectors also observed a 20 to 30-pound container on the metal shelf accumulating universal waste electronics. The container was closed, in good condition, labeled with the words "universal waste" and marked with the date March 18, 2023 (Photograph 8).

<u>Packing Area (Staging for Wholesale Batching)</u>
The processed pharmaceuticals are batched in containers on shelves by scanning the bar code until the batch container is full. The PharmaLink representatives indicated it takes approximately one week to one month to batch fill a container. The full container is transferred to the Packaging Area. Hazardous waste was not observed in this area at the time of the inspection.

<u>Batch Packing Accumulation Area (Hazardous Waste and Universal Waste)</u>
PharmaLink manages three accumulation areas (AA) in Batch Packing accumulating different types of pharmaceuticals. The inspectors observed one 20 to 30-pound cardboard container accumulating waste pharmaceuticals in the first AA and one 55-gallon container accumulating waste pharmaceuticals in a second AA. The inspectors observed the containers were closed, in good condition, labeled with the words "hazardous waste pharmaceuticals", and marked with the date March 21, 2023 and February 23, 2023. The inspectors observed the 20 to 30-pound container in the first AA was not marked or labeled with a hazard indicator. PharmaLink representatives marked the container with a hazard indicator during the inspection (Photograph 9 and 12).

Pursuant to F.A.C. Chapter 62-730.181(1) [40 C.F.R. § 266.508(a)(1)(i-ii], a healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with the following pre-transport requirements, before transporting or offering for transport off-site.

The inspectors observed one 55-gallon container accumulating waste pharmaceutical aerosols in a third SAA. The inspectors observed the container was closed, in good condition, labeled with the words "hazardous waste pharmaceuticals" and marked with the date January 24, 2023. The inspectors observed the container was not marked or labeled with a hazard indicator. PharmaLink representatives indicated the container was not accumulating hazardous waste pharmaceuticals and the container should be labeled with the words "nonhazardous waste" (Photograph 13). A follow up email from PharmaLink dated April 12, 2023 indicated the 55-gallon container was accumulating waste pharmaceutical aerosols.

Pursuant to F.A.C. Chapter 62-730.181(1) [40 C.F.R. § 266.508(a)(1)(i-ii], a healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with the following pre-transport requirements, before transporting or offering for transport off-site.

The inspectors observed a 20 to 30-pound cardboard container accumulating universal waste electronics. The inspectors observed the container was closed, in good condition and labeled with the words "universal waste". The inspectors observed the container was not marked with a date (Photograph 10). PharmaLink representatives marked the container with the date March 8, 2023 (Photograph 11 and 12).

Pursuant to F.A.C. Chapter 62-730.185(1) [40 C.F.R. § 273.15(c), a SQHUW must be able to demonstrate the length of time that the universal waste has been accumulated from the date it becomes a waste or is received. The handler may make this demonstration by following F.A.C. Chapter 62-730.185(1) [40 C.F.R. § 273.15(c)(1-6).

The inspectors observed one empty cubic yard container. The inspectors observed the container was in good condition, labeled with the words "hazardous waste pharmaceuticals", labeled with hazard indicators and marked with the date March 22, 2023.

<u>Schedule III through V DEA Controlled Substance Area</u>
The inspectors observed two 20 to 30-pound cardboard containers on a wooden pallet accumulating waste pharmaceuticals. The containers were closed, in good condition, labeled with the words "hazardous waste pharmaceuticals" and marked with the date March 20, 2023. The inspectors observed the containers were not marked or labeled with a hazard indicator (Photograph 14). PharmaLink representatives marked the containers with a hazard indicator (Photograph 15).

Pursuant to F.A.C. Chapter 62-730.181(1) [40 C.F.R. § 266.508(a)(1)(i-ii], a healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with the following pre-transport requirements, before transporting or offering for transport off-site.

Shipping Area

The packaged pharmaceuticals are transferred to the Shipping Area for pending shipment by PharmaLink upon receipt of a return authorization from the manufacturer. Hazardous waste was not observed in this area at the time of the inspection.

Central Accumulation Area (CAA)

The inspectors observed the CAA is constructed of heavy-duty steel columns and rows for storage of one cubic yard containers on shelves. The inspectors observed 34 one cubic yard containers accumulating hazardous waste pharmaceuticals on the floor and on shelves three rows high with adequate aisle space. The inspectors observed the top row was approximately 25 to 30 feet high from the floor. The inspectors observed the containers on the third row could not be inspected because of the container's storage height. The inspectors asked the facility to move the containers to floor level for inspection. The inspectors returned to the CAA at approximately 3:07 p.m. to inspect the containers. The inspectors observed the containers were closed, in good condition, labeled with words "hazardous waste pharmaceuticals", labeled with a hazard indicator and marked with dates in January, February or March 2023.

Located on the floor next to the one-cubic yard containers the inspectors observed three 55-gallon containers accumulating hazardous waste pharmaceuticals. The inspectors observed the containers were closed, in good condition, labeled with words "hazardous waste pharmaceuticals", labeled with a hazard indicator and marked with dates of 180 or less.

The inspectors also observed a large cardboard container accumulating universal waste mercury lamps. The inspectors observed the container was closed, in good condition, labeled with the words "universal waste" and marked with the date December 12, 2022.

Waste Management

Employees in process operations that generate hazardous waste pharmaceuticals accumulate it in containers at the point of generation. Full containers are transferred to the central accumulation area.

Records Review

Manifests

The hazardous waste manifests, land disposal restriction notifications, nonhazardous waste manifests, and universal waste manifests for the calendar years 2019 through 2023 were reviewed. The inspectors observed hazardous waste manifest 02427772 JJK with the generator date of July 8, 2022 did not have the signed and dated manifest copy from the destination facility.

Pursuant to F.A.C. Chapter 62-730.181(1) [40 C.F.R. § 266.510(c)(9)(ii)], a reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of paragraph (a) of this section, for the management of evaluated hazardous waste pharmaceuticals: Exception reporting by a reverse distributor for a missing copy of the manifest.

The EPA inspector reviewed 17 hazardous waste manifests from the EPA's E-Manifest Record System from August 2022 to February 2023.

Records of Potentially Creditable Hazardous Waste Pharmaceuticals (PCHWP)
The records were not reviewed at the time of the CEI because of insufficient time for the review. The inspectors requested PharmaLink to electronically submit a 30-day record of PCHWP and manifests for a pharmaceutical manufacturer, a wholesaler, a hospital, a pharmacy, and a two-day record showing the shipment for destruction of PCHWP to a destination facility. On March 24, 2023 PharmaLink representatives emailed the PCHWP records to the inspectors. The PCHWP records received were for the facilities listed below.

- A manufacturer - Amerisource Bergen for June 2022
- A wholesaler - McKesson for January 2023
- A hospital - VAMC Palm Beach for August 2022
- A pharmacy - Diamond Pharmacy Services for March 2021
- Inmar shipment of Sandoz waste for July 6, 2021 and July 29, 2021

A review of the data for the returnable pharmaceuticals and nonreturnable pharmaceuticals on the PharmaLink Excel spreadsheet included the pharmaceutical receipt date, the debit memo, the pharmaceutical entry date, the pharmaceutical name, the national drug code (NDC), the pharmaceutical quantity, full and partial package amounts, the amount of credit, the pharmaceutical expiration date, the shipped tracking number, the date shipped, the shipped facility and shipping information, the destruction information, the manifest tracking number, the destination facility and address, the pharmaceutical disposal date and the waste stream hazard indicator.

A review of the data for the returnable pharmaceuticals and nonreturnable pharmaceuticals on the PharmaLink Excel spreadsheet for the Inmar/Sandoz shipments include the pharmaceutical receipt date, the debit memo, the pharmaceutical entry date, the pharmaceutical name, the national drug code (NDC), the pharmaceutical quantity, full and partial package amounts, the amount of credit, the pharmaceutical expiration date, the shipped tracking number, the date shipped, the shipped facility and shipping information, the destruction information, the manifest tracking number, the destination facility and address, the pharmaceutical disposal date and the waste stream hazard indicator.

PharmaLink's hazardous waste manifest records indicate hazardous waste pharmaceuticals are transported by Trilogy Medwaste Southeast, LLC, Freehold Cartage, A.R. Parquette and Company, Heritage Transport, LLC and Clean Harbors Environmental Services, Inc. to the destination facilities Clean Earth of Alabama, Inc., Heritage Thermal Services. Inc, Triumvirate Environmental Services, Inc, Clean Harbors Florida, LLC and Clean Harbors Deer Park, LLC.

Nonhazardous waste pharmaceuticals are transported by Smith Cargo Transportation to Covanta Lake, Inc. in Okahumpka, Florida.

Waste Determination/Profiles/Safety Data Sheets (SDS)
The inspector reviewed the waste determination record, waste profile and SDS for the hazardous waste pharmaceutical aerosols accumulating in a 55-gallon container in the Batch Packing Area.

Contingency Plan
The inspectors observed the facility developed three separate written plans providing emergency and spill response information. The facility's RCRA Emergency Contingency Plan was amended on November 7, 2022. The plan did not indicate site evacuation routes and alternate site evacuation routes and did not indicate the location of the CAA.

Pursuant to F.A.C. Chapter 62-730.181(1) [40 C.F.R. § 266.510(a)(7)], a reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of 40 CFR part 262 subpart M.

On April 28, 2023 PharmaLink representatives emailed the amended contingency plan dated April 26, 2023 to the inspectors.

Quick Reference Guide
The facility did not develop a quick reference guide (QRG).

Pursuant to F.A.C. Chapter 62-730.181(1) [40 C.F.R. § 266.510(a)(7)], a reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of 40 CFR part 262 subpart M.

On April 28, 2023 PharmaLink representatives emailed the QRG dated April 26, 2023 to the inspectors.

Arrangements with the Local Authorities
The inspectors observed the facility notified the local authorities in 2017. It appears the facility did not maintain documentation of the arrangements.

