

2309 Sunset Lake Road Newark, DE 19702, USA Phone: (302)737-9916 Fax: (302)261-7000 Web: www.WilmingtonPharmaTech.com

July 28, 2023

VIA UPS EXPRESS

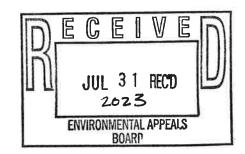
Environmental Appeals Board 89 Kings Highway Dover, DE 19901

Attn: Administrative Assistant to the Environmental Appeals Board

Telephone: (302) 739-9000

Re: Statement of Appeal of Order No. 2023-WH-0017

Dear Secretary Garvin,



I write on behalf of Wilmington PharmaTech ("WPT" or "Appellant") in response to the Notice of Administrative Penalty Assessment and Secretary's Order No. 2023-WH-0017 ("Order" or "Penalty Assessment") dated July 3, 2023, and received on July 9, 2023. A true and correct copy of the Order is attached hereto as Exhibit A. WPT hereby files the following Statement of Appeal of Order No. 2023-WH-0017.

Statement of Appeal

1. Interest Substantially Affected

Pursuant to 7 Del. Admin. C. §105, WPT's interests are substantially affected by the Order, because if the Order is upheld, the violations will be recorded against WPT's reputation. In the nature of WPT's business, such violations would likely hold significant impact in future business relations. Additionally, WPT would be held responsible for payment of the penalty and assessed costs.

2. Improper Decision

While WPT acknowledges the circumstances of the findings from the DNREC inspection, WPT submits that the conclusions drawn for specific violations are improper. WPT was unable to maintain communications with the DNREC inspector to clarify its position, as the inspector had departed the industry. As such, WPT would like to provide additional context to support its belief of the improper nature of the decision.

- 3. WPT anticipates the need to call 4 or 5 witnesses at the hearing of this matter, and such testimony may take one-half of a day to a full day. WPT does not presently know how many witnesses DNREC will call, or how much time it will require for its presentation.
- 4. Context and Reasons Regarding DNREC's Findings

The violations are addressed as follows:

Violation 1.

On August 9, 2022, Department representatives observed an open I-gallon poly bin containing spent samples and vials in the Analytical Lab Satellite Accumulation Area ("SAA"). Failure to close a SAA container accumulating hazardous waste is a violation of DRGHW Section 262.15(a)(4).



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During the August 9, 2022, inspection, Respondent placed a lid onto the container, thus correcting this violation to the satisfaction of the Department.

Regulation – DRGHW Section 262.15(a)(4) states:

"(a) A generator may accumulate as much as 55 gallons of non-acute hazardous waste and/or either one quart of liquid acute hazardous waste listed in §261.31 or

§261.33(e) of these regulations or 1 kilogram (;:::,2.2 pounds) of solid acute hazardous waste listed in §261.31 or §261.33(e) of these regulations in containers at or near any point of generation where wastes initially accumulate which is under the control of the operator(s) of the process generating the waste, without a permit or interim status and without complying with the requirements of Parts 124, 264 through 266, and 122 of these regulations, provided that all of the conditions for exemption in this section are met. A generator may comply with the conditions for exemption in this section instead of complying with the conditions for exemption in §262. 1 6(b) or §262. 1 7(a), except as required in §262. 1 5(a)(7) and (8). The conditions for exemption for satellite accumulation are: ...

- (4) A container holding hazardous waste must be closed at all times during accumulation, except:
- (i) When adding, removing, or consolidating waste; or
- (ii) When temporary venting of a container is necessary"

Explanation:

Our staff accidentally used the container, which was incorrectly labeled, for holding samples. The container was not intended to hold waste, and in fact, the one-gallon bin is not our typical waste container. We will train our staff to properly label the sample container.

Violation 2.

On August 9, 2022, Department representatives observed an unlabeled container that was accumulating used oil in the Central Accumulation Area ("CAA") Room G174. Failure to label a used oil container with the words "Used Oil" is a violation of DRGHW Section 279.22(c)(l).

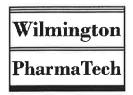
During the August 9, 2022, inspection, Respondent labeled the container with the phrase "Used Oil," correcting this violation to the satisfaction of the Department.

Regulation – DRGHW Section 279.22(c)(l) states:

- "(c) Labels.
- (I) Containers and aboveground tanks used to store used oil at generator facilities must be labeled or marked clearly with the words 'Used Oil'. "

Explanation:

The container of used motor oil was intended to be recycled. It was placed in the CAA by mistake without the correct label. The container has since been labeled properly and relocated.



