

Resource Conservation and Recovery Act (RCRA) Compliance Evaluation Inspection (CEI)

Farmacias Plaza #2

PRN008031031

US Environmental Protection Agency – Region 2
Caribbean Environmental Protection Division
Response and Remediation Branch



Resource Conservation and Recovery Act (RCRA)
Compliance Evaluation Inspection (CEI)

Facility Name:	Farmacias Plaza #2						
EPA ID Number:	PRN008031031¹						
Completion Date:	March 2, 2023						
Generator Status in Record:	Non-Notifier ²						
RCRA Permitted:	No						
Corrective Action:	No						
Project ID	CEPD-RCRA-23-0430						
Basis for Inspection:	Core Program (Activity conducted as a result of the Non-notifiers initiative. Conducted during the COVID-19 pandemic timeframe.)						
Facility Personnel:							
Name:	Title:	Email:	Phone:	Attend to:			
				OM ³	FW ⁴	DR ⁵	CM ⁶
Ms. Madeline Aponte	Store Manager	plaza02@aliviahealth.com	787-630-2351	✓	-	-	✓
Ms. Muriel Peguero	Pharmacy Staff	mpeguero@aliviahealth.com	787-620-9602	✓	✓	✓	✓
Ms. Nabila Vallés	VP ⁷ Operations of Farmacias Plaza	nvalles@aliviahealth.com	787-516-0745	-	-	✓ ⁸	-
EPA Personnel:							
Inspector's Name	EPA Region 2-CEPD		Enforcement Officer	phone/email			

¹ This facility was identified as part of the Non-notifiers' initiative. An EPA ID No. was not available for this facility. At the time of the inspection, the facility identified itself as Very Small Quantity Generator (VSQG). As a result of the latter, an EPA ID No. was requested afterwards.

² At the time of the inspection, the facility identified itself as VSQG. This facility is subject to the Hazardous Waste Pharmaceuticals rule (40 CFR part § 266 subpart P). For additional information, please refer to Section 2.2 of this Report.

³ Opening Meeting

⁴ Facility Walkthrough

⁵ Documents Review. For additional information related to this item, please refer to Section 3 and 5 of this Report.

⁶ Closing Meeting, if apply.

⁷ Acronym usually stands for Vice President.

⁸ Ms. Valles was not physically at the facility but, as part of this CEI, provided the information requested on March 3, 2023, via email.

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Ms. Rosana Caballer-Cruz		EPA Region 2-CEPD	Enforcement Officer	787-977-5880/ caballer.rosana@epa.gov
Status:	FINAL			
EPA Inspector Signature/Date	X ROSANA CABALLER-CRUZ Digitally signed by ROSANA CABALLER-CRUZ Date: 2023.04.18 10:01:55 -04'00'			
Supervisor Signature/Date	X DAVID CUEVAS MIRANDA Digitally signed by DAVID CUEVAS-MIRANDA Date: 2023.04.18 10:09:21 -04'00' David N. Cuevas Miranda, Ph.D.			

1 FACILITY SUMMARY

Facility Physical Location: (Municipality, PR, zip code)	MARGINAL D-32 EXT FORREST HILLS - BAYAMON, PUERTO RICO, 00959.		
Geographical Coordinates:	18.386038, -66.163860		
Facility Information:	FARMACIAS PLAZA #2 787-620-9602 Mailing address: MARGINAL D-32 EXT FORREST HILLS– BAYAMON, PUERTO RICO, 00959.		
NAICS:	446110 - Pharmacies and Drug Stores ⁹		
Previously inspected:	NO		
Area:	ONE BUILDING; ft ² not available		
Employees	APPROXIMATELY 9		
HW ¹⁰ transferred via pipeline?	NO ¹¹		
UST ¹² available at the facility?	NO ¹³		
NRC ¹⁴ orientation provided?	YES		

2 INTRODUCTION

On March 2, 2023, a Resource Conservation and Recovery Act (RCRA) Compliance Evaluation Inspection (inspection) was conducted at Farmacias Plaza #2 (the facility), pursuant to Section 3007 of RCRA. As part of the inspection, I explained to the facility representative that an opening meeting, walkthrough, and document review section would be conducted to evaluate the

⁹ This information was not provided during the CEI nor available in RCRA Info System. The reference used is available at: <https://www.naics.com/naics-code-description/?code=446110> . This information can be subject to change.

