



REGION 5

CHICAGO, IL 60604

ELECTRONIC MAIL DELIVERY RECEIPT REQUESTED

Mr. John J. Ring
EHS Manager
Pharmacia & Upjohn Company, LLC
7171 Portage Road
Kalamazoo, Michigan 49001
john.j.ring@pfizer.com

Re: **Notice of Violations**
Pharmacia & Upjohn Company, LLC
Kalamazoo, Michigan
Facility ID MID000820381

Dear Mr. Ring:

On June 25-26, 2024, the U.S. Environmental Protection Agency conducted a Resource Conservation and Recovery Act (RCRA) compliance evaluation inspection of the Pharmacia & Upjohn Company, LLC, ("Pharmacia & Upjohn", "facility" or "you") located in Kalamazoo, Michigan. The purpose of the inspection was to evaluate Pharmacia & Upjohn's compliance with its Hazardous Waste Management Facility Operating License, and certain provisions of RCRA and its implementing regulations related to the generation, treatment and storage of hazardous waste. We have enclosed a copy of the inspection report for your convenience.

Information currently available to EPA suggests that Pharmacia & Upjohn is in violation of RCRA. By this letter, EPA is extending to you an opportunity to advise the Agency, in person or in writing, of any further information EPA should consider with respect to the violations. We request that you voluntarily submit a response in writing to us no later than 30 calendar days after receipt of this letter documenting the actions, if any, which you have taken since the inspection to address the violations identified below or demonstrating why the violation(s) have not occurred.

Storage of Hazardous Waste without a License or Interim Status Which Violated Section 3005 of RCRA, 42 U.S.C. § 6925(a) and State Licensing Requirements

During the inspection, EPA observed Pharmacia & Upjohn's failure to comply with the RCRA license exemption conditions, below. When a hazardous waste generator fails to comply with the conditions for a license exemption, the generator is an operator of a hazardous waste storage facility without a license in violation of Mich. Admin. Code. r. 299.9502(1), 299.9508 and 299.9510 [40 C.F.R. §§ 270.1(c),

and 270.10(a) and (d)]. Many of the RCRA license exemption conditions are also independent requirements that apply to licensed and interim status hazardous waste management facilities that treat, store, or dispose of hazardous waste (TSD requirements). When a hazardous waste generator loses its license exemption due to a failure to comply with an exemption condition incorporated from Mich. Admin. Code. r. 299.9601(1)-(3) and 299.11003(1)(n) and (q), the generator: (a) is an operator of a hazardous waste storage facility; and (b) simultaneously violates the corresponding TSD requirement. For purposes of remedying noncompliance or preventing future violations, EPA recommends that Pharmacia & Upjohn comply with the conditions below instead of applying for a hazardous waste storage license.

1. Hazardous Waste Accumulation Over 90 Days in a Non-Licensed Area

Under Mich. Admin. Code. r. 299.9307(1)(a), Mich. Admin. Code. r. 299.9502(1), 299.9508 and 299.9510 [40 C.F.R. §§ 270.1(c), and 270.10(a) and (d)], a large quantity generator may accumulate hazardous waste on-site for 90 days or less without a license or interim status unless the generator has been granted an extension of the 90-day period.

At the time of the inspection, at the 291 Pad 90-day area, there were five 275-gallon totes and two 330-gallon totes that were labeled as “Hazardous Waste”, “D001, D002”, and “50% Caustic Waste Liquid”, were labeled with a hazard indicator, were closed, but were all dated 2/5/24 (51 days over the allowed 90 days of accumulation). Please confirm if the hazardous waste described in this paragraph was shipped off-site, if so please provide/correlate documentation of the associated manifest for this waste stream.

At the time of the inspection, at the 291 Pad 90-day area, there was one blue 55-gallon drum that was labeled as “Hazardous Waste”, was closed, but was dated 2/29/24 (27 days over the allowed 90 days of accumulation). Please confirm if the hazardous waste described in this paragraph was shipped off-site, if so please provide/correlate documentation of the associated manifest for this waste stream.

At the time of the inspection, at the 291 Pad 90-day area, there were four 275-gallon totes that were labeled as “Hazardous Waste”, “D001, D002”, “Octane THF”, “B73 T1826”, and “50% Caustic Waste Liquid”, were closed, but were dated 2/2/24 (54 days over the allowed 90 days of accumulation). Since the inspection, Pharmacia & Upjohn submitted correspondence via email dated 7/19/24 that documented that the hazardous waste described in this paragraph was shipped off-site on manifest # 002314939 VES on 6/28/24 (57 days over the allowed 90 days of accumulation). No further actions are necessary for this paragraph.

At the time of the inspection, at the 291 Pad 90-day area, there were two 55-gallon drums that were labeled as “Hazardous Waste”, “CIP 100”, and “D002”, were closed, were marked with a hazard indicator, but were dated 4/12/23 (350 days over the allowed 90 days of accumulation). Please confirm if the hazardous waste described in this paragraph was shipped off-site, if so please provide/correlate documentation of the associated manifest for this waste stream.

At the time of the inspection, at the 291 Pad 90-day area, there were approximately eighteen 275-gallon totes that were labeled as “Hazardous Waste”, “D002”, and “Sodium Hydroxide

Rinse Water”, and were closed. At least two of the totes were dated 12/30/23 and 12/31/23 (88 days over the allowed 90 days of accumulation). Since the inspection, Pharmacia & Upjohn submitted correspondence via email dated 7/19/24 that documented that at least a portion of the hazardous waste described in this paragraph was shipped off-site on manifest # 002314993 VES on 7/10/24 (103 days over the allowed 90 days of accumulation). Please confirm if any of the remaining hazardous waste described in this paragraph was shipped off-site, if so please provide/correlate documentation of the associated manifest for this waste stream.

At the time of the inspection, at the 291 Pad 90-day area, there was one 275-gallon tote that was labeled as “Hazardous Waste”, “F002, F003, F005”, and “Tank Bottoms”, was closed, but was dated 12/30/23 (88 days over the allowed 90 days of accumulation). Since the inspection, Pharmacia & Upjohn submitted correspondence via email dated 7/19/24 that documented that the hazardous waste described in this paragraph was shipped off-site on manifest # 002314941 VES on 7/10/24 (103 days over the allowed 90 days of accumulation). No further actions are necessary for this paragraph.

At the time of the inspection, at the 291 Pad 90-day area, there were four 55-gallon drums, situated on a pallet, that were labeled as “Hazardous Waste”, “D001”, and “Water/Toluene”, were closed, were labeled with a hazard indicator, but were dated 1/10/24 (77 days over the allowed 90 days of accumulation). Please confirm if the hazardous waste described in this paragraph was shipped off-site, if so please provide/correlate documentation of the associated manifest for this waste stream.

At the time of the inspection, at the 291 Pad 90-day area, there were two 275-gallon totes that were labeled as “Hazardous Waste”, “D001, D002”, were closed, but were dated 2/5/24 (51 days over the allowed 90 days of accumulation). Please confirm if the hazardous waste described in this paragraph was shipped off-site, if so please provide/correlate documentation of the associated manifest for this waste stream.

At the time of the inspection, at the 291 Pad 90-day area, there were two 275-gallon totes that were labeled as “Hazardous Waste”, “D001, D002”, “B73 T1826 Octane/THF”, and “50% Caustic Waste Liquid”, were closed, but were dated 2/2/24 (54 days over the allowed 90 days of accumulation). Since the inspection, Pharmacia & Upjohn submitted correspondence via email dated 7/19/24 that documented that the hazardous waste described in this paragraph was shipped off-site on manifest # 002314939 VES on 6/28/24 (57 days over the allowed 90 days of accumulation). No further actions are necessary for this paragraph.

