



EPA REGION 2
CARIBBEAN ENVIRONMENTAL PROTECTION DIVISION

February 13, 2024

VIA EMAIL AND CERTIFIED MAIL

Mr. Jose Aleman
Environmental Health Safety Manager
Pfizer Pharmaceuticals LLC. (Viatris)
689 State Road Km.1.9 Carmelita Ward,
Vega Baja, Puerto Rico 00694
jose.alemanfigueroa@viatris.com

RE: RCRA § 3007 – REQUEST FOR INFORMATION
Pfizer Pharmaceuticals LLC. (Viatris)
EPA ID: PRD0901144709

Dear Mr. Jose Aleman:

The U.S. Environmental Protection Agency (EPA) is charged with the protection of human health and the environment under Section 3008 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA) of 1976 and the Hazardous and Solid Waste Amendments (HWSA) of 1984, 42 U.S.C. § 6901, 6928.

This request for information is made pursuant to the provisions of Section 3007 of RCRA, 42 U.S.C. § 6927, which requires that you provide the information requested in **Enclosure I** to this letter using the instructions and definitions included in **Enclosure II**. This information is required to evaluate the full regulatory and compliance status of the facility. The information requested in Enclosure I must be submitted no later than thirty (30) calendar days from receipt of this letter. Requests for additional time to provide the information requested in Enclosure I must be justified and must be made in writing within ten (10) calendar days of receipt of this letter. The response must be signed by a responsible official or agent of your facility, using the form in **Enclosure III** to this letter.

Failure to respond to this letter truthfully and accurately within the time provided may subject you to sanctions authorized by federal law, including but not limited to a potential enforcement action pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, including the assessment of a monetary penalty. Please also note that all information you provide may be used in an administrative, civil judicial or criminal action. This information is not subject to the requirements of the Paperwork Reduction Act as amended, 44 U.S.C. § 3501 et seq.

You may, if you desire, assert a business confidentiality claim covering all or part of the information herein requested. This claim may be asserted by placing on (or attaching to) the information at the time it is submitted, a cover sheet, stamped or typed legend, or other suitable form of notice employing language such as "trade secret", "proprietary", or "company confidential". The claim should set forth the information requested in 40 C.F.R. § 2.204(e)(4). Information covered by such a claim will be disclosed by EPA only to the extent permitted by, and by means of procedures set forth in 40 C.F.R. Part 2. EPA will review the information to determine the extent of confidentiality of the information, and may, at its discretion challenge the confidentiality claim pursuant the procedures set forth at 40 C.F.R. Part 2. If no such claim accompanies the information when it is received by EPA, it may be available to the public by EPA without further notice you.

The responses to the information request in Enclosure I must be mailed to the following address:

Khrystian M. Vazquez, Enforcement Officer
Response and Remediation Branch
U.S. Environmental Protection Agency - Region 2
Caribbean Environmental Protection Division
City View Plaza II, Suite 7000
#48 PR-165 Km 1.2
Guaynabo, Puerto Rico 00968

If you have any questions regarding this matter, please contact Khrystian M. Vazquez from my staff at 787-977-5860 or via e-mail at: vazquez.khrystian@epa.gov

Sincerely,

**HECTOR
VELEZ-CRUZ**

Digitally signed by
HECTOR VELEZ-CRUZ
Date: 2024.02.13
17:13:49 -04'00'

Héctor L. Vélez-Cruz, Esq.
Acting Director

Enclosures:

cc: Ms. Lorna Rodríguez, RCRA Enforcement Section Chief
Puerto Rico Dept. Natural & Environmental Resources

bcc: [CEPD-RRB BRANCH CHIEF]
[CEPD-RRB ENFORCEMENT OFFICER]
RCRA Enforcement Files

ENCLOSURE I – RCRA § 3007 Request for Information

Pfizer Pharmaceuticals LLC. (Viatris)

EPA ID No. PRD0901144709

On or about 05 July 2023, duly authorized representatives of EPA conducted a RCRA Hazardous Waste Compliance Evaluation Inspection of the Pfizer Pharmaceuticals LLC. (Viatris) at 689 State Road Km. 1.9 Carmelita Ward, Vega Baja, Puerto Rico 00694 pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927.

Based on the information obtained during the inspection, EPA determined that the following information is required to determine the compliance status of Pfizer Pharmaceuticals (VIATRIS).

1. General Information

- a. Provide the full legal name of Pfizer Pharmaceuticals (VIATRIS). If the company has used any other names, please provide them. Provide the date that Pfizer Pharmaceuticals (VIATRIS) started business at 689 State Road Km. 1.9 Carmelita Ward, Vega Baja, Puerto Rico 00694.
- b. Provide the management structure of the company (President/Owner, Partners, General Manager, etc.). If the company is a subsidiary, indicate the parent company.
- c. Provide the number of employees of Pfizer Pharmaceuticals (VIATRIS) and numbers of employee that manage hazardous materials and hazardous waste.
- d. Provide copies of any environmental training records for those employees who manage hazardous materials and hazardous wastes that they have taken in the past.
- e. Provide the type of company (corporation, partnership, etc.), employer identification number, Department of State certificate number, DUNS number and business licenses, if applicable.

