UNITED STATES INTERNATIONAL TRADE COMMISSION Washington, D.C.

In the Matter of

CERTAIN PRODUCTS CONTAINING TIRZEPATIDE AND PRODUCTS PURPORTING TO CONTAIN TIRZEPATIDE **Investigation No. 337-TA-1377**

NOTICE OF ISSUANCE OF A GENERAL EXCLUSION ORDER, A LIMITED EXCLUSION ORDER, AND CEASE AND DESIST ORDERS; TERMINATION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined to issue a general exclusion order ("GEO") prohibiting the importation of products containing tirzepatide and products purporting to contain tirzepatide that infringe U.S. Trademark No. 6,809,369 or include a false designation of origin; a limited exclusion order ("LEO") prohibiting the entry of falsely advertised products containing tirzepatide and products purporting to contain tirzepatide that are imported by or on behalf of certain defaulting respondents; and cease and desist orders ("CDOs") directed against certain defaulting respondents. This investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone (202) 205-3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at https://www.usitc.gov. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 27, 2023, based upon a complaint filed on behalf of Eli Lilly and Company of Indianapolis, Indiana ("Lilly"). 88 FR 82914-15 (Nov. 27, 2023). The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain products containing tirzepatide or purporting to contain tirzepatide by reason of false designation of source and false and misleading advertising, the threat or effect of which is to destroy or substantially injure an industry in the United States, and by reason of infringement of U.S. Trademark No. 6,809,369. *Id.* The complaint also alleges that a domestic industry exists

pursuant to subsection (a)(2) of section 337. *Id.* The Commission's notice of investigation named as respondents Arctic Peptides LLC of Akeny, Iowa ("Arctic Peptides"); Audrey Beauty Co. of Hong Kong, China ("Audrey Beauty"); Biolabshop Limited of Lancaster, United Kingdom ("Biolabshop"); Mew Mews Company Limited of Hong Kong, China ("Mew Mews"); Strate Labs LLC of Spring, Texas ("Strate Labs"); Steroide Kaufen of Bialystok, Poland ("Steroide Kaufen"); Super Human Store of Barcelona, Spain ("SHS"); Supopeptide of Cedar Grove, New Jersey ("Supopeptide"); Triggered Supplements LLC (d/b/a The Triggered Brand) of Clearwater, Florida ("Triggered Brand"); Unewlife of Cedar Grove, New Jersey ("Unewlife"); and Xiamen Austronext Trading Co., Ltd. (d/b/a AustroPeptide) ("AustroPeptide") of Fujian, China. *Id.* at 82915. The Office of Unfair Import Investigations ("OUII") is also named as a party in this investigation. *Id.*

On March 21, 2024, the investigation terminated in part with respect to respondents Unewlife, Supopeptide, and Steroide Kaufen. Order No. 8 (Mar. 7, 2024), *unreviewed* by Comm'n Notice (Mar. 21, 2024). On May 15, 2024, Arctic Peptides, Audrey Beauty, Biolabshop, Mew Mews, Strate Labs, SHS, Triggered Brand, and AustroPeptide were found in default. Order No. 10 (Mar. 26, 2024), *unreviewed by* Comm'n Notice (Apr. 22, 2024). And on May 21, 2024, the complaint was amended to add as respondents Total Compounding Pharmaceuticals of Australia and Singularity Marketing Limited (d/b/a Swiss Chems) of Hong Kong, China ("Swiss Chems"). Order No. 12 (Apr. 22, 2024), *unreviewed by* Comm'n Notice (May 21, 2024). On June 13, 2024, the complaint was further amended to add as a respondent Total Compounding Pharmaceuticals of Australia. Order No. 16 (May 8, 2024), *unreviewed by* Comm'n Notice (June 13, 2024).