Please see photos # 9, # 10, # 19 - # 21, # 22 - # 29, # 31 - # 38, # 39 - # 46, # 47 - # 50, and # 51 - # 54 of the enclosed inspection report.

2. Description of Hazardous Waste Marking on Containers

Under Mich. Admin. Code. r. 299.9307(1)(b)(i)(I)(II), Mich. Admin. Code. r. 299.9502(1), 299.9508 and 299.9510, a large quantity generator shall mark or label each container of hazardous waste with the description of the waste or the hazardous waste number, and an indication of the hazards of the contents. The indication of the hazards of the contents may

include the applicable hazardous waste characteristic(s), the hazard communication consistent with 49 CFR part 172, subpart E or F, a hazard statement or pictogram consistent with 29 CFR 1910.1200, or a chemical hazard label consistent with the NFPA standard no. 704.

At the time of the inspection, at the 291 Pad 90-day area, there were two 275-gallon totes that were labeled as "Hazardous Waste", were dated 4/19/24, were closed, but were not marked with the description of the waste or hazardous waste codes, and were not labeled with hazard indicators.

At the time of the inspection, at the 291 Pad 90-day area, there were two 55-gallon drums, situated on a pallet, that were labeled as "Hazardous Waste" and were closed, but were not marked with the description of the waste or hazardous waste codes, and were not labeled with hazard indicators.

At the time of the inspection, at the 291 Pad 90-day area, there was one blue 55-gallon drum that was labeled as "Hazardous Waste", was closed, and was dated 2/29/24, but was not marked with the description of the waste or hazardous waste codes, and was not labeled with a hazard indicator.

At the time of the inspection, at the 291 Pad 90-day area, there was one 55-gallon drum that was labeled as "Hazardous Waste" but was not marked with a description of the waste or hazardous waste codes, and was not labeled with a hazard indicator.

At the time of the inspection, at the 291 Pad 90-day area, there were ten 275-gallon totes that were labeled as "Hazardous Waste" and were closed, but were not marked with a description of the waste or hazardous waste codes, and was not labeled with hazard indicators.

At the time of the inspection, at the 291 Pad 90-day area, there was one 55-gallon drum that was labeled as "Hazardous Waste", was dated 5/23/24, was closed, and was marked with hazard indicators, but was not marked with a description of the waste or hazardous waste codes."

Please see photos # 7, # 8, # 9, # 10, # 14, # 15, # 16, and # 55 of the enclosed inspection report.

3. Date When Each Period of Accumulation Begins and Making Clearly Visible for Inspection

Under Mich. Admin. Code. r. 299.9307(1)(b)(i)(I)(III), Mich. Admin. Code. r. 299.9502(1), 299.9508 and 299.9510, a large quantity generator shall mark or label each container of hazardous waste with the date upon which each period of accumulation begins clearly visible for inspection on each container.

At the time of the inspection, at the 291 Pad 90-day area, there were two 55-gallon drums, situated on a pallet, that were labeled as "Hazardous Waste" and were closed, but were not marked with accumulation start dates.

At the time of the inspection, at the 291 Pad 90-day area, there was one 55-gallon drum that was labeled as “Hazardous Waste” but was not marked with an accumulation start date.

At the time of the inspection, at the 291 Pad 90-day area, there were approximately eighteen 275-gallon totes that were labeled as “Hazardous Waste”, “D002”, and “Sodium Hydroxide Rinse Water”, and were closed. Approximately sixteen of the eighteen totes were not marked with an accumulation start date.

At the time of the inspection, at the 291 Pad 90-day area, there were two 275-gallon totes that were situated in such a position that their labels were not clearly visible for inspection.

At the time of the inspection, at the 291 Pad 90-day area, there were ten 275-gallon totes that were labeled as “Hazardous Waste” and were closed, but were not marked with accumulation start dates, or were situated in a position that the dates were not clearly visible.

Please see photos # 9, # 10, # 14, # 15, and # 16 of the enclosed inspection report.

The license exemption conditions identified below are also independent TSD requirements.