2. Specific Information

a. Waste Generation

- i. Provide a complete description of the manufacturing process and how and where hazardous wastes are generated. Please specify where hazardous wastes are generated in relation to the manufacturing process. The use of diagrams may be useful.
- ii. Provide and describe the process of how hazardous waste is collected from the point of generation and stored in all the Satellite Accumulation Areas (SAAs). Please describe the container's marking and labeling procedures.

- iii. Provide and describe process of who manage or store the collection of generated hazardous waste in all the SAAs.
- iv. Provide and describe the process of the final disposition of the hazardous waste from the SAAs to the 90-days Hazardous Storage Area.

b. Waste Determination

- i. For each waste indicated in response to Question 2a. i. ii. iii. iv above, that was determined to be a hazardous waste, please indicate the EPA and/or Commonwealth of Puerto Rico hazardous waste number and describe how the waste was determined to be a hazardous waste. For each such waste please include copies of all analytical results and/or documentation used in determining that the waste was a hazardous waste. If generator knowledge of the waste(s) was used to determine that the waste was a hazardous waste, please provide a narrative which details the knowledge employed in such determination.
- ii. For each waste indicated in response to Question 2a. i. ii. iii. iv above, that was determined not to be a hazardous waste, please describe how the waste was determined not to be a hazardous waste. For each such waste please include copies of all analytical results and/or documentation used in determining that the waste was not a hazardous waste. If generator knowledge of the waste(s) was used to determine that the waste was not a hazardous waste, please provide a narrative which details the knowledge employed in such determination.
- iii. Provide copies of the Safety Data Sheet of the chemicals used at the facility.
- iv. For each hazardous and each non-hazardous waste described in response to Question 2a. i. ii. iii. iv above, please provide copies of any documentation of the treatment or disposal of such waste since 2020 to present, including copies of hazardous waste manifests used. If no such documentation is available, please provide the name, address, and representative, if known, for each corporate or municipal entity involved in the disposal of the waste.
- v. Please provide a description of the process (preparing batch products, dispensing of the product, management of leftover product, etc.) performed at the facility. Indicate in which part of the process waste is generated and what type of waste it is.
- vi. Provide a description of the training provided to the employees to manage chemicals/waste at the facility. Include supporting documentation such as training certificates, training plans, etc.

ENCLOSURE II – Instructions and Definitions

In responding to this Request for Information, apply the following instructions and definitions:

1. The signatory should be an officer or agent who is authorized to respond on behalf of the company or facility. The signatory must complete and return the attached Certification of Answers to Responses (ENCLOSURE III).
2. A complete response must be made to each individual question in this Request for Information. Identify each answer with the number of the question to which it is addressed.
3. In preparing your response to each question, consult with all present and former employees and agents of the company or facility who you have reason to believe may be familiar with the matter to which the question pertains.
4. In answering each question, identify all contributing sources of information.
5. If you are unable to answer a question in a detailed and complete manner or if you are unable to provide any of the information or documents requested, indicate the reason for your inability to do so. If you have reason to believe that there is an individual who may be able to provide more detail or documentation in response to any question, state that person's name and last known address and phone number and the reasons for your belief.
6. If you cannot provide a precise answer to any violation, please approximate and state the reason for your inability to be specific.
7. For each document produced in response to this Request for Information, indicate on the document or in some other reasonable manner, the number of the question to which it applies.
8. If anything is deleted from a document produced in response to this Request for Information, state the reason for and the subject matter of the deletion.
9. If a document is requested but is not available, state the reason for its unavailability. In addition, identify any such document by author, date, subject matter, number of pages, and all recipients and their addresses.
10. The company and/or facility for the purposes of this Request for Information is Pfizer Pharmaceuticals LLC. (Viatris) at 689 State Road Km. 1.9 Carmelita Ward, Vega Baja, Puerto Rico 00694.
11. A generator of hazardous waste for the purposes of this Request for Information shall be defined as any person (which includes this facility), by site, whose act or process produces hazardous waste or whose act first causes a hazardous waste to become subject to regulation.
12. Solid waste shall be defined for the purposes of this Request for Information as that term is defined in Section 1004(27) of RCRA, as amended, 42 U.S.C. Part 6903(27).

13. Hazardous waste shall be defined for the purposes of this Request for Information as that term is defined in Section 1004(5) of RCRA, as amended, 42 U.S.C. Part 6903(5).
14. Manage shall be defined for the purposes of this Request for Information as to market, generate, treat, store, dispose or otherwise handle.
15. Used oil shall be defined for the purposes of this Request for Information as any oil that has been refined from crude oil, or any synthetic oil, that has been used and as a result of such use is contaminated by physical or chemical impurities.

ENCLOSURE III – Certification of Answers to Responses

I certify, under penalty of law, that I have personally examined and am familiar with the information submitted in this document (response to EPA Request for Information Pfizer Pharmaceuticals LLC. (VIATRIS) EPA ID PRD0901144709) and all documents submitted herewith, that the submitted information is true, accurate and complete, and that all documents submitted herewith are complete and authentic, unless otherwise indicated. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

Name (Print or Type)

Title (Print or Type)

Signature

Date (Print or Type)

Pfizer Pharmaceuticals LLC. (Viatris)

EPA ID: PRD0901144709