NABP
National Association of Boards of Pharmacy

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: William “Bill” Cover, Associate Executive Director

DATE: April 3, 2025

RE: FDA Letter- Retatrutide in Compounded Drug Products

As part of NABP’s continuing partnership with the United States Food and Drug Administration (FDA) to safeguard pharmacy practice and the pharmaceutical drug supply chain in the United States, NABP is sharing the attached letter from the FDA which details concerns of drug products containing retatrutide.

This letter clearly indicates that compounding prescription drug products with retatrutide is prohibited by all pharmacies compounding under either Section 503A or 503B of the Federal Food, Drug and Cosmetic Act FD&C Act).

Please contact the FDA Office of Compounding Quality and Compliance at compounding@fda.hhs.gov with any additional questions or specific concerns.

In addition, if you have any questions specific to NABP you can contact me at wcover@nabp.pharmacy.

cc: NABP Executive Committee
Lemrey “Al” Carter, Executive Director/Secretary

March 31, 2025

Lemrey “Al” Carter, MS, PharmD, RPh
Executive Director/Secretary
National Association of Boards of Pharmacy
1600 Feehanville Dr.
Mount Prospect, IL 60056

Dear Dr. Carter:

The purpose of this letter is to bring to the attention of the National Association of Boards of Pharmacy information related to compounded drug products containing retatrutide, some of which claim to treat chronic weight management, diabetes, and related conditions. FDA believes that health care professionals should be advised about the current regulatory status of compounded retatrutide.

Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) describe the conditions that must be satisfied for compounded human drug products to be exempt from certain sections of the FD&C Act, including the requirements of premarket approval and labeling with adequate directions for use. Among the conditions of sections 503A and 503B are restrictions on the bulk drug substances (active pharmaceutical ingredients or APIs) that may be used to compound human drug products.

One of the conditions that must be met for a compounded drug product to qualify for the exemptions under section 503A of the FD&C Act is that a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, compounds the drug product using bulk drug substances that: (1) comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or (3) if such a monograph does not exist and the bulk drug substance is not a component of a drug approved by FDA, appear on a list developed by FDA through regulation (“503A Bulks List”) (section 503A(b)(1)(A)(i) of the FD&C Act). Retatrutide is not the subject of an applicable USP or NF monograph, is not a component of an FDA-approved drug product, and does not appear on the 503A Bulks List. Therefore, compounded retatrutide products would not at this time qualify for the exemptions under section 503A of the FD&C Act.

One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for the exemptions under section 503B of the FD&C Act, is that the outsourcing facility does not compound drug products using a bulk drug substance unless: (1) the bulk drug

substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need ("503B Bulks List"), or (2) the drug product compounded from such bulk drug substance appears on FDA's drug shortage list in effect under section 506E at the time of compounding, distribution and dispensing (section 503B(a)(2)(A)(i) and (ii) of the FD&C Act). Retatrutide does not appear on the 503B Bulks List, nor does it appear on FDA's drug shortage list. Therefore, compounded retatrutide products would not at this time qualify for the exemptions under section 503B of the FD&C Act.

Additionally, FDA has warned companies that have illegally sold unapproved drugs containing retatrutide and other ingredients that are falsely labeled "for research purposes" or "not for human consumption."[1] These products have been sold directly to consumers for human use with dosing instructions. The agency recommends that consumers not purchase these products which are of unknown quality and may be harmful to their health and encourages health care providers to discuss this issue with their patients.

We are also sending this letter to the Federation of State Medical Boards and National Council of State Boards of Nursing to facilitate communication among associations with shared goals regarding these matters.

We look forward to continuing to work with you on matters related to drug compounding. If you have additional questions, please contact the Office of Compounding Quality and Compliance at compounding@fda.hhs.gov.

Sincerely,

Edisa Gozun, PharmD
Division Director, Division of Compounding II
Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research

[1] See e.g. FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss (https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss).