MISSISSIPPI
BOARD OF PHARMACY

Compounded Products Due to Shortage or Due to Special Patient Needs

The FDA does not typically allow compounding of commercially available drugs unless the drug is not readily available and is listed on the FDA drug shortage list OR there is a specific change for an identified patient whose medical needs cannot be met by the commercially available product. While correctly applying either of the above exceptions prevents FDA action on compounding drugs that are essentially copies of a commercially available drug product, compounders must ensure that compounded bulk drug substance complies with FDA Bulk Drug Substance Requirements.

Semaglutide compounding: The compounding of semaglutide salts by pharmacies and outsourcers has risen due to the FDA shortage status of Wegovy® and Ozempic®. Below is an explanation of how semaglutide compounding does not meet FDA requirements:

1. Comply with the standards of applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding: **Semaglutide does not have a USP or NF monograph.**
2. If such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary: **Semaglutide base is in the approved FDA products list but not semaglutide sodium, semaglutide acetate or other salt forms. The FDA has verbally stated that compounding with semaglutide salts does not meet this requirement.**
3. If such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary under section 503A or section 503b: **Semaglutide does not meet the bulk substance requirements and is not included in the categories of nominated substances.**

Mississippi Board of Pharmacy staff are utilizing this communication to inform all licensees involved in compounding that semaglutide compounding does not meet the requirements as set by FDA; therefore, compounding in this manner may result in enforcement action being taken by FDA and/or the Mississippi Board of Pharmacy. We would also like to make licensees aware of the need to read the fine print on any invoices received for bulk drug substances as there may be instances where these substances are actually research grade product and not pharmaceutical grade product. Lastly, drug manufacturers have become aware of the practice of using semaglutide salts for compounding and may choose to initiate legal proceedings to combat this practice.

References:

- Compounded Drug Products that Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act.
- Compounded Drug Products that Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act.
- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act.
- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.