4. Hazardous Waste Container Condition

Under Mich. Admin. Code. r. 299.9307(1)(b)(i)(B) and r. 299.9614(1)(a), and 40 C.F.R. §§ 262.17(a)(1)(ii) and 264.171, if a container holding hazardous waste is not in good condition, or if it begins to leak, the large quantity generator shall immediately transfer the hazardous waste from this container to a container that is in good condition and does not leak, or immediately manage the waste in some other way that complies with the conditions for exemption of this rule.

At the time of the inspection, at the 291 Pad 90-day area, there were four 55-gallon drums, situated on a pallet, that were labeled as “Hazardous Waste”, “D001”, and “Water/Toluene”, were closed, but were not in good condition as their lid tops were bulging and two of the drums’ lids were rusted.

At the time of the inspection, at licensed Building 388. There was one container that was not in good condition as its sides were sucked in. The container was labeled as “Hazardous Waste”, “D002”, and “Hexanoic Anhydride”, was labeled with a hazard indicator, was dated 4/1/24, and was closed. Since the inspection, Pharmacia & Upjohn submitted correspondence via email dated 7/19/24 that documented that the hazardous waste described in this paragraph was shipped off-site on manifest # 002314941 VES on 7/10/24 (14 days over the allowed 365 days of storage). No further actions are necessary for this paragraph.

Please see photos # 39 - # 46 of the enclosed inspection report.

5. Conducting and Documenting Weekly Inspections for Hazardous Waste Containers

Under Mich. Admin. Code. r. 299.9307(1)(b)(i)(F), 299.9614(1)(a), and 299.9311(7), and 40 C.F.R. §§ 262.17(a)(1)(v) and 264.174, a large quantity generator shall inspect central accumulation areas where containers are stored, at least weekly looking for leaks and for deterioration of containers caused by corrosion or other factors. The generator shall keep documentation of all inspections required under r. 299.9307.

At the time of the inspection, during the review of records, the inspectors reviewed the facility's hazardous waste weekly container inspection logs for the 291 Pad, Building 155, and Building 173. The 291 Pad documented inspections were reviewed for years 2022 (December), 2023 (January, February, March, and May), and 2024 (April). The inspectors observed that the April 2024 logs documented that the 291 Pad containers in storage were in good condition, were stored for less than ninety days, were labeled appropriately, were marked with hazardous waste codes, and were marked with accumulation start dates. The inspectors observed the issues described above that were not accurately documented on the reviewed facility's hazardous waste weekly container inspection logs for April 2024.

License Requirements

6. Operating License Condition, II.O. – Prohibitions on Storage Over One Year

Under Pharmacia & Upjohn's License, the licensee shall comply with all of the requirements of 40 C.F.R. Part 268 {Mich. Admin. Code. r. 299.9627 and 40 C.F.R. § 268.50(b)}, which states an owner/operator of a treatment, storage or disposal facility may store such waste for up to one year unless the Agency can demonstrate that such storage was not solely for the purpose of accumulation of such quantities of hazardous waste as are necessary to facilitate proper recovery, treatment, or disposal.

At the time of the inspection, at licensed Building 388, there was one 55-gallon drum that was labeled as "Hazardous Waste", "D002", and "Dibromoheptanitrite", was labeled with a hazard indicator, was dated 6/15/23, and was closed. The drum had been in storage for 376 days (11 days over the allowed 365 days of storage). Since the inspection, Pharmacia & Upjohn submitted correspondence via email dated 7/19/24 that documented that the hazardous waste described in this paragraph was shipped off-site on manifest # 002314939 VES on 6/28/24 (14 days over the allowed 365 days of storage). No further actions are necessary for this paragraph.

Please see photo # 3 of the enclosed inspection report.

7. Operating License Condition, III.C.1. – Use and Management of Containers

Under Pharmacia & Upjohn's License, the licensee shall manage all containers in compliance with Mich. Admin. Code. r. 299.9521(3)(b), r. 299.9614, and r. 299.9627 and 40 C.F.R. §§ 264.171, 264.172, 264.173, and 268.50(a)(2)(i).

