IN THE MATTER OF: **CASE NO. A-2019-0278**

Flash Returns, LLC. **License No. 01-2662100**
c/o Bobby Black
340 Gest Street
Cincinnati, OH 45203

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Flash Returns, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and Flash Returns are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Flash Returns is a licensed Wholesaler Distributor of Dangerous Drug, License No. 01-2662100, which lists Bobby Black as the Responsible Person.

FACTS

1. The Board initiated an investigation of Flash Returns, LLC, Wholesaler Distributor of Dangerous Drugs License No. 01-2662100, related to the condition of Flash Returns' facility.

2. On or about September 29, 2021, the Board sent a Notice of Opportunity for Hearing to Flash Returns, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

3. Flash Returns, through counsel, requested a hearing on October 13 ,2021. The hearing was subsequently scheduled for February 8, 2022.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Flash Returns neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated September 29, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Flash Returns agrees to pay to the Board a monetary penalty in the amount of $5,000.00, with $2,500.00 of that penalty being stayed upon the condition that the Board performs a full inspection of Flash Returns and the inspection confirms substantial compliance with Ohio's Pharmacy Practice Act as set forth in Chapters 3719. and 4729. Of the Ohio Revised Code and related rules.

    a. The monetary penalty of $2,500.00 will be attached to Flash Returns' license record and must be paid no later than 90 days from the effective date of the Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

    b. If additional violations are discovered during the inspection or otherwise and not corrected within 30 days, the stayed $2,500.00 monetary penalty will be imposed. Notice will be provided to Flash Returns for payment of the stayed fine within 90 days of the notice.

    c. Any violations discovered during the inspection and not corrected within 30 days can still result in a Notice of Opportunity for Hearing/Citation and the payment of the stayed fined would not resolve the outstanding issues from the new violations.

4. Flash Returns agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. Flash Returns agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Flash Returns of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Flash Returns by the Board and will NOT discharge Flash Returns from any obligation under the terms of this Agreement.

6. Flash Returns agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. Flash Returns understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Flash Returns will operate.

9. Flash Returns waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Bobby Black

Bobby Black, on behalf of,
Flash Returns, Respondent

1/5/2022
Date of Signature

Rick Lauer
Attorney for Respondent

1/6/2022
Date of Signature

Rich Miller, RPh, President,
State of Ohio Board of Pharmacy

1/21/2022
Date of Signature

Henry G. Appel, Ohio Assistant Attorney General

1/21/2022
Date of Signature

STATE OF OHIO
BOARD OF PHARMACY

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 9/29/2021
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST LICENSEE

IN THE MATTER OF: **CASE No. A-2019-0278**

Flash Returns, LLC. **License No. 01-2662100**
c/o Bobby Black
340 Gest Street
Cincinnati, OH 45203

September 29, 2021

Dear Flash Returns and Mr. Bobby Black:

You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the State of Ohio Board of Pharmacy (Board) proposes to take action against your license as a Wholesale Distributor of Dangerous Drugs under authority of Section 4729.56 of the Revised Code.

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code (ORC) and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to renew any registration certificate issued to a wholesale distributor of dangerous drugs (WDDD) pursuant to section 4729.52 of the Revised Code or may impose a monetary penalty of forfeiture not to exceed in the severity any fine designated under the Revised Code for a similar offense or $2,500 if the acts committed have not been classified as an offense by the Revised Code.

2. Flash Returns, LLC has a current WDDD license with the Board under license number 01-2662100, which lists Bobby Black as the Responsible Person.

ALLEGATIONS

1. On or about April 26, 2019, the Drug Enforcement Administration (DEA) conducted an inspection at Flash Returns, LLC, located at 340 Gest Street, Cincinnati, Ohio. The DEA found Flash Returns to be in poor condition. The following issues were observed:

    a. Boxes of dangerous drugs were on the warehouse floor leaking liquid and powders.

    b. Loose bottles of dangerous drugs found in an office.

c. Boxes of dangerous drugs that were broken with bottles falling out.

d. Controlled substances found in boxes that were not segregated from other boxes.

e. No accurate method of record keeping for the facility regarding their inventory.

f. Schedule III-V controlled substances cage was not being utilized for all Schedule III-V controlled substances.

2. On or about May 2, 2019, Board personnel and DEA investigators conducted another inspection at Flash Returns. The following issues were observed:

a. 103 unopened boxes of dangerous drugs were observed still needing to be processed.

b. During inspection of one of the unopened boxes, one box was found to contain Schedule IV and Schedule V controlled substances mixed in with non-controlled drugs.

c. Multiple opened boxes were found pushed up against the controlled substances cage.

d. Flash Returns was receiving dangerous drugs and controlled substances from pharmacies for reverse distribution or destruction without verifying that the pharmacies were properly licensed.

e. Flash Returns was not verifying the contents of the shipments they received and only scanned a barcode on the box.

f. Flash Returns did not have specific records for non-controlled and controlled substances sent for destruction or redistribution.

g. There was no quarantine area for adulterated drugs to be stored.

h. Flash Returns did not have temperature or humidity controls in the warehouse that stored the dangerous drugs that could potentially be resold.

i. Flash Returns was not following their written policies and procedures for the receipt, security, storage, inventory, and distribution of dangerous drugs.

j. Flash Returns did not have an appropriate inventory of controlled substances.

3. On or about May 7, 2019, Flash Returns, LLC. voluntarily surrendered its DEA license.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in paragraph (2)(d) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:6-3-04(E) of the OAC, Verification of licensure prior to sale or purchase, as effective March 1, 2019, except as provided in paragraph (F) of this rule, before a drug distributor located in this state may purchase or receive dangerous drugs, the distributor shall conduct a documented query of a

roster maintained by the board to determine if the seller is licensed as a distributor of dangerous drugs. If a licensed drug distributor conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, the distributor shall be deemed not to have violated this rule, each violation punishable by a maximum penalty of $2,500.

