



**SUMMARY SUSPENSION/NOTICE OF OPPORTUNITY FOR HEARING
TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE**



IN THE MATTER OF:

**CASE NOS. A-2025-0118
A-2024-0502**

Brooksville Pharmaceuticals

c/o Alan Michael Kruger, RPh
16140 Flight Path Drive
Brooksville, FL 34604

License No. 02-42000206

May 12, 2025

Dear Brooksville Pharmaceuticals and Alan Michael Kruger, RPh:

You are notified, in accordance with Section 119.07 of the Revised Code, the State of Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS Brooksville Pharmaceuticals' (Brooksville) license as a Terminal Distributor of Dangerous Drugs (TDDD), under authority of Sections 4729.57 and 4729.571 of the Ohio Revised Code.

Furthermore, the Board finds that based upon the facts set forth in the Allegations Section, there is clear and convincing evidence of a danger of immediate and serious harm to others due to Brooksville's method used to possess or distribute dangerous drugs. As such, the Board summarily suspends Brooksville's license as a Terminal Distributor of Dangerous Drugs.

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code (ORC) 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 Sections 4729.54 and 4729.55 of the ORC to practice as a TDDD in the state of Ohio. Additionally, Section 4729.57 of the Revised Code grants the Board the authority to impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or \$1,000 if the acts committed have not been classified as an offense by the ORC.
2. Pursuant to Section 4729.571(A)(1) of the ORC and the rules adopted thereunder, the Board has the authority to suspend a terminal distributor's license without a hearing if it determines that there is clear and convincing evidence of a danger of immediate and serious harm to others due to the method used by the terminal distributor to possess or distribute dangerous drugs.

3. Brooksville Pharmaceuticals, located at 16140 Flight Path Drive, Brooksville, Florida, a 503A Pharmacy, is a licensed TDDD under license number 02-42000206 and lists Alan Michael Kruger, RPh, license number 03-445139, as the Responsible Person.

ALLEGATIONS

1. From on or about April 18, 2024, to on or about April 17, 2025, Brooksville dispensed 580 compounded prescriptions that lack USP/NF monograph, are not drug substances that are components of approved drugs, and do not appear on the 503A bulk substances list into Ohio, as set forth in Attachment A, attached hereto and incorporated as though fully set forth herein. Of those 580 prescriptions, 153 prescriptions were for compounded retatrutide. Brooksville did not have an Ohio licensed responsible person until March 3, 2025.
2. On or about July 22, 2024, a Board Specialist sent a records request for a list of all prescriptions shipped into Ohio from July 22, 2021, to July 21, 2024, to Brooksville. As of August 5, 2024, the Board had not received a response. A Board Specialist called Brooksville on August 5, 2024, August 14, 2024, and August 20, 2024, to check on the records. The Board sent a letter to Brooksville on August 23, 2024, regarding their duty to cooperate with records requests. The requested records were received on August 26, 2024.
3. Brooksville is a non-resident pharmacy engaged in drug compounding and shipping into Ohio. Brooksville did not have an Ohio-licensed pharmacist as its Responsible Person from on or about August 1, 2021, to on or about March 3, 2025. Brooksville shipped approximately 14,503 compounded drugs into Ohio during this time.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of section 3715.52 of the ORC, prohibited acts, each, a misdemeanor of the fourth degree, each punishable by a maximum penalty of \$2,000 if committed by an organization: The following acts and causing them are prohibited:
 - a. The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated¹ or misbranded, ORC Section 3715.52(A)(1); and/or

¹ ORC Section 3715.63 states: A drug or device is adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if any of the following apply: 1. It consists, in whole or in part, of any filthy, putrid, or decomposed substance, ORC Section 3715.63(A)(1); and/or 2. It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, ORC Section 3715.63(A)(2); and/or 3. It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health, ORC Section 3715.63(A)(3); and/or 4. It purports to be or is represented as a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and its strength differs from or its quality or purity falls below the standard set forth in those compendiums. A determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendiums, or in the absence or inadequacy of such tests or methods of assay, those prescribed under the authority of the "Federal Food, Drug, and Cosmetic Act." A drug recognized in the compendiums is not adulterated under this division because it differs from the standard of strength, quality, or purity set forth for that drug in the compendiums, if the difference in strength, quality, or purity is plainly stated on its label. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia

- b. The adulteration or misbranding of any food, drug, device, or cosmetic, ORC Section 3715.52(A)(2); and/or
 - c. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 3715.61 or 3715.65 of the Revised Code, ORC Section 3715.52(A)(4).
- 2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 3715.65(A) of the ORC, effective April 15, 2005, No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless an application with respect to the drug has become effective under section 505 of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, each violation is a misdemeanor of the fourth degree, each violation punishable by a maximum penalty of \$2,000 if committed by an organization.
- 3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 2925.09(A) of the ORC, effective March 22, 2019, no person shall administer, dispense, distribute, manufacture, possess, sell, or use any drug, other than a controlled substance, that is not approved by the United States food and drug administration, or the United States department of agriculture, each violation is a felony of the fifth degree, each violation punishable by a maximum penalty of \$7,500 if committed by an organization.
- 4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, as effective March 1, 2019, and April 25, 2022, each violation punishable by a maximum penalty of \$1,000:
 - a. The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs, OAC Rule 4729:5-2-01(E)(4); and/or
 - b. The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC Rule 4729:5-2-01(E)(6).
- 5. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective September 29, 2017, and April 4, 2023, each violation punishable by a maximum penalty of \$1,000:
 - a. Violating any rule of the board, ORC Section 4729.57(B)(2); and/or
 - b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and/or

and national formulary, ORC Section 3715.63(A)(5); and/or 5. It is not subject to the provisions of division (A)(5) of this section, and its strength differs from or its purity or quality falls below that which it purports or is represented to possess, ORC Section 3715.63(A)(6).

- c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, ORC Section 4729.57(B)(4); and/or
 - d. Any other cause for which the board may impose discipline as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.57(B)(10).
- 6. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-8-03 of the OAC, Compliance, as effective February 1, 2022, each violation punishable by a maximum penalty of \$1,000:
 - a. A nonresident terminal distributor of dangerous drug shall comply with all the statutory requirements of the state of Ohio set forth in Chapters 4729., 3719., 3715., and 2925. of the Revised Code for all drugs sold, dispensed or personally furnished into this state, unless the licensee can demonstrate that such compliance would cause the nonresident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements, OAC Rule 4729:5-8-03(E); and/or
 - b. A nonresident terminal distributor of dangerous drugs shall operate in compliance with all applicable laws, regulations and standards set forth by the United States food and drug administration and the United States drug enforcement administration, OAC Rule 4729:5-8-03(H); and/or
 - c. A nonresident terminal distributor of dangerous drugs shall supply, within three business days of a request, all information needed by the board of pharmacy to carry out its responsibilities as a licensing, regulatory, and drug law enforcement agency of the state of Ohio, OAC Rule 4729:5-8-03(J); and/or
 - d. A nonresident terminal distributor of dangerous drugs shall supply, within three business days of a request, all information needed by the board of pharmacy and any local, state, or federal agency to carry out its responsibilities in enforcing the federal and state laws governing the distribution of drugs in the state of Ohio, OAC Rule 4729:5-8-03(K).
- 7. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729:5-8-04(G)(1) of the OAC, Drugs compounded by a nonresident pharmacy, a pharmacy licensed as a non-resident pharmacy that is engaged in drug compounding shall have an Ohio licensed pharmacist as the responsible person on its license, as effective February 1, 2022, each violation punishable by a maximum penalty of \$1,000:
- 8. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, Responsible Person of a Terminal Distributor, as effective March 1, 2019, and April 25, 2022, each violation punishable by a maximum penalty of \$1,000:

- a. The responsible person shall be responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC Rule 4729:5-2-01(A)(2); and/or
 - b. The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy, OAC Rule 4729:5-2-01(A)(3).
 - c. The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs, OAC 4729:5-2-01(E)(4); and/or
 - d. The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC 4729:5-2-01(E)(6).
9. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of \$1,000:
- a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or
 - b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or
 - c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, OAC Rule 4729:5-4-01(B)(4); and/or
 - d. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this rule prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor, OAC Rule 4729:5-4-01(B)(6); and/or
 - e. Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice, OAC Rule 4729:5-4-01(B)(18); and/or

- f. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to others, OAC Rule 4729:5-4-01(B)(23).
- 10. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000:
 - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or
 - b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or
 - c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, OAC Rule 4729:5-4-01(B)(4); and/or
 - d. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this rule prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor, OAC Rule 4729:5-4-01(B)(6); and/or
 - e. Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice, OAC Rule 4729:5-4-01(B)(20); and/or
 - f. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to others, OAC Rule 4729:5-4-01(B)(25).

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 Ohio Board of Pharmacy, if you request such a hearing within thirty (30) days of the date of the service of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the 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 SERVICE 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 business entity, including but not limited to a corporation, limited liability company, or a limited partnership, 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 service of this notice, the Ohio Board of Pharmacy, upon

consideration of the aforementioned allegations against you, may take action without such a hearing, and may adopt a final order that contains the board's findings. In the final order, the board may impose any of the sanctions listed in division RC 4729.57(A).

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 OHIO BOARD OF PHARMACY



Steven W. Schierholt, Esq., Executive Director



SWS/jak/jrn

Attached:

Attachment A – Brooksville unapproved prescription sales April 18, 2024, to on or about April 17, 2025-

CONFIDENTIAL