At the time of the inspection, at licensed Building 388, there was one container that was not in good condition as its sides were sucked in. The container was labeled as "Hazardous Waste", "D002", and "Hexanoic Anhydride", was labeled with a hazard indicator, was dated 4/1/24, and was closed. Since the inspection, Pharmacia & Upjohn submitted correspondence via email dated 7/19/24 that documented that the hazardous waste described in this paragraph was shipped off-site on manifest # 002314941 VES on 7/10/24. No further actions are necessary for this paragraph.

Please see photo # 2 of the enclosed inspection report.

Other Violations

8. Hazardous Waste Determination and Recordkeeping

Under Mich. Admin. Code. r. 299.9302(1), a person who generates a waste shall make an accurate waste determination if that waste is a hazardous waste.

Under Mich. Admin. Code. r. 299.9311(1), a large quantity generator shall keep records supporting the hazardous waste determinations made under r. 299.9302 for not less than 3 years from the date that the waste was last sent to on-site or off-site treatment, storage, or disposal.

At the time of the inspection, at the 291 Pad 90-day area, there was one 275-gallon tote that was closed, but not labeled and was situated in the same row as the previously mentioned seven totes (see paragraph 1, above) that were labeled as "Hazardous Waste", "D001, D002", and "50% Caustic Waste Liquid", and Mr. Maynard and Mr. Ring were unaware of the tote's contents. Pharmacia & Upjohn had not made a determination whether the waste generated.

At the time of the inspection, at the 291 Pad 90-day area, there were two black 55-gallon drums, situated by the berm, that were not labeled, and Mr. Maynard and Mr. Ring were unaware of the drums' contents. Pharmacia & Upjohn had not made a determination whether the waste generated.

At the time of the inspection, at the 291 Pad 90-day area, there was one 275-gallon tote that was closed but was not labeled and Mr. Maynard and Mr. Ring were unaware of the tote's contents. Pharmacia & Upjohn had not made a determination whether the waste generated.

Please see photos # 6 and # 30 of the enclosed inspection report.

Actions Requested

In order to ensure compliance, by no later than 30 calendar days after receipt of this letter, please provide information documenting the actions, if any, which you have taken since the inspection to address the identified violations or demonstrating why the violation(s) have not occurred.

Please send all reports requested by this letter by electronic mail to:

R5LECAB@epa.gov
and
gangwisch.bryan@epa.gov

The subject line of all email correspondence must include MID000820381. All electronically submitted materials must be in final and searchable format, such as Portable Document Format (PDF) with Optical Character Recognition (OCR) applied. If you are unable to send a response to these email addresses due to email size restrictions or other problems, contact Bryan Gangwisch to make additional arrangements for transmission of the response.

This letter is not subject to the Paperwork Reduction Act, 44 U.S.C. § 3501 *et seq.*, because it seeks information from specific individuals or entities as part of an administrative investigation. You may assert a claim of business confidentiality under 40 C.F.R. Part 2, Subpart B for any part of the information you submit to EPA in response to this letter. Information subject to a business confidentiality claim is available to the public only to the extent, and by means of the procedures, set forth at 40 C.F.R. Part 2, Subpart B. If you do not assert a business confidentiality claim when you submit the information, EPA may make this information available to the public without further notice.

The EPA contact in this matter is Bryan Gangwisch. You may call him at (312) 886-0989 if you have additional questions. Thank you for your prompt attention to these concerns and your efforts to protect human health and the environment.

Sincerely,

**MICHAEL
HARRIS**

 Digitally signed by
MICHAEL HARRIS
Date: 2025.05.29 10:58:23
-05'00'

Michael D. Harris
Division Director
U.S. EPA Region 5 Enforcement and Compliance
Assurance Division

cc: Alexandra Clark, EGLE, clarka37@michigan.gov
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