On July 12, 2024, Lilly moved for summary determination on violation based on allegations of trademark infringement, false designation of origin, and/or false advertising against (1) Arctic Peptides, (2) Audrey Beauty, (3) Biolabshop, (4) Mew Mews, (5) Strate Labs, (6) SHS, (7) Triggered Brand, (8) AustroPeptide, (9) GenX Peptides, (10) Paradigm Peptides, and (11) Total Compounding. On December 6, 2024, the ALJ issued Order No. 26, which partially granted the motion. *See* Order No. 26 (Dec. 6, 2024). Order No. 26 granted Lilly's motion regarding trademark infringement as to respondents Audrey Beauty, Mew Mews, SHS, and Triggered Brand, but denied the motion as to GenX Peptides, Total Compounding, Paradigm Peptides, and Strate Labs. That order also granted Lilly's motion regarding false designation of origin as to respondents Audrey Beauty, Mew Mews, SHS, Triggered Brand, and Strate Labs, but denied the motion as to GenX Peptides, Total Compounding, Paradigm Peptides, and Biolabshop. The order further granted Lilly's motion as to false advertising as to respondents SHS, AustroPeptide, and Arctic Peptides, but denied the motion as to Total Compounding. The order additionally found that Lilly is entitled to summary determination as to the domestic industry requirement.

Order No. 26 also included a preliminary recommendation on remedy and bonding ("RD"), should a violation be found. The RD recommended: (1) as to Lilly's trademark infringement and false designation of origin allegations, a GEO directed to certain products containing tirzepatide and products purporting to contain tirzepatide imported, sold for importation, and/or sold after importation; (2) also as to Lilly's trademark infringement and false designation of origin allegations and in the alternative to a GEO, an LEO directed to certain

products containing tirzepatide and products purporting to contain tirzepatide imported, sold for importation, and/or sold after importation by Audrey Beauty, Mew Mews, SHS, Triggered Brand, Strate Labs, and AustroPeptide; (3) as to Lilly's false advertising allegations, an LEO directed to certain products containing tirzepatide and products purporting to contain tirzepatide imported, sold for importation, and/or sold after importation by AustroPeptide and SHS; and (4) in addition to either a GEO order or LEOs, CDOs directed to Arctic Peptides, Triggered Brand, and Strate Labs. The RD also recommended that the Commission set the bond during the Presidential review period at one hundred percent (100%) of entered value.

On January 22, 2025, the Commission determined not to review Order No. 26. Comm'n Notice (Jan. 22, 2025).

Because Lilly's motion for summary determination was not granted as to all issues, the ALJ sought a submission from the parties regarding any further necessary proceedings. *See* Order No. 27 (Dec. 6, 2024), *unreviewed by* Comm'n Notice (Jan. 6, 2025). In response, the parties provided a joint submission in which Lilly indicated that it would seek to terminate all claims on which summary determination was not granted. Then, on December 19, 2024, Lilly moved to withdraw the allegations remaining before the ALJ as to GenX Peptides, Paradigm Peptides, Total Compounding, Biolabshop, and Strate Labs. On January 10, 2025, the ALJ issued an initial determination granting Lilly's motion. *See* Order No. 29 (Jan. 10, 2025), *unreviewed by* Comm'n Notice (Jan. 31, 2025).

The Commission issued a notice soliciting comments regarding any public interest concerns raised by the recommend relief in the RD. *See* 89 FR 101048 (Dec. 13, 2024). The Commission's notice received two responses in support of the recommended relief. Additionally, Lilly filed a statement on public interest pursuant to Commission Rule 210.50(a)(4), 19 CFR 210.50(a)(4).

The Commission requested briefing on remedy, bonding, and the public interest. Comm'n Notice (Jan. 22, 2024). On February 5, 2025, Lilly and OUII filed opening submissions. On February 12, 2025, OUII filed a responsive submission. No other party filed a submission before the Commission.

Having reviewed the record of the investigation, including the RD and the parties' submissions, the Commission has determined that the appropriate remedy is: (1) a GEO prohibiting the importation of products containing tirzepatide and products purporting to contain tirzepatide that infringe U.S. Trademark No. 6,809,369 and/or include a false designation of origin; (2) an LEO prohibiting prohibiting the entry of falsely advertised products containing tirzepatide and products purporting to contain tirzepatide that are imported by or on behalf of SHS, AustroPeptide, and Arctic Peptides; and (3) CDOs directed to Arctic Peptides, Triggered Brand, and Strate Labs.

The Commission has further determined that the public interest factors enumerated in subsections (d)(l) and (g)(l) (19 U.S.C. 1337(d)(l), (g)(l)) do not preclude issuance of the above referenced remedial orders. Additionally, the Commission has determined to impose a bond of

100% of entered value of the covered products during the period of Presidential review (19 U.S.C. 1337(j)).

This investigation is terminated.

The Commission vote for this determination took place on April 9, 2025.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.

Lisa R. Barton

Secretary to the Commission

Issued: April 9, 2025