Pursuant to F.A.C. Chapter 62-730.181(1) [40 C.F.R. § 266.510(a)(7)], a reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of 40 CFR part 262 subpart M.

Weekly Container Inspection Records
The inspectors reviewed the weekly container inspection records for 2020, 2021, 2022 and 2023.

The inspectors reviewed RCRA personnel training, job titles, position descriptions and the 2021 biennial report.

12) Closing Conference

The inspectors conducted a closing conference with PharmaLink representatives. During this meeting, the inspectors stated their preliminary conclusions of the inspection.

13) Sampling Overview

Sampling was not conducted.

14) List of Appendices

Appendix 1 – Photograph Log:
Photos taken on: March 22, 2023
Photos taken by: William Kappler
Samsung Camera (Model WB250F)
EPA Property Tag# S75917

15) Signed

WILLIAM KAPPLER Digitally signed by WILLIAM KAPPLER
Date: 2023.05.25 18:48:04 -04'00'

William Kappler — Date
Physical Scientist

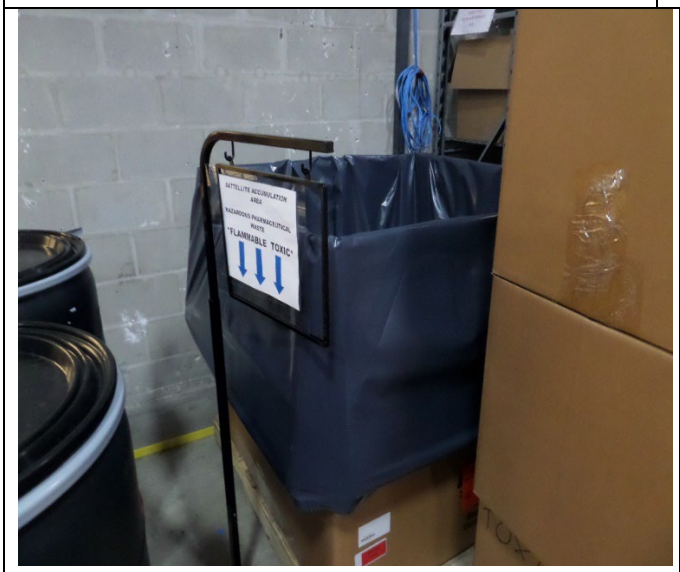
Concurrence

ARACELI CHAVEZ Digitally signed by ARACELI CHAVEZ
Date: 2023.05.26 07:59:32 -04'00'

Araceli B. Chavez — Date
Chief
RCRA Enforcement Section

Pre-Processing Area. The inspectors observed container of pharmaceuticals opened for pre-processing. Photograph 1 taken at 11:54 a.m.

Process Area SAA. The inspectors observed one 55-gallon SAA and a second 55-gallon SAA. Photograph 2 taken at 12:21 p.m.



Process Area SAA. The inspectors observed a one cubic yard container accumulating closed pharmaceutical solid packages and marked with a date. Photograph 3 taken at 12:24 p.m.

Process Area SAA. The inspectors observed a one cubic yard container accumulating closed pharmaceutical solid packages and marked with a date. Photograph 4 taken at 12:249 p.m.

	
Process Area SAA. Sign indicating the SAA. The inspectors observed a one cubic yard container accumulating closed pharmaceutical solid packages and marked with a date. Photograph 5 taken at 12:24 p.m.	Process Area SAA. The inspectors observed a third SAA. Container was not marked/labeled with a hazard indicator. Photograph 6 taken at 12:32 p.m.
	
Process Area SAA. The inspectors observed a third SAA. Container was not marked/labeled with a hazard indicator. The facility marked the container with a hazard indicator Photograph 7 taken at 12:34 p.m.	Process Area SAA. The inspectors observed a container of universal waste. Photograph 8 taken at 12:35 p.m.

	
Batch Packing Area. Refactory Area. The inspectors observed the container was not marked/labeled with a hazard indicator. The facility marked the container with a hazard indicator. Photograph 9 taken at 12:49 p.m.	Batch Packing Area. Refactory Area. The inspectors observed the universal waste container was not marked with a date Photograph 10 taken at 12:51 p.m.
	
Batch Packing Area. Refactory Area. The inspectors observed the universal waste container was not marked with a date The facility marked the container with the date March 8, 2023. Photograph 11 taken at 12:52 p.m.	Batch Packing Area. The inspectors observed a view of containers of hazardous waste pharmaceuticals and universal waste. Photograph 12 taken at 12:52 p.m.

	
Batch Packing Area. The inspectors observed a 55-gallon container of hazardous waste pharmaceutical aerosols not marked/labeled with a hazard indicator. The facility indicated it was accumulating nonhazardous waste. Photograph 13 taken at 12:59 p.m.	Schedule III through V DEA Controlled Substance Area. The inspectors observed the container was not marked or labeled with a hazard indicator. Photograph 14 taken at 1:04 p.m.

Schedule III through V DEA Controlled Substance Area. The inspectors observed the container was not marked or labeled with a hazard indicator. The facility marked the container with a hazard indicator. Photograph 15 taken at 1:04 p.m.