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

IN THE MATTER OF: **CASE NOS. A-2025-0295**

Yi Wellness dba Yi Wellness
1194 Old Henderson Road, Suite A
Columbus, OH 43220

License No. 02-60002596

-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: 9/30/2025
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

September 30, 2025

Dear Dr. Guan and YiWellness dba Yi Wellness:

You are notified, in accordance with Section 119.07 of the Revised Code, the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS YiWellness dba Yi Wellness' 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 YiWellness dba Yi Wellness' method used to possess or distribute dangerous drugs. As such, the Board summarily suspends YiWellness dba Yi Wellness' 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. Further, pursuant to Section 4729.55(E), the Board shall refuse to issue a future license to an applicant for a TDDD if the applicant, or any agent (including any owner or responsible person) or employee of the applicant, has been found to have violated any of the specified laws identified therein or any rule of the board, absent proof of adequate safeguards assuring prevention of a recurrence of the violation. 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. YiWellness dba Yi Wellness, located at 1194 Old Henderson Road, Suite A, Columbus, Ohio 43220, is a licensed TDDD under license number 0260002596 and lists Stacey Yi Guan, MD [Ohio Medical Board license number 35.120145] as the owner and Responsible Person.

ALLEGATIONS

1. On or about September 15, 2025 a Board Inspector and Board Agent (Board inspectors) conducted an inspection at YiWellness dba Yi Wellness (Yi Wellness), located at 1194 Old Henderson Road, Suite A, Columbus, Ohio. Stacey Yi Guan, MD, Responsible Person, was present and assisted the Board inspectors with the inspection.

2. The Board inspectors observed one box labeled "Liporase" for injection in the clinic refrigerator. The box contained five unopened 1500-unit vials, also labeled as Liporase and "inj" (injection). The box and vials were labeled with Korean writing.

    a. NOTE: Liporase is a specialized enzyme that accelerates the absorption of Hyaluronic Acid and is used for correcting issues with fillers. Liporase is not authorized by the Food and Drug Administration (FDA) for use in the United States.

3. The inspection resulted in three warnings requiring written responses, including:

    a. Purchased dangerous drugs from unlicensed entity.

        i. The clinic ordered and possessed Liporase, a non-FDA approved medication, and Fillmed M-HA 10, a device, from an entity not licensed in Ohio, Med Supply Solutions.

    b. Clinic refrigerator used for storage of drugs and/or devices was not in compliance.

        i. The clinic did not have a thermometer or temperature records for the refrigerator used to store drug stock.

    c. Adulterated drugs were comingled in the active drug stock.

        i. Adulterated Liporase from Med Supply Solutions was present within the clinic's active drug stock.

4. During the September 15, 2025 inspection, the Board inspectors spoke with Dr. Stacey Yi Guan. She stated the following:

    a. The Liporase products were purchased from Med Supply Solutions.

i. Note, Med Supply Solutions is not a licensed drug distributor in Ohio and not permitted to sell/distribute drugs into Ohio.

b. She uses the Liporase to dissolve aesthetic filler.

c. She used a vial of Liporase as a test to see how it dissolves filler externally, administered some of the Liporase to her mother to dissolve old aesthetic filler, and administered some of the Liporase to patients in the clinic.

d. Since Dr. Guan was able to order the product into her clinic, she thought the Liporase was approved for use.

e. About 90% of Dr. Guan's patients are Asian and most prefer Asian beauty products.

5. Records were provided to the Board after the inspection. A January 14, 2025 invoice from "MedSupplySolutions" included one box of Liporase and four boxes of Fillmed M-HA 10. Drug administration records stated Liporase had been administered five times since it was purchased in January 2025.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, 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 adulterated[1] or misbranded,[2] ORC Section 3715.52(A)(1); and/or

   b. The adulteration or misbranding of any food, drug, device, or cosmetic, ORC Section 3715.52(A)(2); and/or

   c. The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise, ORC Section 3715.52(A)(3); and/or

   d. 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, constitutes a violation of Section 4729.51(F) of the ORC, effective September 29, 2017 and April 6, 2017, No licensed terminal distributor of dangerous drugs or person that is exempt from licensure under section 4729.541 of the Revised Code shall purchase dangerous drugs or investigational drugs or products from

[1] ORC Section 3715.63 - When drug or device is adulterated.
[2] ORC Section 3715.64 – Misbranded drug or device.

any person other than a licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor, each violation is a misdemeanor of the first degree, each violation punishable by a maximum penalty of $5,000 if committed by an organization.

3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(B) of the ORC, Before a licensed terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the roster established pursuant to section 4729.59 of the Revised Code to confirm the seller is licensed to engage in the sale or distribution of dangerous drugs at wholesale, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

4. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-3-04 of the OAC, as effective May 19, 2025, each violation punishable by a maximum penalty of $1,000:

    a. Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the board's online roster (available on the board's website: www.pharmacy.ohio.gov) to confirm any of the following:

        i. The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code, OAC Rule 4729:5-3-04(A)(1); and/or

        ii. The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code, OAC Rule 4729:5-3-04(A)(2); and/or

    b. If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code, OAC Rule 4729:5-3-04(B).

5. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, as effective 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).

6. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective 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

    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. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, ORC Section 4729.57(B)(5); and/or

    e. 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).

7. Such conduct as set forth in 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. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, OAC Rule 4729:5-4-01(B)(5); 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).

8. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729:5-3-06 of the OAC, as effective July 1, 2024, each violation punishable by a maximum penalty of $1,000: To prevent their use, adulterated drugs, as defined in agency 4729 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding, and administration.

9. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000: All terminal distributors of dangerous drugs shall provide effective controls and procedures to: Ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

10. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-03(K) of the OAC, as effective February 4, 2021, each violation punishable by a maximum penalty of $1,000: All areas where dangerous drugs and devices are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Refrigerators and freezers used for the storage of drugs and devices shall comply with the following:

    a. Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

        i. Temperature logs with, at a minimum, daily observations, OAC Rule 4729:5-19-03(K)(1)(a); or

        ii. A temperature monitoring system capable of detecting and alerting staff of a temperature excursion, OAC Rule 4729:5-19-03(K)(1)(b).

11. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of Rule 4729:5-19-04 of the OAC, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000: Records of temperature control monitoring described in paragraph (K)(1) of rule 4729:5-19- 03 of the Administrative Code shall include any of the following: (1) For temperature logs, either: (a) The date and time of observation, the full name or the initials of the person performing the check, and the temperature recorded; or (b) For systems that perform automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded * * *, OAC Rule 4729:5-19-04(C).

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/alg/rlj

cc: Melinda Snyder, State Medical Board of Ohio, at: Melinda.Snyder@med.ohio.gov