



STATE OF DELAWARE
**DEPARTMENT OF NATURAL RESOURCES AND
ENVIRONMENTAL CONTROL**
RICHARDSON & ROBBINS BUILDING
89 KINGS HIGHWAY
DOVER, DELAWARE 19901

OFFICE OF THE
SECRETARY

PHONE
(302) 739-9000

SECRETARY'S ORDER
Pursuant to *7 Del. C. §§ 6005(b)(2) and (b)(3)*

Order No. 2023-WH-0017

***SERVED VIA CERTIFIED MAIL
RETURN RECEIPT***

Issued To:

Karen Jia
EHS Manager
Wilmington PharmaTech Glasgow Site
2309 Sunset Lake Road
Newark, DE 19702

Registered Agent:

Hui-Yin Li
2309 Sunset Lake Road
Newark, DE 19702

Dear Ms. Jia:

The Secretary of the Department of Natural Resources and Environmental Control (“Department”) has found Wilmington PharmaTech Glasgow Site (“Respondent” or “Wilmington PharmaTech”) in violation of *7 Del. C. Chapters 60 and 63, and 7 DE Admin. Code § 1302, Delaware’s Regulations Governing Hazardous Waste* (“DRGHW”). Accordingly, pursuant to *7 Del. C. § 6005*, the Department is issuing this Notice of Administrative Penalty Assessment and Secretary’s Order.

BACKGROUND

Wilmington PharmaTech operates a pharmaceutical research and development facility located at 2309 Sunset Lake Road, Newark, Delaware 19702 ("facility"). During the operation of its facility, Wilmington PharmaTech generates hazardous waste. As such, pursuant to 7 DE Admin. Code § 1302, Respondent is subject to compliance inspections conducted by the Department's Compliance and Permitting Section ("CAPS").

On August 9, 2022, the Department conducted a compliance inspection of Respondent's facility. At the time of the inspection, Respondent was classified as a Large Quantity Generator ("LQG")¹ of hazardous waste. The facility is assigned EPA ID number DE0001017102. Based upon the information gathered during the inspection, the Department found Respondent to be in violation of DRGHW and applicable state statutes governing the generation and management of hazardous waste.

The Department notified Respondent of the violations identified during the August 9, 2022 inspection by issuing to Respondent Notice of Violation ("NOV") No. 22-HW-38, dated November 14, 2022. Respondent received the NOV on November 16, 2022. The NOV documented nine violations of DRGHW.

Respondent corrected three of the nine violations during the August 9, 2022, inspection. On August 17, 2022, Respondent submitted documentation to the Department demonstrating that it corrected another four of the nine violations. On August 27, 2022, Respondent submitted documentation to the Department demonstrating that it corrected another one of the nine violations. Additionally, on December 1, 2022, Respondent submitted documentation to the Department in response to the NOV addressing the one remaining violation documented in the NOV.

¹ Generators of more than 1,000 kilograms (2,200 pounds) of hazardous waste in any calendar month are large quantity generators (Delaware's *Regulations Governing Hazardous Waste*, 2021).

**FINDINGS OF FACT AND VIOLATION INCLUDING
REGULATORY REQUIREMENTS**

1. **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 §262.16(b) or §262.17(a), except as required in §262.15(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”*

On August 9, 2022, Department representatives observed an open 1-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).

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

2. DRGHW Section 279.22(c)(1) states:

“(c) Labels.

(1) Containers and aboveground tanks used to store used oil at generator facilities must be labeled or marked clearly with the words ‘Used Oil’.”

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)(1).

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

3. 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 of 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 for exemption in paragraphs (b) through (e) of this section.”

DRGHW Section 122.1(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.”

On August 9, 2022, in the 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 122.1(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.

4. DRGHW Section 262.17(a)(5)(i)(A) states:

(5) Labeling and marking of containers and tanks

(i) Containers. A large quantity generator must mark or label its containers with the following:

(A) The words ‘Hazardous Waste.’”

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.

5. 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."

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.

6. DRGHW Section 273.13(d)(1) 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."

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)(1).

During the August 9, 2022, inspection, Respondent closed the fiberboard box thus correcting this violation to the satisfaction of the Department.

7. DRGHW Section 262.260 states:

Purpose and implementation of contingency plan.

“(a) A large quantity generator must have a contingency plan for the facility. The contingency plan must be designed to minimize hazards to human health or the environment from fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water.

(b) The provisions of the plan must be carried out immediately whenever there is a fire, explosion, or release of hazardous waste or hazardous waste constituents which could threaten human health or the environment.”

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.”

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.

8. 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. Documentation of written submission and receipt must be maintained at the facility for three (3) years from the requirement last being applicable.”

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.

9. DRGHW Section 262.17(a)(1)(vi) states:

“(1) 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 for leaking containers and for deterioration of containers caused by corrosion or other factors. See paragraph (a)(1)(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.”

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.

CONCLUSIONS

Based on the foregoing, the Department has concluded that Respondent has violated the above-cited statutory and regulatory provisions.

ASSESSMENT OF PENALTY

Pursuant to 7 *Del. C.* § 6005(b)(3), the Secretary may impose an administrative penalty of not more than \$10,000.00 for each day of violation detailed in this Order. This Order is written notice to Respondent, that based upon its findings, the Department is assessing Respondent an administrative penalty for the violations identified in this Assessment and Order. In assessing the administrative penalty, 7 *Del. C.* § 6005(b)(3) instructs the Secretary to consider the following factors: (1) the nature, circumstances, extent, and gravity of each violation of the violation, or violations; (2) the ability of the violator to pay; (3) any prior history of such violations; (4) the degree of culpability; (5) the economic benefit or savings (if any) resulting from each violation; and (6) such other matters as justice may require. A brief discussion of these factors is set forth below.

1. The Nature, Circumstances, Extent and Gravity of the Violation, or Violations:

The nature, circumstances, extent, and gravity of the violations are significant. This Order identifies and describes nine separate regulatory violations. Failing to ensure compliance with the regulatory requirements for the accumulation of hazardous waste, including labeling and dating of containers, closing containers, accumulation time limits, and maintenance of records are significant deviations from the statutory and regulatory requirements cited herein.

2. Respondents' Ability to Pay:

The record contains no information that Respondent lacks the ability to pay the administrative penalty assessed.

3. Prior History of Violations:

Respondent had not previously undergone an inspection by the Department at the 2309 Sunset Lake Road, Newark, Delaware 19702 location, therefore, there is no prior history of violations at this site. However, the Respondent operates two other pharmaceutical research and development facilities in Delaware. One location is a SQG of hazardous waste and is assigned EPA ID number DER000502096 and the second location is a LQG of hazardous waste and is assigned EPA ID number DER000503714. Both of the aforementioned sites were previously inspected by Department representatives. On November 24, 2009, a NOV was issued to Respondent's SQG location citing Respondent with failing to make arrangements with local emergency response agencies and failing to conduct or maintain records of weekly inspections. On April 11, 2017, a NOV was issued to Respondent's other LQG location, citing Respondent for failing to close two SAA containers and failing to label three SAA containers with the phrase "Hazardous Waste" or "Waste" followed by a description of the waste. Said violations are identical or similar to Respondent's violations cited within this Secretary's Order.

Respondent's history of similar violations at its other locations supports imposition of the administrative penalty assessed for the violations cited herein in order to deter Respondent from future violations.

4. Degree of Culpability:

The degree of culpability is significant, as Respondent was previously provided notice of many of these same regulatory violations and afforded the opportunity to come into voluntary compliance. In addition, had Respondent employed reasonable oversight measures as DRGHW require, these violations would not have occurred.

5. Economic Benefit or Savings Resulting from the Violation(s):

With respect to the economic benefit, the record contains no information that Respondent incurred any meaningful economic benefit from these violations, and thus this was not a factor in the administrative penalty assessment.

6. Such Other Matters as Justice May Require:

Lastly, considering such other matters as justice may require, the Secretary has determined that the penalty assessed is proportional to the violations cited herein and has been calculated to deter Respondents and those similarly situated from engaging in future violations.

Pursuant to 7 *Del. C.* § 6005(b)(3), this is written notice to Respondent that on the basis of the above findings and factors, an administrative penalty of \$10,000.00 is assessed for the violations cited in this Order.

Respondent shall submit one check to the Department in the amount of \$10,000.00 to pay the administrative penalty within 30 days from the receipt of this Assessment and Order. The check shall be made payable to the "State of Delaware" and shall be directed to: Travis Groski, Deputy Attorney General, 391 Lukens Drive, New Castle, Delaware 19720.

PUBLIC HEARING AND APPEAL RIGHTS

This Assessment and Order affects Respondent's legal rights and is effective and final upon receipt by Respondent. Pursuant to Section 6008 of Title 7 of the Delaware Code, any person whose interest is substantially affected by this action of the Secretary may appeal to the Environmental Appeals Board within **20 days** of the receipt of the Assessment and Order. In the alternative, Respondent may, pursuant to *7 Del. C. § 6005(b)(3)*, request a public hearing on the Assessment and Order within **30 days** of receipt of the Assessment and Order. A public hearing pursuant to *7 Del. C. § 6005(b)(3)* would be conducted pursuant to *7 Del. C. § 6006*, and the Secretary's order following the hearing would be subject to appeal, pursuant to *7 Del. C. § 6008*, by any person substantially affected.

Respondent is further advised that the above assessed administrative penalty shall be due and owing within 30 days of Respondent's receipt of this Assessment and Order. In the event of nonpayment of the administrative penalty assessed above, and after Respondent has exhausted all legal appeals, if any, a civil action may be brought by the Secretary in Superior Court for collection of the administrative penalty, including interest, attorneys' fees and costs, and the validity, amount and appropriateness of such administrative penalty and/or costs shall **not** be subject to review pursuant to *7 Del. C. §§ 6005(b)(3) and (c)*.

