



An ABF Ingredients Company

503 Carr Road • Wilmington DE 19809 • 302.576.8555 • spipharma.com

April 12, 2024

By Overnight and Certified Mail

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

Re: Statement of Appeal of Notice of Administrative Penalty Assessment and Secretary's Order No. 2023-WH-0012

Dear Secretary Garvin:

I write on behalf of SPI Pharma, Inc. ("SPI" or "Appellant"), and pursuant to 7 Del. C. § 6008 and 7 Del. Admin. C. § 105. SPI hereby appeals the issuance of the Department of Natural Resources and Environmental Control's ("DNREC") Notice of Administrative Penalty Assessment and Secretary's Order No. 2023-WH-0012 ("Order" or "Penalty Assessment") dated March 15, 2024, and received by SPI on March 25, 2024. A true and correct copy of the Order as received is attached hereto as Exhibit A.

Statement of Appeal

1. Interest Substantially Affected

SPI's interests are substantially affected by the Order, because if the Order is upheld, the violations will be recorded against SPI's reputation. In the nature of SPI's business, such violations may hold significant impact in future business relations. Additionally, SPI would be held responsible for payment of the penalty and assessed costs.

2. Improper Decision

SPI submits that the Order, including its recitation of the facts, alleged violations, conclusions, and assessment of penalty, is improper based on the following reasons, along with such other reasons which may be raised at the expected public hearing:

- A. The DNREC's understanding of the facts supporting the alleged violations is not accurate and complete. For example, DNREC's understanding and description of the pH levels of the SPI's sodium aluminate waste is not accurate.
- B. Contrary to the DNREC's conclusions, SPI did not violate the DNREC's regulations. For example, SPI made timely hazardous waste determinations for its laboratory chemicals at

the point of generation for each of the shipments in question which was when the chemicals were discarded or intended to be discarded. In addition, with regard to the sodium aluminate waste, such waste was non-hazardous at the time it was generated and shipped off-site. SPI did not have control over the waste once it left its facility, does not know what events or circumstances may have caused the waste to become hazardous as DNREC alleges, or if it became a regulated hazardous waste at all. SPI is not responsible for changes to the waste after the waste left SPI's facility as alleged in the Notice, and SPI had a reasonable basis to believe such waste would remain a non-hazardous waste during its management by others after it left SPI's custody and control.

- C. DNREC's alleged violation related to SPI's aerosol can puncturing device was de minimis at most, and SPI corrected the situation at the time of DNREC's inspection. Because of the minor nature of this incident, it should not have been included in the Order, nor have any impact on DNREC's penalty assessment.
- D. DNREC's Assessment of Penalty is improper because it gives undue weight to several factors including SPI's prior history of violations by citing to alleged violations from over ten years in the past while not acknowledging SPI's strong history of compliance and lack of hazardous waste violations since 2012. Also, the Assessment of Penalty is based on incomplete or erroneous facts as alleged in the Order.

3. Estimate of Number of Witnesses and Time Involved.

SPI currently estimates that presentation of its appeal will involve 3-4 witnesses and will take between 4-6 hours. Depending on the volume of the entire record before the Secretary, and the parties' ability to narrow issues in advance of a hearing, SPI may be able to reduce these estimates.

Enclosed is the \$50.00 deposit for costs required under 7 Del. Admin C. § 105(2.3).

4. Conclusion

For the forgoing reasons, DNREC's issuance of the Order was improper. SPI looks forward to presenting its appeal to the Environmental Appeals Board if no resolution with DNREC can be achieved beforehand.

Respectfully Submitted,



Scott Hirsch
Manager of Technical, Environmental, Security and Engineering
Office: 302-360-7234 | Cell: 302-841-1257 | SHirsch@spipharma.com

Service of Process Transmittal Summary

TO: Anne Dorminey
ABF North America Corp.
ONE PARKVIEW PLAZA, SUITE 500
OAKBROOK TERRACE, IL 60181

RE: Process Served in Delaware

FOR: SPI Pharma, Inc. (Domestic State: DE)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION: Department of Natural Resources and Environmental Control vs. SPI Pharma, Inc.

CASE #: None Specified

PROCESS SERVED ON: The Corporation Trust Company, Wilmington, DE

DATE/METHOD OF SERVICE: By Traceable Mail on 03/25/2024

JURISDICTION SERVED: Delaware

ACTION ITEMS: CT will retain the current log
Image SOP
Email Notification, Anne Dorminey adorminey@abfamericas.com
Email Notification, Leigh Miller lmiller@abfamericas.com
Email Notification, Anne Dorminey adorminey@abfamericas.com
Email Notification, Laura McAuliffe lmcauliffe@abfamericas.com

REGISTERED AGENT CONTACT: The Corporation Trust Company
1209 Orange Street
Wilmington, DE 19801
866-539-8692
CorporationTeam@wolterskluwer.com

The information contained in this Transmittal is provided by CT for quick reference only. It does not constitute a legal opinion, and should not otherwise be relied on, as to the nature of action, the amount of damages, the answer date, or any other information contained in the included documents. The recipient(s) of this form is responsible for reviewing and interpreting the included documents and taking appropriate action, including consulting with its legal and other advisors as necessary. CT disclaims all liability for the information contained in this form, including for any omissions or inaccuracies that may be contained therein.

STATE OF DELAWARE
DEPARTMENT OF NATURAL RESOURCES
AND ENVIRONMENTAL CONTROL

89 KINGS HIGHWAY
DOVER, DELAWARE 19901
"Official Business, Penalty
for Private Use \$300.00"



9514 7066 1816 4080 5231 10

RETURN RECEIPT



EXHIBIT A

The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

Delaware's good nature depends on you!

EXHIBIT A



STATE OF DELAWARE
**DEPARTMENT OF NATURAL RESOURCES AND
ENVIRONMENTAL CONTROL**

OFFICE OF THE
SECRETARY

RICHARDSON & ROBBINS BUILDING
89 KINGS HIGHWAY
DOVER, DELAWARE 19901

PHONE
(302) 739-9000

NOTICE OF ADMINISTRATIVE PENALTY ASSESSMENT AND SECRETARY'S ORDER

Pursuant to 7 *Del. C.* §§ 6005(b)(2) and (b)(3)

Order No. 2023-WH-0012

VIA CERTIFIED MAIL, RETURN RECEIPT

Issued To:

Paul Swarm
EHS Manager
SPI Pharma, Inc.
40 Cape Henlopen Drive
Lewes, Delaware 19958

Registered Agent:

The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, Delaware 19801

Dear Mr. Swarm

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

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BACKGROUND

SPI is an antacid and digestives compound manufacturing facility located at 40 Cape Henlopen Drive, Lewes, Delaware 19958 ("Facility"). During the operation of its Facility, Respondent generates hazardous waste. As such, Respondent is subject to compliance inspections conducted by the Department's Compliance and Permitting Section ("CAPS"), pursuant to 7 DE Admin. Code § 1302.

On June 22, 2023, the Department conducted a compliance inspection of the Facility. At the time of the inspection, Respondent was classified as a very small quantity generator ("VSQG")¹ of hazardous waste. The Facility is assigned EPA ID number DED053269270. Based on the information gathered during the inspection, the Department found Respondent to be in violation of applicable state statutes and regulations governing the generation and management of hazardous waste.

The Department notified Respondent of the violations identified during the inspection by issuing Notice of Violation ("NOV") No. 23-HW-24, dated July 17, 2023. The NOV identified two (2) violations of DRGHW and was received by Respondent on July 31, 2023.

Respondent corrected one (1) of the two (2) violations during the June 22, 2023, inspection. On August 22, 2023, Respondent submitted documentation to the Department demonstrating that it corrected the remaining violation.

¹ Generators of less than or equal to 100 kilograms (220 pounds) of non-acute hazardous waste in any calendar month and less than 1 kilogram (2.2 pounds) of acute hazardous waste are very small quantity generators (Delaware's *Regulations Governing Hazardous Waste*, 2021).

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FINDINGS OF FACT AND VIOLATION INCLUDING REGULATORY REQUIREMENTS

1. DRGHW Section 262.11 states:

"A person who generates a solid waste, as defined in §261.2, must make an accurate determination as to whether that waste is a hazardous waste in order to ensure wastes are properly managed according to these regulations..."

On June 22, 2023, Department representatives observed in the Chemical Storage/Washing Room, eleven (11) various-sized containers of expired lab chemicals being accumulated within a safety cabinet. When Department representatives asked what was in the containers, Respondent stated that the containers held expired lab chemical wastes for which a hazardous waste determination had not been made. Failure to make an accurate hazardous waste determination at the point of generation is a violation of DRGHW Section 262.11.

Additionally, on August 4, 2022, Respondent shipped 3,200 pounds of sodium aluminate waste on manifest 024220882JJK. On February 22, 2023, Respondent shipped 2,000 pounds of sodium aluminate waste on manifest 025142565JJK. Respondent indicated on each manifest accompanying the shipments that the waste was non-hazardous.

On June 22, 2023, Department representatives reviewed correspondence from the designated facility where the waste had been shipped to, addressed to Respondent. Said correspondence indicated that Respondent had incorrectly identified the waste sodium aluminate as non-hazardous waste on the manifests, when in fact, the waste was hazardous waste. According to the designated facility's correspondence identifying the discrepancy and Respondent's own acknowledgement of the discrepancy, the designated facility concluded that because the waste contained liquid with a pH less than 2.0, it met the corrosivity characteristic criteria in DRGHW Section 261.22 to warrant a determination that it was hazardous. Failure to make an accurate hazardous waste determination is a violation of DRGHW Section 262.11.

