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MAY 1, 2023 - UPDATE

STATEMENT CONCERNING SEMAGLUTIDE COMPOUNDING

The West Virginia Board of Pharmacy (Board) staff has received inquiries concerning the compounding of semaglutide. This topic has become very prominent across the nation[1], as the medication has gained notoriety for various reasons. Semaglutide is, of course, a commercially available drug product marketed as Ozempic™ for treating diabetes and as Wegovy™ for weight loss. The Board of Pharmacy in both Mississippi[2] and North Carolina[3] have already issued statements, and the Boards of Pharmacy in other states appear ready to make similar statements.

The federal Food Drug & Cosmetic Act prohibits pharmacies from compounding "drug products that are essentially copies of a commercially available drug product."[4] In general, compounding pharmacies may not compound semaglutide, a commercially available drug product.

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.[5] According to the FDA, a drug "appears on the drug shortage list in effect under section 506E" if the drug is in the "currently in shortage" status (and not in "resolved" status) in the FDA's drug shortage database.[6] As is true of all drug products, pharmacists and pharmacies should regularly monitor FDA's shortage list at the link provided below.[5]

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[1] We are aware that at least Mississippi and North Carolina have taken action. See FNs 2 & 3.
[2] https://www.mbp.ms.gov/news/semaglutide-compounding
[3] http://www.ncbop.org/PDF/SemaglutideCompounding.pdf
[4] FD&C Act § 503A(b)(1)(D).
[5] The FDA's shortage list may be found at https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
[6] 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. 5.

Also, the federal FD&C Act 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.[7] 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.[8]

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

When compounding of a semaglutide drug product is allowed under 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.[9]

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 human drug product. 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.[10] 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 the FDA under Section 510 of the FD&C Act.[11] Board staff is aware that some "wholesalers" offer "research use only" products and products produced by establishments which are not registered with the FDA. These products may not be used for compounding in any circumstance.

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[7] FD&C Act § 503A(b)(2).
[8] 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.
[9] FD&C Act § 503A(b)(1)(A)(i).
[10] Section 503A Bulks List Final Rule Questions and Answers
[11] FD&C Act § 503A(b)(1)(A)(ii) – (iii).

The Bottom Line

Compounding a commercially available product is allowable only in certain narrow circumstances, as described above. Even when the compounding of a semaglutide drug product is allowed 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.

The Board is charged with protecting the public.[12] Therefore, compounding semaglutide drug products in a way that fails to conform with governing law may lead to enforcement action by the Food and Drug Administration and the West Virginia Board of Pharmacy.

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

[12] W. Va. Code § 30-1-1a.