¹⁰ Acronym stands for hazardous waste.

¹¹ Information provided by the facility representative.

¹² Acronym stands for underground storage tanks.

¹³ Information provided by the facility representative.

¹⁴ Acronym stands for National Response Center.

facility's compliance with the requirements that govern hazardous waste generators, universal waste handlers, and used oil generators, as applicable.

According to records, the facility has never been inspected by the EPA before this inspection, however, it was identified by the Agency as part of the Non-notifiers initiative¹⁵. I arrived at the facility around 9:40 am and the CEI was conducted completely inside the building.

2.1 NON-NOTIFIERS INITIATIVE

This facility was one of the facilities identified as part of the Non-notifiers initiative. Those facilities identified as Non-notifiers, such as Farmacias Plaza #2, Bayamón, are facilities that EPA has a reason to believe that is a generator of hazardous waste, based on EPA's review of eManifests(s). As a generator of hazardous waste, Farmacias Plaza #2, Bayamón, is subject to Sections 3002 and 3010 of RCRA, 42 U.S.C. §§ 6922 and 6930, and the regulations set forth at 40 C.F.R. Parts 262 and/or 270, or the authorized State equivalent. Henceforth, the facility was identified and included to be inspected as soon as the COVID-19 Pandemic health situation allowed us to physically visit it.

2.2 SUBPART P – HAZARDOUS WASTE PHARMACEUTICALS

On August 21st, 2019, the final rule, Hazardous Waste Pharmaceuticals, was effective¹⁶. Part 266 subpart P only applies to the management of hazardous waste pharmaceuticals at healthcare facilities and reverse distributors. The Regulation citation of Subpart P – Hazardous Waste Pharmaceuticals can be found at 40 CFR part § 266 subpart P: healthcare facilities and reverse distributors. Here, 40 CFR § 266.500(2) defines a Healthcare facility as *“means any person that is lawfully authorized to Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to... pharmacies...”* The rule also established that “healthcare facilities that generate above VSQGs amounts of hazardous waste (i.e., SQG or LQG) must manage their hazardous waste pharmaceuticals under 40 CFR part § 266 subpart P. Healthcare facilities that generate VSQG amounts of hazardous waste are subject to the hazardous waste generator regulations for VSQGs in 40 CFR section § 262.14, as well as three sections of part 266 subpart P: 40 CFR section §§ 266.505, 266.507, and 266.504”, respectively, in order to comply with Hazardous waste pharmaceutical requirements. Farmacias Plaza #2 fulfills the definition of a healthcare facility, hence, the facility is subject to the Subpart P – Hazardous Waste Pharmaceuticals rule.

2.3 FACILITY PHYSICAL DESCRIPTION AND OPERATION

The Farmacias Plaza #2 (Plaza #2) has been placed at this location since approximately six (6) years ago. According to the facility representatives, is a local pharmacy (aka community pharmacy) that sells OTC¹⁷ and prescribes mainly for human consumption, sells goods such as

¹⁵ For additional information of this item, please refer to Section 2.1 of this Report.

¹⁶ Reference: <https://www.epa.gov/hwgenerators/frequent-questions-about-management-standards-hazardous-waste-pharmaceuticals-and#app1>

¹⁷ Acronym stands for Over the Counter.

food¹⁸, women-related products (i.e., makeup, nail polish, etc.), baby-related products (i.e., pampers, baby food, etc.), among others. The facility consists of one building, a parking lot and approximately 9 employees work in the prescription area. The schedule for the facility is Monday to Friday from 8:00 am to 9:00 pm, Saturday from 8:00 am to 5:00 pm, and Sunday from 9:00 am to 6:00 pm¹⁹. The current CEI was conducted at the facility's prescription area.

