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STATEMENT CONCERNING SEMAGLUTIDE COMPOUNDING

New Jersey Board of Pharmacy (the Board) staff have received inquiries concerning compounding of semaglutide. Semaglutide is, of course, a commercially available drug product marketed as Ozempic™ for treatment of diabetes and as Wegovy™ for weight loss.

The federal Food Drug & Cosmetic Act prohibits pharmacies from compounding “drug products that are essentially copies of a commercially available drug product.” FD&C Act § 503A(b)(1)(D). In general, then, compounding pharmacies may not compound semaglutide, a commercially available drug product.

Board regulations address this topic in [N.J.A.C.13:39-11.25 PROHIBITED COMPOUNDING](#):

- a) *A pharmacist shall not compound preparations that contain drug products that appear on the Federal Food and Drug Administration’s List of Drug Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness, codified at 21 CFR 216.24.*
- b) *A pharmacist shall not compound any commercially available drug products unless:*
 - 1) *The commercially available product is modified to produce a significant difference, in the professional judgment of the prescriber, between the compounded product for the patient and the comparable commercially available product; or*
 - 2) *The commercially available product is not available from normal distribution channels in a timely manner to meet the patient’s needs, and the dispensing of the compounded product has been approved by the prescriber and the patient.*
- c) *A pharmacist who compounds a commercially available product consistent with the requirements of (b) above shall maintain documentation of the reason for such compounding.*

When Is Compounding of Semaglutide Permissible?

FDA does not consider a drug to be “commercially available” if it appears on the FDA’s shortage list – <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm> Ozempic™ and Wegovy™ have, at times, appeared on the shortage list. On April 27, 2023, FDA officials clarified that a drug is considered in shortage by the FDA if it is listed at the above site and its “status” is described as “currently in shortage.” As is true of all drug products, pharmacists and pharmacies should regularly monitor FDA’s shortage list at the link above to determine semaglutide’s shortage status.

The federal FD&C Act also states that a compounded drug product is not “essentially a copy” of a commercially available drug product if a change is made for an identified individual patient and the prescribing practitioner has determined that the change will produce a significant difference for that patient. FD&C Act § 503A(b)(2). FDA has explained:

However, if a prescription identifies only a patient name and drug product formulation, this would not be sufficient to establish that the prescriber made the determination described by section 503A(b)(2). Note also that the significant benefit that the prescriber identifies must be produced by the change the compounder will make to a commercially available drug product (i.e., a change in drug product formulation). Other factors, such as a lower price, are not sufficient to establish that the compounded drug product is not essentially a copy of the commercially available drug product.

[Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act](#) at pp. 8-9.

Adding additional substances to a compounded product that is otherwise an essential copy of a commercially available drug product is not included in FDA’s list of circumstances meeting Section 503A(b)(2)’s requirements.

If/When Compounding of Semaglutide Is Permissible, How Must It Be Performed?

If and when compounding of a semaglutide drug product is allowed under the terms of the FD&C Act, pharmacists should be aware that substances used to compound must: (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, be components of drugs approved by the Secretary [of HHS]; or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary [of HHS], appear on a list developed by the Secretary through regulation. FD&C Act § 503A(b)(1)(A)(i).

With respect to semaglutide:

- (1) There is no USP or NF monograph for semaglutide.
- (2) Ozempic™ and Wegovy™ contain semaglutide base. Hence, only the base is a component of an FDA-approved drug. No salt form of semaglutide is contained in an FDA-approved drug.
- (3) Semaglutide does not – in any form – appear on the FDA’s “bulks list” for compounding. [Section 503A Bulks List Final Rule Questions and Answers](#) So, for this separate and independent reason, no salt form of semaglutide may be used in a compounded drug product.

Even if a pharmacy obtained semaglutide base for potential compounding use, the pharmacy must ensure that the API received is a pharmaceutical grade product, accompanied by a valid certificate of analysis, and is sourced from an establishment registered with FDA under Section 510 of the FD&C Act. FD&C Act § 503A(b)(1)(A)(ii) – (iii). Board staff are aware that some “wholesalers” are offering “research use only” products and/or products produced by establishments not registered with FDA. These may not be used for compounding in any circumstance.

The Bottom Line

Compounding of a commercially-available product is allowable only in certain narrow circumstances described above. Even when compounding of a semaglutide drug product is allowable under the FD&C Act, the use of semaglutide salts, the use of any non-pharmaceutical grade API, or one not produced by an FDA-registered establishment, is prohibited.

Compounding semaglutide drug product in a way that fails to conform with governing law may lead to enforcement action by the Food and Drug Administration and/or the New Jersey Board of Pharmacy.

Pharmacies should be aware that pharmaceutical manufacturers may choose to initiate their own legal proceedings against prescribers and compounders to combat illegal semaglutide drug product compounding.