August 12, 2026

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Dear Dr. Chaudhry:

The purpose of this letter is to bring to the attention of the Federation of State Medical Boards information related to the labeling of compounded GLP-1 (glucagon-like peptide-1 (GLP-1) receptor agonists) medications and handling of multi-dose vials.

FDA is aware of many compounders dispensing compounded GLP-1 medications in vials containing more than one dose of medication for the patient to draw up for self-administration. We are also aware of an increase in patient complaints related to the use of compounded GLP-1 multi-dose vials. For example, prescription labels instruct patients to withdraw small-volume doses from compounded multi-dose vials; however, depending on the prescribed dose, not all contents of the vial may be used within the customary 28-day beyond-use period after first puncture. Complaints have also been received regarding patients being dispensed a vial of drug product that far exceeds the volume that would be administered within a 28-day period as well as patients being advised to extend the use of multi-dose vials beyond the 28-day beyond use date after first puncture.

For FDA-approved products, FDA guidance generally defines a multi-dose container as a container of sterile medication for parenteral administration that has met antimicrobial effectiveness testing requirements with an expectation that the beyond-use date for an opened or entered multi-dose container be 28 days unless otherwise specified by the manufacturer on the label.

Compounded drug products[1] often have different concentrations than FDA approved products, and the prescription labeling and instructions may differ from what patients may expect based on their experience with an FDA approved product.

[1] Compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product. However, these drugs present a higher risk to patients than approved drugs. Compounded drugs are not FDA-approved and have not been reviewed by the Agency for safety, effectiveness, or quality before they are marketed. Because compounded drugs are subject to a lower regulatory standard than approved drugs, patients should not receive them unless an approved drug does not meet their medical needs.

For example, a prescription label for a GLP-1 compounded drug product might state, *"Inject subcutaneously weekly; inject 0.12 mL for 4 weeks; then 0.24 mL for 4 weeks; then 0.36 mL for 4 weeks; then 0.48 mL for 4 weeks; then 0.54 mL weekly."* The patient would then receive a compounded drug product vial with a total volume of 4 mL. Depending on where the patient is in their regimen, these instructions may be confusing and difficult to accurately follow. If this was the start of the regimen, in practice, the patient would only administer 0.48 mL of drug within the 28 days after first puncture, then be expected to discard almost 90% of the vial contents.

In contrast to the FDA-approved tirzepatide drug product, which comes in standard concentration of either 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg, or 15mg per 0.5 mL in a vial or pen, a compounded strength of tirzepatide, as shown in the example below, may come in a concentration of 17 mg/mL with a total volume of 4 mL in a single multi-dose vial.

Compounded Tirzepatide (concentration: 17 mg/mL in a 4 mL vial)

Dose	Volume to Draw
2.5 mg	0.15 mL
5 mg	0.29 mL
10 mg	0.59 mL
15 mg	0.88 mL

Because compounded and FDA-approved products may have different concentrations, it is important to note the volumes are not interchangeable between the two. In addition, some compounded GLP-1s may contain other active ingredients, such as vitamins and supplements, which may further complicate dose measurement and increase the risk of dosing errors. Depending on the type of syringe dispensed, the volume marking may be difficult to find and read when measuring out the dose. It is important for patients and healthcare providers to be aware of the risks of medication dosing errors and potential for contamination if multi-dose vials are used beyond 28 days. Therefore, we recommend clear instructions be provided to patients on when to discard multi-dose vials. For example, if the patient is prescribed once weekly dosing, consider the following instructions, *"Discard vial after the 4th injection."*

We encourage you to share the information in this letter with your members and encourage state boards of medicine to be aware of these activities and provide any relevant information to the FDA. We look forward to continuing to work with you on matters related to drug compounding. If you have questions or wish to submit any relevant information, please contact the Office of Compounding Quality and Compliance at compounding@fda.hhs.gov.

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

Sincerely,

MATTHEW J. LASH -S

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