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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: 5/12/2025
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

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

IN THE MATTER OF: **CASE NO. A-2025-0116**

Harmony Aesthetics **License No. 02-60002171**
c/o Dorit Gilman, CNP
5300 Socialville Foster Rd.
Suite 130, Room 3
Mason, OH 45040

May 12, 2025

Dear Harmony Aesthetics and Dorit Gilman, CNP:

You are hereby notified, in accordance with Section 119.07 of the Ohio Revised Code (ORC), the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS Harmony Aesthetics' 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 Harmony Aesthetics' method used to possess or distribute dangerous drugs, and the method of prescribing dangerous drugs used by a licensed health professional authorized to prescribe drugs who holds a terminal distributor license or practices in the employ of or under contract with a terminal distributor. As such, the Board summarily suspends Harmony Aesthetics' license as a Terminal Distributor of Dangerous Drugs.

JURISDICTION

1. Pursuant to section 4729.57 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 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 Ohio 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. Pursuant to Section 4729.571(A)(2) 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 of prescribing dangerous drugs used by a licensed health professional authorized to prescribe drugs who holds a terminal distributor license or practices in the employ of or under contract with a terminal distributor.

4. Harmony Aesthetics, located at 5300 Socialville Foster Road, Suite 130, Room 3, Mason, Ohio, is a licensed TDDD under license number 02-60002171 and lists Dorit Gilman, CNP [Ohio Board of Nursing license number APRN.CNP.16441] as the Responsible Person (RP) and owner.

ALLEGATIONS

1. On or about April 18, 2025, during an inspection at Harmony Aesthetics, TDDD license number 02-60002171, a prescriber clinic licensed by the Board, a Board Specialist observed a product labeled "Dysport" in the clinic refrigerator. There was one partially used vial and one unopened vial, still in the cardboard overwrap. The "Dysport" box was labeled as manufactured by Ipsen, "For Export Only," "UK Only," and Clostridium botulinum type A toxin-haemagglutinin complex. (NOTE: In the United States, Dysport is distributed by Galderma and is labeled AbobutulinumtoxinA injection rather than Clostridium botulinum type A toxin-haemagglutinin complex.)

2. During the inspection on April 18, 2025, RP Gilman stated she had administered "Dysport" from the partially used vial and the administration records indicated that she provided it to two patients. The lot number documented in the records of administration matched the lot number on the vial in the refrigerator. RP Gilman falsely stated that she had purchased the "Dysport," from Galderma in late 2024. However, the lot numbers on packing slips provided by RP Gilman to the Board Specialist did not match the lot number on the vial from the refrigerator.

3. By email dated April 19, 2025, RP Gilman admitted that she purchased two vials of Dysport through a Facebook group from a provider who was closing their business. She purchased the vials at a "large discount" and "had no idea that 'not legal' Dysport existed." By email dated April 21, 2025, RP Gilman stated that she was "part of multiple groups on Facebook" and could not identify the source of the Dysport. She stated that it was delivered to her office, and she paid cash.

4. The inspection conducted on April 18, 2025, resulted in warnings requiring written responses and multiple warnings, including;

    a. RP Gilman stated that eLicense queries had not been conducted prior to purchase of dangerous drugs.

b. Refrigerator and/or freezer logs only capture days the clinic was open. Observed temperatures were outside the allowed range of 36-46 degrees.

c. Some records of receipt of dangerous drugs did not include date of receipt and/or address of seller.

d. Although the clinic used a paper log to document administration of non-controlled substances, not all non-controlled administration was documented.

e. Clinic did not possess records of all orders/administration of drugs.

f. Clinic did not maintain a record of the disposal of non-controlled drugs.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of section 3715.52(A) 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 or misbranded,[1] ORC Sections 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).

[1] ORC Section 3715.64 states: A drug or device is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:
1. Its labeling is false or misleading in any particular, ORC Section 3715.64(A)(1); and/or
2. It is in package form and does not bear a label containing both of the following:
a. In clearly legible form, the name and place of business of the manufacturer, packer, or distributor, ORC Section 3715.64(A)(2)(a); and/or
3. Any word, statement, or other information that is required by or under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code to appear on the label or labeling is not prominently placed on the label or labeling in a conspicuous manner, as compared with other words, statements, designs, or devices on the label or labeling, and in terms that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, ORC Section 3715.64(A)(5); and/or
4. It is an imitation of another drug, ORC Section 3715.64(A)(10)(b); and/or
5. It is offered for sale under the name of another drug, ORC Section 3715.64(A)(10)(c).

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(F) of the ORC, effective October 3, 2023, 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 any person other than a licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor, 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, each constitutes a violation of the following sections of Rule 4729:5-3-04 of the OAC, as effective March 1, 2019, 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 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:

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

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

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

ii. The terminal distributor shall develop and implement policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs, OAC Rule 4729:5-19- 03(K)(2); and/or

iii. The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs, OAC Rule 4729:5-19-03(K)(3).

6. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-04 of the OAC, as effective February 4, 2021, each violation punishable by a maximum penalty of $1,000:

   a. A clinic or prescriber office shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold or transferred, OAC Rule 4729:5-19-04(A); and/or

   b. Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement, OAC Rule 4729:5-19-04(B); and/or

   c. Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the name and date of birth of the person to whom or for whose use the dangerous drugs were administered, the date of administration and either: (a) For non-controlled substance dangerous drugs: the identification of the health care professional administering the drug. * * *, OAC Rule 4729:5-19-04(E)(1); and/or

   d. Records of dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph, OAC Rule 4729:5-19-04(E)(2); and/or

   e. Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the identification of the licensed health care professional that performed the disposal, OAC Rule 4729:5-19-04(F).

7. 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 April 25, 2022, each 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).

8. 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. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); 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).

9. 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. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7); 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).

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/sam/jrn

cc: David M. Geiger, Esq., Ohio Board of Nursing (david.geiger@nursing.ohio.gov)