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On August 22, 2023, Respondent submitted to the Department, documentation, including photos, demonstrating that the expired lab chemical wastes observed in the Chemical Storage/Washing Room were placed in containers labeled "Hazardous Waste – Pending Determination."

Additionally, the documentation included a procedure to ensure sodium aluminate waste is properly characterized prospectively. The Department considers the violations satisfactorily corrected.

2. DRGHW Section 262.14(a)(3)(B) states:

"(B) A container holding hazardous waste must always be closed during accumulation, except when it is necessary to add or remove waste."

On June 22, 2023, Department representatives observed a device used to puncture aerosol cans. Said device was located along an exterior wall of the Maintenance Building. The puncturing device was attached to the bung² of a 55-gallon drum and was being used to drain the hazardous waste contents from each of the punctured aerosol cans into the 55-gallon drum for accumulation. Despite the puncturing device not being in current use, the lid was nonetheless, in the open position. Since the aerosol can lid puncturing device was in the open position, Department representatives considered the 55-gallon drum accumulating the drained contents of the punctured aerosol cans to be open. Failure to close a container holding hazardous waste, except when adding or removing waste, is a violation of DRGHW Section 262.14(a)(3)(B).

At the time of the June 22, 2023, inspection, Respondent closed the lid to the aerosol can puncturing device, correcting the violation to the Department's satisfaction.

² A bung is a cylindrical or conical stopper used to close the hole of a container.

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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 Secretary's Order. This Secretary's 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 Secretary's 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 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 the 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 Secretary's Order identifies and describes two (2) separate regulatory violations. Failing to ensure compliance with the regulatory requirements for hazardous waste, including accumulating hazardous waste in an open container and failing to make accurate hazardous waste determinations are significant deviations from the statutory and regulatory requirements cited herein.

2. Respondent's Ability to Pay:

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

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3. Prior History of Violations:

On March 14, 2012, a compliance inspection was conducted at Respondent's facility. As a result of said compliance inspection, on April 2, 2012, Notice of Violation No. 23-HW-24 was issued. The regulatory requirement violations found during the March 14, 2012 inspection were similar to the violations found on June 22, 2023. As such, assessment of a penalty is warranted.

4. Degree of Culpability:

The degree of culpability is significant as Respondent has had numerous instances of mis-identifying and/or completely failing to identify hazardous waste. For example, during the March 14, 2012, compliance inspection, Department representatives identified that Respondent had previously failed to make an accurate hazardous waste determination on waste sodium aluminate that was shipped in June 2011 using manifest 00766251JJK. Further, following an August 4, 2022, shipment of waste sodium aluminate as non-hazardous waste, on October 31, 2022, Respondent received correspondence from the designated facility indicating the received sodium aluminate waste was a corrosive hazardous waste. Despite the October 31, 2022, correspondence, on February 22, 2023, Respondent again shipped sodium aluminate waste as non-hazardous waste. Upon receipt of the February 2023 shipment by the designated facility, correspondence was again sent to Respondent indicating the 2023 shipment of received sodium aluminate waste was also hazardous waste.

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.

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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 calculated to deter Respondent, 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 its findings, the Department is assessing the Respondent an administrative penalty of \$10,000.00 for the violations identified in this Secretary's 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 Secretary's Order. The check shall be made payable to the "State of Delaware" and shall be directed to Leslie Reese, 89 Kings Hwy SW, Dover, Delaware 19901.

PUBLIC HEARING AND APPEAL RIGHTS

This Secretary's 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 Secretary's Order. In the alternative, Respondent may, pursuant to *7 Del. C. § 6005(b)(3)*, request a public hearing on the Secretary's Order within **30 days** of receipt of the Secretary's 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.

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Respondent is further advised that the above assessed administrative penalty shall be due and owing within 30 days of Respondent's receipt of this Secretary's 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. C. § 105*.

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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 \$2,737.00 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 \$2,737.00 within thirty (30) days of receipt of this Secretary's Order to Leslie Reese, 89 Kings Hwy SW, Dover, Delaware 19901.

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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 \$2,737.00 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, Esq., Deputy Attorney General at 302-395-2500.

03/15/24

Date



For Shawn M. Garvin, Secretary

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

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WAIVER OF STATUTORY RIGHT TO A HEARING

SPI Pharma, Inc. hereby waives its right to a public hearing and its opportunity to appeal or contest this Secretary's Order, and agrees to the following:

1. **SPI Pharma, Inc.** 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 Secretary's Order. The check shall be directed to Leslie Reese, 89 Kings Hwy SW, Dover, Delaware 19901.
2. **SPI Pharma, Inc.** will pay the Department's Costs in the amount of \$2,737.00 by sending a check payable to the State of Delaware within 30 days of receipt of this Secretary's Order. The check shall be directed to Leslie Reese, 89 Kings Hwy SW, Dover, Delaware 19901.

SPI Pharma, Inc.

Date: _____

By: _____
(Signature)

Title: _____

Name: _____
(Print)