ALABAMA STATE BOARD OF PHARMACY
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FDA Considerations for 503A Compounding of GLP-1 Medications

Recent FDA enforcement activity provides additional insight into the Agency's expectations for pharmacies compounding under Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), particularly when compounding semaglutide, tirzepatide, or other drug products that are commercially available.

Patient-Specific Need and "Essentially a Copy"
Section 503A places limitations on the compounding of drug products that are essentially copies of commercially available drug products.

When a compounded preparation differs from a commercially available drug, the prescribing practitioner must determine that the change produces a significant difference for the identified individual patient when relying on this provision of Section 503A.

Recent FDA enforcement activity has raised concerns regarding practices such as:

- Routinely adding ingredients, including vitamins, to distinguish a compounded preparation from a commercially available drug;
- Using standardized or repetitive statements regarding a "significant difference" that may not reflect an individualized prescriber determination;
- Using prescribing platforms that provide pre-generated or pre-selected reasons to support a significant difference; and
- Compounding regularly or in quantities that may be inconsistent with the limitations applicable to copies of commercially available drug products.

The addition of an ingredient, by itself, does not establish that a compounded preparation is not essentially a copy. When applicable, the prescriber should determine that the formulation change produces a significant difference for the individual patient.

Considerations for GLP-1 Compounding
Pharmacies engaged in 503A compounding of semaglutide, tirzepatide, or similar products should evaluate their practices for compliance with applicable federal requirements.

Consideration should be given to:

- Whether the commercially available drug is available at the time of compounding;
- Whether the compounded preparation may be considered essentially a copy of a commercially available drug;
- Whether a formulation difference is supported by an individualized prescriber determination of significant difference;
- Whether the prescription and supporting records adequately document the patient-specific basis for compounding; and
- Whether the frequency and volume of compounding are consistent with Section 503A.

Standardized formulation changes or documentation should not be used as a substitute for an individualized prescriber determination when necessary to satisfy Section 503A.

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Why 503A Status Matters
The exemptions provided under Section 503A are conditional upon meeting the applicable requirements of that section.

When a compounded drug does not meet the conditions of Section 503A, it may no longer qualify for exemptions from certain provisions of the FD&C Act, including:

- Current Good Manufacturing Practice (CGMP) requirements;
- FDA new drug approval requirements; and
- Certain labeling requirements, including adequate directions for use.

As a result, failure to meet the conditions of Section 503A may cause a compounded drug to be considered adulterated, an unapproved new drug, and/or misbranded under federal law.

Key Takeaway
Pharmacies engaged in 503A compounding should ensure that compounding practices are based on legitimate patient-specific needs and are supported by appropriate documentation.

For compounded GLP-1 medications, pharmacies should pay particular attention to FDA requirements concerning commercially available products and drugs that may be considered essentially copies. Routine formulation changes or standardized statements of clinical significance should not replace the individualized prescriber determination required under Section 503A.

Pharmacies are encouraged to review their current compounding practices, prescribing documentation, and procedures to ensure compliance with applicable state/federal requirements.

This information is provided for educational purposes and summarizes considerations identified through recent FDA enforcement activity. Pharmacies remain responsible for compliance with all applicable state and federal laws, rules, and standards.