2.4 AERIAL PHOTOGRAPH

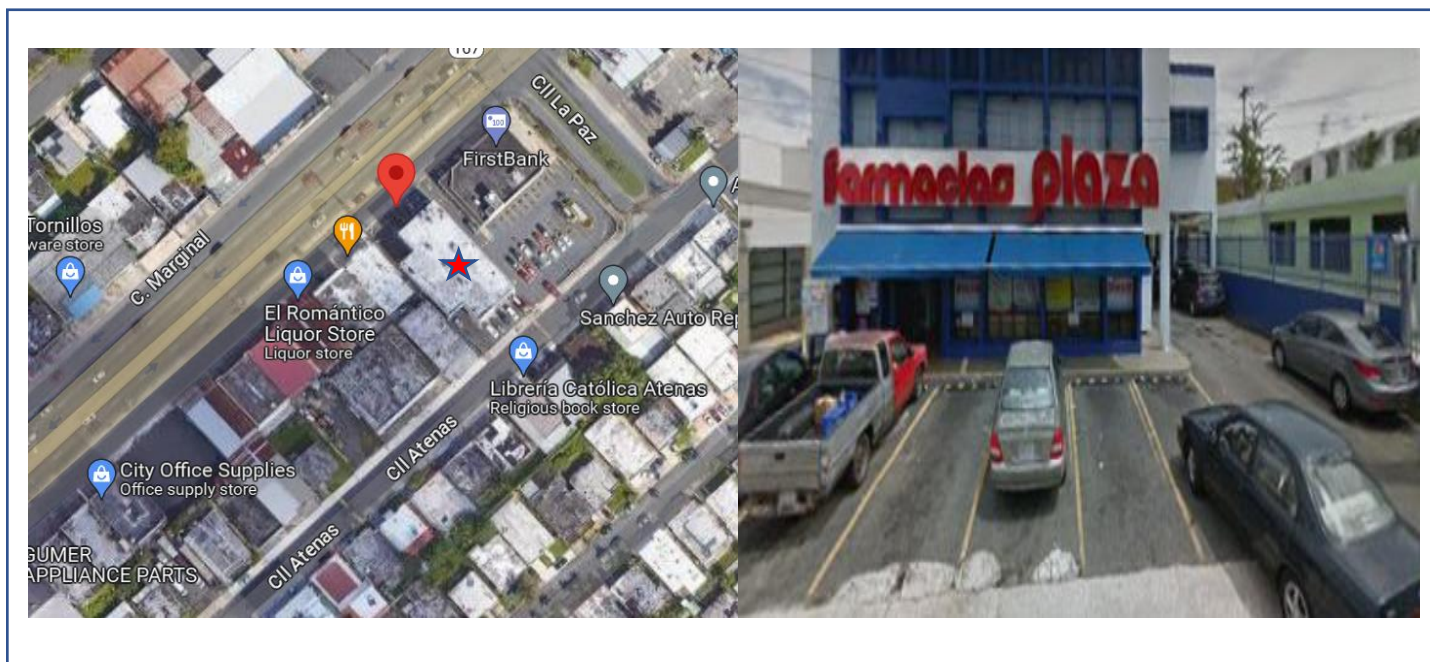


Figure 1: Right: Facility Location. Left: Picture of the facility. The picture was taken from the internet.

2.4 SOLID AND HAZARDOUS WASTE GENERATION

According to the facility representative, they are currently generating hazardous waste. She informed me that the facility's prescription area-container area is the only location available for handling, storing, and/or disposal of hazardous waste in the facility. The hauler company for their hazardous waste is Stericycle²⁰. Also, I asked the facility representative about their universal waste and used oil generation, handling, and/or disposal activities. She told me, that universal waste and used oil are not generated at the facility. Information related to any spills and/or chemical releases in their facility was asked, as well. According to her, spills nor chemical releases in the facility have occurred. Finally, I provided the Farmacias Plaza #2

¹⁸ Food already prepared such as can foods. Preparation of food and/or meals are not conducted at this facility.