To request a public hearing pursuant to *7 Del. C. § 6005(b)(3)*, please submit your request, in writing, to:

Department of Natural Resources and Environmental Control
Office of the Secretary
89 Kings Highway
Dover, DE 19901
Telephone: (302) 739-9000

To submit an appeal to the Environmental Appeals Board pursuant to *7 Del. C. § 6008*, you must file your written statement of appeal and submit a check, made payable to: "Environmental Appeals Board," for the \$50.00 filing fee, to:

Department of Natural Resources and Environmental Control
Office of the Secretary
Attn: Assistant to the Environmental Appeals Board
89 Kings Highway
Dover, DE 19901
Telephone: (302) 739-9000

For additional information on filing an appeal with the Environmental Appeals Board and what information you must include in your written statement of appeal, please refer to the Environmental Appeals Board Regulations, codified at *7 DE Admin. Code § 105*.

The Department, to the extent necessary, reserves the right to take additional enforcement actions regarding these and other violations by Respondent, including but not limited to one or more of the following: an action under *7 Del. C. § 6005(b)(1)* seeking penalties for past violations, an action under *7 Del. C. § 6005(b)(2)* seeking penalties for continuing violations, an action in the Court of Chancery pursuant to *7 Del. C. § 6005(b)(2)* seeking a temporary restraining order or an injunction, and the imposition of civil penalties and recovery of the Department's costs and attorney's fees pursuant to *7 Del. C. §§ 6005(b)(3) & (c)(1)*. Nothing in this document shall be deemed to estop, or in any way preclude any additional enforcement action for these or any other violations, including administrative and civil penalties for each day of violation, or an action for the recovery of Department costs expended in abating these violations.

SECRETARY'S ORDER FOR COST RECOVERY

Pursuant to 7 *Del. C.* § 6005(c), Respondent is liable for all expenses incurred by the Department in abating the violations detailed in this Secretary's Order. "Such expenses shall include, but not be limited to, the costs of investigation, legal fees and assistance, public hearings, materials, equipment, human resources, contractual assistance and appropriate salary and overtime pay for all state employees involved in the effort notwithstanding merit system laws, regulations or rules to the contrary." (7 *Del. C.* § 6005(c)(1)).

Respondent is liable for \$3,398.93 in costs, which costs the Department has incurred to date in abating the violations detailed in this Secretary's Order. The Department has attached to this Secretary's Order a detailed billing of expenses detailing these costs. Respondent shall remit a check payable to the State of Delaware in the amount of \$3,398.93 within 30 days of receipt of this Secretary's Order, to: Travis Groski, Deputy Attorney General, 391 Lukens Drive, New Castle, Delaware 19720.

In the event that Respondent appeals this Secretary's Order pursuant to 7 *Del. C.* § 6008 or requests a public hearing pursuant to 7 *Del. C.* § 6005(b)(3), or in the event Respondent fails to comply with this Secretary's Order, the Department will rescind the detailed billing attached to this Secretary's Order. The Department will issue Respondent a new detailed billing and Cost Recovery Order following exhaustion of Respondent's appeal rights that will include all additional recoverable costs incurred by the Department. Respondent is further advised that Respondent may challenge the Department's final detailed billing in accordance with 7 *Del. C.* § 6005(c)(2).

PRE-PAYMENT

Respondent may prepay the administrative penalty of \$10,000.00 and the Department's costs in the amount of \$3,398.93 in the manner described in the attached "**Waiver of Statutory Right to A Hearing.**" By doing so, Respondent waives its right to a hearing and the opportunity to appeal or contest this Secretary's Order and the Department's Cost Recovery.

If you have any questions, please contact, or have your attorney contact Travis Groski, Deputy Attorney General, at (302) 395-2600.

07/03/2023

Date



For Shawn M. Garvin, Secretary

cc. Travis Groski, Deputy Attorney General
Timothy Ratsep, Division Director

WAIVER OF STATUTORY RIGHT TO A HEARING

Wilmington PharmaTech hereby waives its right to a public hearing and its opportunity to appeal or contest this Assessment and Order, and agree to the following:

1. **Wilmington PharmaTech** will pay the administrative penalty in the amount of \$10,000.00 by sending a check payable to the "State of Delaware" within 30 days of receipt of this Assessment and Order. The check shall be directed to: Travis Groski, Deputy Attorney General, 391 Lukens Drive, New Castle, Delaware 19720.
2. **Wilmington PharmaTech** will pay the Department's Costs in the amount of \$3,398.93 by sending a check payable to the State of Delaware within 30 days of receipt of this Assessment and Order. The check shall be made payable to the "State of Delaware" and be directed to: Travis Groski, Deputy Attorney General, 391 Lukens Drive, New Castle, Delaware 19720.

Wilmington PharmaTech

Date: _____

By: _____

Title: _____