2. Such conduct as set forth in paragraphs (1)(e) and (2)(j) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:6-3-06(A) of the OAC, Controlled Substances Inventory Requirements, as effective March 1, 2019, all category III drug distributor licenses shall complete a controlled substances inventory in accordance with section 1304.11 of the Code of Federal Regulations (9/9/2014), each violation punishable by a maximum penalty of $2,500.

3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:6-5-01(A) of the OAC, Wholesale Distributors General Operations, all facilities shall follow these requirements, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500:

    a. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions, OAC Rule 4729:6-5-01(A)(2); and/or

    b. Have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored in accordance with paragraph (B) of this rule, OAC Rule 4729:6-5-01(A)(3); and/or

    c. Be maintained in a clean and orderly condition, OAC Rule 4729:6-5-01(A)(4).

4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:6-5-01(B) of the OAC, Wholesale Distributors General Operations, adulterated drug storage, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500:

    a. Adulterated drugs shall be stored no longer than two years from the date of adulteration or expiration. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons, OAC Rule 4729:6-5-01(B)(1); and/or

    b. Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in paragraph (B)(2) (a) of this rule, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons, OAC Rule 4729:6-5-01(B)(2).

5. Such conduct as set forth in paragraph (2)(h) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:6-5-01(D)(2) of the OAC, Wholesale Distributors General Operations, as effective

March 1, 2019, All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF). Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to regularly document proper storage of dangerous drugs. Temperature and humidity documentation shall be made readily retrievable and maintained for a period of not less than three years from the last documented temperature and humidity reading, each violation punishable by a maximum penalty of $2,500.

6. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:6-5-01(E) of the OAC, Wholesale Distributors General Operations, examination of shipments of dangerous drugs, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500:

    a. Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents, OAC Rule 4729:6-5-01(E)(1); and/or

    b. Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions, OAC Rule 4729:6-5-01(E)(2).

7. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:6-5-01(F) of the OAC, Wholesale Distributors General Operations, handling of returned, damaged, and expired dangerous drugs, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500:

    a. Dangerous drugs that are expired, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to the supplier, OAC Rule 4729:6-5-01(F)(1); and/or

    b. Any dangerous drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier, OAC Rule 4729:6-5-01(F)(2); and/or

    c. If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, identify, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity,

strength, quality, or purity, the drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping, OAC Rule 4729:6-5-01(F)(3).

8. Such conduct as set forth in paragraphs (2)(i) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:6-5-01(G) of the OAC, Wholesale Distributors General Operations, as effective March 1, 2019, Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories, each violation punishable by a maximum penalty of $2,500.

9. Such conduct as set forth in paragraphs (1)(e), (2)(a), (2)(b), (2)(e), and (2)(f) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:6-5-02(A)(2) of the OAC, Wholesale Distributors Recordkeeping, as effective March 1, 2019, Wholesale distributors of dangerous drugs shall establish and maintain inventories and records of all transactions regarding the receipt, sale and distribution or other disposition of dangerous drugs. All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs, each violation punishable by a maximum penalty of $2,500.

10. Such conduct as set forth in paragraphs (1)(e) and (2)(f) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:6-5-02(B) of the OAC, Wholesale Distributors Recordkeeping, as effective March 1, 2019, The recordkeeping requirements in paragraph (A) of this rule shall be followed for all damaged, deteriorated, misbranded, or adulterated dangerous drugs, each violation punishable by a maximum penalty of $2,500.

11. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:6-4-01(B) of the OAC, Wholesale Distributors Disciplinary Actions, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500:

    a. Violating any federal, state, or local drug law; any provision of Chapter 2925., 3715., 3719., or 4729. of the Revised Code; or any rule of the board, OAC Rule 4729:6-4-01(B)(2); and/or

    b. Being the subject of any of a disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.by the drug enforcement administration or licensing agency of any state or jurisdiction, OAC Rule 4729:6-4-01(B)(15); and/or

c. The method used by the drug distributor to store, possess or distribute dangerous drugs poses serious harm to others, OAC Rule 4729:6-4-01(B)(24).

12. Such conduct as set forth in paragraphs (1)(a) and (2)(g) of the Allegations Section, if proven, constitutes the following violations of Section 3715.52(A)(1) of the ORC, Prohibited Acts, the manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded, each violation punishable by a maximum fine of $2,500 if committed by an organization.

13. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of Section 4729.53(A)(3) of the ORC, Registration Requirements, the applicant is properly equipped as to land, buildings, equipment, and personnel to properly carry on its business, including providing adequate security for and proper storage conditions and handling for dangerous drugs, and is complying with the requirements under this chapter and the rules adopted pursuant thereto for maintaining and making available records to properly identified board officials and federal, state, and local law enforcement agencies, each violation punishable by a maximum fine of $2,500 if committed by an organization.

14. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of Section 4729.56 of the ORC, each violation punishable by a maximum fine of $2,500 if committed by an organization:

    a. Violating any federal, state, or local drug law; any provision of chapter 4729. or Chapter 2925., 3715., or 3719. of the Revised Code; or any rule of the board, ORC Section 4729.56(A)(2)(b); and/or

    b. Failing to satisfy the qualifications for registration under section 4729.53 of the Revised Code or the rules of the board or ceasing to satisfy the qualifications after the registration is granted or renewed, ORC Section 4729.56(A)(2)(d); and/or

    c. Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301, or Chapter 3715. of the Revised Code, 4729.56(A)(2)(f).

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (**please note faxes will not be accepted**). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE MAILING DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the mailing of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY

Steven W. Schierholt, Esq., Executive Director

SWS/jak/pae

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