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Violation 3.

On August 9, 2022, in Room G174 CAA, Department representatives observed a 55- gallon drum accumulating high-performance liquid chromatography ("HPLC") hazardous waste labeled with the date March 16, 2022. Additionally, in the CAA in Room G420, Department representatives observed a drum containing solid waste contaminated with hazardous waste solvents that was dated April 27, 2022. On the date of the inspection, these wastes were accumulated on site for 147 days and 115 days, respectively. This exceeds the 90-day accumulation limit allowed for a LQG, which is a violation of DRGHW Section 262. 17(a).

Because Respondent exceeded the 90-day accumulation limit, Respondent is subject to the hazardous waste permitting requirements. Failure to obtain a permit for the storage of hazardous waste is a violation of DRGHW Section 122.l(c).

On December 1, 2022, Respondent submitted documentation to the Department acknowledging the violation and understanding DRGHW Section 262.17(a). Additionally, Respondent provided a copy of manifest 024230457JJK, dated August 10, 2022, demonstrating that the observed hazardous waste had been shipped off-site for management. This violation has been corrected to the satisfaction of the Department.

Regulation – DRGHW Section 262.17(a) states:

- "A large quantity generator may accumulate hazardous waste on site without a permit or interim status, and without complying with the requirements of Parts 124, 264 through 266, and 122 of these regulations, or the notification requirements o/7 Del.C. §6304(a), provided that all of the following conditions for exemption are met:
- (a) Accumulation. A large quantity generator accumulates hazardous waste on site for no more than 90 days, unless in compliance with the accumulation time limit extension or F006 accumulation conditions/or exemption in paragraphs (b) through (e) of this section."

DRGHW Section 122.l(c) states:

"(c) Scope of the hazardous waste permit requirement. DNREC requires a permit for the 'treatment', 'storage', and 'disposal' of any 'hazardous waste' as identified or listed in Part 261."

Explanation:

One of our staff did not follow our SOP for correctly dating waste accumulation. The accumulation date labels were applied to the containers on the day when they were initially prepared in the satellite accumulation areas.

Violation 4.

On August 9, 2022, Department representatives observed three 55-gallon poly drums of hazardous waste within the Storage Shed CAA. The drums were labeled with the contents and the associated hazards of the drummed wastes, but none were labeled to indicate that the contents of the drums were hazardous waste. Failure to label containers with the phrase "Hazardous Waste" is a violation of DRGHW Section 262. 17(a)(5)(i)(A).

On August 17, 2022, Respondent submitted documentation to the Department demonstrating that the observed containers have been labeled with "Hazardous Waste," thus correcting this violation to the satisfaction of the Department.

Regulation – DRGHW Section 262.17(a)(5)(i)(A) states:

(5) Labeling and marking of containers and tanks



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- (i) Containers. A large quantity generator must mark or label its containers with the following:
- (A) The words 'Hazardous Waste. "

Explanation:

At the time, a staff member was coincidentally in the process of labeling but had already placed the waste containers into the CAA. Then, he returned to the office to prepare labels. More training will be provided to ensure labels are applied prior to relocation to the CAA.

Violation 5.

On August 9, 2022, Department representatives observed three 55-gallon poly drums of hazardous waste within the Storage Shed CAA. The drums were labeled with the contents and their hazards, but not marked with an accumulation start date. Failure to mark a CAA container with an accumulation start date is a violation of DRGHW Section 262.17(a)(5)(i)(C).

On August 17, 2022, Respondent submitted documentation to the Department demonstrating that the observed containers have been marked with the accumulation start date of August 9, 2022. Additionally, Respondent provided a written statement acknowledging the applicability of DRHGW Section 262.17(a)(5)(i)(C). This violation has been corrected to the satisfaction of the Department.

Regulation - DRGHW Section 262.17(a)(5)(i)(C) states:

- "(5) Labeling and marking of containers and tanks
- (i) Containers. A large quantity generator must mark or label its containers with the following: ...
- (C) The date upon which each period of accumulation begins clearly visible for inspection on each container. "

Explanation:

Same explanation as above for violation 4.

Violation 6.

On August 9, 2022, Department representatives observed an open fiberboard box containing spent traditional high-mercury lamps. Failure to close a container holding universal waste is a violation of DRGHW Section 273.13(d)(l). During the August 9, 2022, inspection, Respondent closed the fiberboard box thus correcting this violation to the satisfaction of the Department.