¹⁹ Prescription area schedule could differ from this statement. This information is subject to change and may not reflect all the hours where the facility is open to the public.

²⁰ At the time of the inspection, it was informed by the facility representative that a new hauler company would be conducting their disposal services. The name of the new company is Reverse Distributors.

representative with an orientation and information related to NRC, such as but not limited to the phone number.

3 OPENING MEETING

I met at the facility with Ms. Madeline Aponte, Store Manager. I identified myself as an EPA RCRA enforcement officer and told the facility representative that the purpose of my visit was because the Agency identified Farmacias Plaza #2 facility as part of the Non-notifiers initiative and to conduct a CEI at the facility to evaluate its hazardous waste, universal waste, and used oil management practices and compliance. I told her that documentation related to RCRA, universal wastes, and/or used oil would be requested as part of this CEI. Finally, I also explained that we needed to visit the waste generation areas in her facility. She told me that she would introduce me to Ms. Muriel Peguero, from the Pharmaceutical Staff, in order to obtain the information needed for this inspection.

Just after, she introduced me to Ms. Muriel Peguero, Pharmaceutical Staff. Ms. Peguero accompanied me and provided information related to this inspection. I identified myself, again, as an EPA RCRA enforcement officer²¹. As part of my conversation with Ms. Peguero, I observed that the information provided was not familiar to her. As a result, I asked her if she knew or was aware of RCRA, universal wastes, and used oil Regulations. She replied that she did not know much about them. Nevertheless, she was willing to provide the information to the best of her knowledge. Hence, I explained to her the Regulations and what would be our goals as part of this inspection.

After briefly describing to her the Regulations, I asked her if hazardous wastes, universal wastes, and/or used oil are currently generated at his facility. Ms. Jiménez told me that she understands that hazardous wastes are being generated at the facility, but universal wastes and/or used oil are not generated. I also asked her for information about any spill and/or chemical release at her facility in the last five (5) years. She replied that spills and/or chemical releases have not occurred in the last five (5) years.

Finally, as part of the inspection, I mentioned to the facility representative that I needed to take photos related to any RCRA-related issues. She approved and permitted me to take them.

4 FACILITY WALKTHROUGH

Just after the opening meeting, we started the facility walkthrough at the Farmacias Plaza #2 Prescription Area, where a blue plastic approximately 16-gallon container²² was found. The observations for the mentioned area are described below:

4.1 FARMACIAS PLAZA #2 PRESCRIPTION AREA

²¹ The purpose of the inspection and matters related to it were also explained to Ms. Peguero.

²² Approximation was provided by the facility representative.

General Picture of the Area	 <i>Figure 2: Farmacias Plaza #2 Prescription Area-Container Area</i>
Description of the Area	This area is located inside the Prescription Area. To gain access to the latter, I needed to sign in and sign out in the facility's log. The area is aimed to store the hazardous waste generated at the facility. It consists of a blue plastic approximately 16-gallon container²³.

At the time of the inspection, the blue plastic container was observed labeled as hazardous waste, with a red bag (inside the blue container) and approximately ¼ full. This 16-gallon blue plastic container was observed clean and appears to be in good condition. Once opened by the facility representative, inside the container, I observed different sizes of containers that once were filled with medicines. I asked the facility representative if the containers observed inside the 16-gallon blue plastic container were empty. According to her, those containers observed inside the 16-gallon blue plastic container were, indeed, empty. The information gathered from

²³ The facility representative was not able to confirm the size of the mentioned container.

the hazardous waste label observed in the 16-gallon blue plastic container indicated the following:

Information on the hazardous waste label	
Name:	UN 3248 – Medicine, liquid, flammable, toxic n.o.s. PG 11
Characteristic:	ignitable
Facility Name:	Farmacias Plaza #2-Forrest Hills
EPA ID No.:	VSQG

Also, at the time of the inspection, the container was observed with its lid above it, but it was not closed. As a result, I explained to the facility representative about the latter concern and why the current observation may not be according to the Regulation requirements.²⁴ Finally, I told her that additional information would be shared with her related to this observation and that additional information related to other Regulation matters would be shared for her future reference²⁵.

5 DOCUMENTS

5.1 DOCUMENT REQUEST

I explained to the facility representative that, as part of the CEI, a request and evaluation of documents would be conducted. I asked her for the following documents for review: (1) job description (2) training records, (3) basic contingency plan (Emergency Procedures/ Preparedness and Prevention), and (4) the last three (3) years of manifests. Information related to each document is presented below:

Documents Requested	Requested during CEI	Available during CEI?	Description
1. Job Description	YES	NO	Information was not available at the facility. Information was sent by Ms. Vallés, via email, on a later day.
2. Training Records	YES	YES	Two (2) documents were provided for review.
3. Basic contingency plan (Emergency	YES	NO	Information was not available at the facility.

²⁴ It could be subject to 40 CFR part § 266 subpart P. For additional information, please refer to Section 2.2 of this Report.

²⁵ The email was sent on March 3, 2023.

Procedures/ Preparedness and Prevention)			Information was sent by Ms. Vallés, via email, on a later day.
4. Manifests	YES	NO	Information was not available at the facility. Information was sent by Ms. Vallés, via email, on a later day.

5.2 DOCUMENTS REVIEW

5.2.1 JOB DESCRIPTIONS:

It was informed by the facility representative that these documents needed to be requested to the Farmacias Plaza Central office, which is located outside this facility. As a result, Ms. Peguero provided the following information in order to obtain said documents:

Contact: Ms. Vallés

Phone number: 787-620-9600

As a result of the information provided, on March 3, 2023, an email was sent to Ms. Vallés asking for the job descriptions of the personnel who works with the hazardous waste at the facility. The information was provided via email, as requested before the due date established.

5.2.2 TRAINING RECORDS:

A four-page document was submitted for review with information related to the training “*Dispocisión de medicamentos, desperdicios peligrosos, residuos cortopunzantes y residuos biológicos infecciosos*” was provided. According to the information gathered in this document, this training was provided as a result of a new policy²⁶. A total of 13 employees signed as employees’ recognition of this new policy between 03/09/2020 and 03/10/2020.

Also, a second document for evaluation was provided “*Manejo Sustancias Peligrosas*”, aka FP-OPS-PDP-00-004. The revision date was 11/30/2019 and the effective date was 12/01/2019. This document includes topics such as the use of PPE²⁷, 10 steps to how to clean a spill for hazardous substances, how to fill out the hazardous substances spill report, and the procedure.

5.2.3 BASIC CONTINGENCY PLAN (EMERGENCY PROCEDURES/ PREPAREDNESS AND PREVENTION):

It was informed by the facility representative that this information needed to be requested to

²⁶ The revision date was 08/24/2020 and the effective date was 09/07/2020. The policy was identified as FP-OPS-PDP-00-10-S – Policy and Procedures (Pharmacy).

²⁷ Acronym stands for Personal Protective Equipment.

Farmacias Plaza Central offices, which is located outside this facility. As a result, Ms. Peguero provided the following information in order to obtain said documents:

Contact: Ms. Vallés

Phone number: 787-620-9600

As a result of the information provided, on March 3, 2023, an email was sent to Ms. Vallés asking for the facility's Basic contingency plan (Emergency Procedures/ Preparedness and Prevention related information. The latter was provided via email, as requested before the due date established.

5.2.4 MANIFESTS:

It was informed by the facility representative that these documents needed to be requested to Farmacias Plaza Central offices, which is located outside this facility. As a result, Ms. Peguero provided the following information in order to obtain said documents:

Contact: Ms. Vallés

Phone number: 787-620-9600

As a result of the information provided, on March 3, 2023, an email was sent to Ms. Vallés asking for the last three (3) years of manifests. The information was provided via email, as requested before the due date established.

6 CLOSING MEETING

As part of the CEI, which was conducted on March 2, 2023, it was explained to the facility representatives²⁸ that an email with additional information and supporting documents would be sent for future reference. The latter would include, but would not be limited to RCRA Regulation, Universal waste, Used oil, and additional related items. Also, I told them that additional information related to this CEI would be requested. The email was sent, as agreed, on March 3, 2023²⁹. For more information, please refer to Section 8 and Section 9 of this Report.

7 POTENTIAL AREAS OF CONCERN

7.1 GENERATORS

According to eManifests data, Farmacias Plaza #2 was identified by the Agency as a potential non-notifier facility. Based on the available data, the observations, and information gathered during the inspection, the following area(s) of concern were identified:

²⁸ This information was provided separately to Ms. Peguero and Ms. Aponte.

²⁹ Ms. Peguero acknowledged receipt of the email on March 3, 2023.

7.1.2 § 266.500 - SUBPART P – HAZARDOUS WASTE PHARMACEUTICALS³⁰ - DEFINITIONS FOR THIS SUBPART

i. Since the CEI at Farmacias Plaza #2 was conducted after the final rule Hazardous Waste Pharmaceuticals was effective³¹ and, after the evaluation of the mentioned rule, it seems that the facility fulfills the definition of a healthcare facility. As a result, the facility is subject to the Subpart P – Hazardous Waste Pharmaceuticals rule instead of the standard RCRA generator regulations found in 40 CFR part § 262³². According to Subpart P – Hazardous Waste Pharmaceuticals, different requirements of applicability were established for a healthcare facility that generates *above* VSQGs amounts of hazardous waste (i.e., SQG or LQG)³³ vs a healthcare facility that *generate VSQG amounts* of hazardous waste³⁴.

Hence, in order to properly evaluate the hazardous waste pharmaceuticals management of Farmacias Plaza #2, the facility has to identify and establish if their generation of hazardous waste is above VSQG amounts of or if they are currently generating VSQG amounts of hazardous waste. This information is essential since, if the facility did not provide or gather this information, this would preclude a proper evaluation of the Subpart P that is applicable for this facility.

7.1.3 § 266.502 - SUBPART P – HAZARDOUS WASTE PHARMACEUTICALS –NOTIFICATION AND WITHDRAWAL FROM THIS SUBPART FOR HEALTHCARE FACILITIES MANAGING HAZARDOUS WASTE PHARMACEUTICALS

ii. According to 40 CFR § 266.502(a)(1), which states that *“A healthcare facility must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), that it is a healthcare facility operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each site or EPA identification number.”*

At the time of the inspection, the facility failed to comply with this requirement. This CEI was conducted as a result of the Non-notifiers initiative. The facilities identified in this initiative were included since the Agency had a reason to believe that is a generator of hazardous waste, based on EPA’s review of eManifests. Such notification from the facility, as required by Regulation, was not received nor available, hence, the facility was included as part of the Non-notifiers’ initiative.

³⁰ For additional information, please refer to Section 2.2 of this Report.

³¹ August 21st, 2019.

³² Reference: <https://www.epa.gov/hwgenerators/frequent-questions-about-management-standards-hazardous-waste-pharmaceuticals-and#app2>

³³ Regulation applicable: subject to 40 CFR part § 266 subpart P.

³⁴ Regulation applicable: subject to the hazardous waste generator regulations for VSQGs in 40 CFR section § 262.14, as well as three sections of part 266 subpart P: 40 CFR section §§ 266.505, 266.507, and 266.504.

7.1.4 § 266.502 - SUBPART P – HAZARDOUS WASTE PHARMACEUTICALS – STANDARDS FOR HEALTHCARE FACILITY MANAGING NON-CREDITABLE HAZARDOUS WASTE PHARMACEUTICALS

iii. According to 40 CFR § 266.502(a)(1)(ii), which states that *“A healthcare facility that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart...”*

At the time of the inspection, the facility failed to comply with this requirement. According to the Regulation, this facility has been defined as a healthcare facility. As a result, the facility would have had to request an EPA ID No. since the Hazardous Waste Pharmaceutical rule was effective and identify itself as a healthcare facility. The effective date of the Hazardous Waste Pharmaceutical rule was August 21st, 2019. At the time of the inspection, the facility did not have an EPA ID. No. available, and they still used “VSQG” as their EPA ID No.

8 FOLLOW-UP ACTIONS

As expressed in Section 6 of this Report, an email to the facility representatives was sent on March 3, 2023. The email included direct links which provide information related to the RCRA Regulation (40 CFR §§ 260 to 265), Universal Waste (40 CFR § 273), and Used Oil (40 CFR § 279), among other direct links with specifics, such as aerosol cans, satellites accumulation areas (SAAs), aisle space, P-waste, etc. In addition, the EPA Form 8700-12, and one page with additional links which provide direct links for specific items for the RCRA Regulation was also sent for their future reference. The facility representative, Ms. Muriel Peguero, confirmed and acknowledge receipt of the email on March 3, 2023³⁵. The due date to provide the information requested was March 16, 2023. The facility has complied with the due date established.

8.1 REQUESTS

Information Requested	Reason
1. <i>Training Records - Certification evidence from 2020 to 2022 from personnel who works with hazardous wastes at the facility</i>	- This information was requested to confirm that the person who signed during the mentioned time frame was certified and willing to sign the facility's manifests.

³⁵ For additional information related to this item, please refer to the Attachment identified as OTHER: EMAIL SENT TO FACILITY REPRESENTATIVES ON MARCH 3, 2023.

2. <i>Job description(s)</i>	- This information was requested to identify the personnel who works with hazardous wastes at the facility.
3. <i>Hazardous wastes manifest</i>	- This information was requested since it was not available during the CEI.
4. <i>P-waste generated at the facility</i>	- This information was requested to know the quantity, generation, handling, storage, and disposal activities of P waste at the facility if applicable.
5. <i>Expired medicines</i>	- This information was requested to know the quantity, generation, handling, storage, and disposal activities of expired medicines at the facility if applicable.

8.2 INFORMATION PROVIDED TO THE FACILITY REPRESENTATIVE

Information Requested	Link	Enclosed
1. <i>RCRA (Hazardous Waste)</i>	√	
2. <i>Summary of Requirements for Very Small Quantity Generators (VSQGs)</i>	√	
3. <i>Summary of Requirements for Small Quantity Generators (SQGs)</i>	√	
4. <i>Summary of Requirements for Large Quantity Generators (LQGs)</i>	√	
5. <i>Universal Waste</i>	√	
6. <i>Used Oil</i>	√	
7. <i>Aerosol cans</i>	√	
8. <i>Satellite Accumulation Areas</i>	√	
9. <i>Condition of containers</i>	√	
10. <i>Aisle space</i>	√	
11. <i>Alternative Standards for Episodic Generation</i>	√	
12. <i>National Response Center</i>	√	
13. <i>Hazardous Waste Generator Regulations Compendium</i>	√	
14. <i>Defining Hazardous Waste</i>	√	
15. <i>P-waste</i>	√	
16. <i>Managing your hazardous waste document – English Version</i>		√

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17. EPA Form 8700-12	√	√
18. One page with additional links which provide direct links for specific items for the RCRA Regulation		√
19. Small business guide – Spanish Version		√

9 ATTACHMENTS

I. CAMERA ROLL

II. APPENDIX 1: SITE PICTURES

III. OTHER: EMAIL SENT TO FACILITY REPRESENTATIVES ON MARCH 3, 2023.

ATTACHMENT I: CAMERA ROLL

Agency (EPA) > Desktop > In response of COVID19 > FY'23 > CEIs > Farmacias Plaza #2, Bayamón > Pictures



DSCN1548.JPG



DSCN1549.JPG



DSCN1550.JPG