Regulation - DRGHW Section 273.13(d)(l) states:

- "(d) Lamps. A small quantity handler of universal waste must manage lamps in a way that prevents releases of any universal waste or component of a universal waste to the environment, as follows:
- (1) A small quantity handler of universal waste must contain any lamp in containers or packages that are structurally sound, adequate to prevent breakage, and compatible with the contents of the lamps. Such containers and packages must remain closed and must lack evidence of leakage, spillage or damage that could cause leakage under reasonably foreseeable conditions."

Explanation:



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We replaced our old light fixtures with new high efficiency LED lights. The old fixtures, still functional, were placed in the fiberboard container, and they were not intended to be considered waste, yet. Furthermore, the old fixtures were standard fluorescent lamps, not high mercury lamps.

Violation 7.

On August 9, 2022, Department representatives reviewed Respondent's contingency plan and determined that the plan did not include the locations of the emergency equipment. Failure to provide the locations of emergency equipment in the contingency plan is a violation of DRGHW Section 262.261(e).

On August 17, 2022, Respondent submitted the contingency plan's map showing locations of Respondent's emergency equipment correcting this violation to the satisfaction of the Department.

Regulation – DRGHW Section 262.261(e) states:

Content of contingency plan.

"(e) The plan must include a list of all emergency equipment at the facility (such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external). and decontamination equipment), where this equipment is required. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list, and a brief outline of its capabilities."

Explanation:

We failed to include a map of the locations of the emergency equipment. We have since added this map to the contingency plans promptly as mentioned previously.

Violation 8.

On August 9, 2022, Department representatives determined that Respondent had not provided copies of the contingency plan to first responders. Failure to provide copies of the contingency plan to first responders is a violation of DRGHW Section 262.262(a).

On August 17, 2022, Respondent submitted documentation demonstrating that the updated contingency plan was provided to Newark Police Department, Christiana Care Hospital, and Aetna Fire Hall correcting this violation to the satisfaction of the Department.

Regulation – DRGHW Section 262.262(a) states:

"(a) The large quantity generator must submit a copy of the contingency plan and all revisions to all local emergency responders (i.e., police departments, fire departments, hospitals, and State and local emergency response teams that may be called upon to provide emergency services). This document may also be submitted to the Local Emergency Planning Committee, as appropriate.

Explanation:

We previously distributed the contingency plan to first responders by USPS regular mail without tracking or confirming receipt. We have since sent the contingency plan again by FEDEX/UPS with proper tracking records.



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Violation 9.

On August 9, 2022, Department representatives reviewed Respondent's weekly inspection records and found no evidence that Respondent conducted weekly inspections of the CAAs after March 30, 2022. Failure to complete or maintain records of weekly inspections between March 30, 2022, and August 9, 2022, is a violation of DRGHW Section 262.17(a)(vi).

On August 17, 2022, Respondent submitted documentation to the Department acknowledging the violation and their plan for weekly inspections to be conducted prospectively. Additionally, Respondent provided a copy of a recently completed weekly inspection. This violation has been addressed to the satisfaction of the Department.

Regulation – DRGHW Section 262.17(a)(l)(vi) states:

- "(I) Accumulation of hazardous waste in containers. If the hazardous waste is placed in containers, the large quantity generator must comply with the following: ...
- (vi) Inspections. At least weekly, the large quantity generator must inspect central accumulation areas. The large quantity generator must look/or leaking containers and for deterioration of containers caused by corrosion or other factors. See paragraph (a)(J)(ii) of this section for remedial action required if deterioration or leaks are detected. A written record of the inspections and remedial actions taken, if necessary, must be maintained onsite for a minimum of 3 years. "

Explanation:

Due to COVID and a personnel change, we missed the weekly inspections from March 20, 2022, to August 9, 2022. The inspection has since been performed regularly.

4. Deposit

The \$50.00 deposit was submitted in a previous filing regarding this Order via check #1082.

As a newly established site in Delaware, we are committed to upholding rigorous standards for our operations. We understand the significance of any oversights and have worked to rectify the previous potential issues. We will continue to provide our employees with proper training. We appreciate your time and patience as we grow our company, while upholding our environmental responsibilities.



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Should you require further information or additional action, please contact us.

Thank you for your attention to this matter.

Sincerely,

Karen Jia

Senior EHS Manager

Karen Jia

Wilmington PharmaTech Company

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