

April 27, 2023

Lemrey (Al) Carter, MS, PharmD, RPh Executive Director National Association Boards of Pharmacy 1600 Feehanville Drive Mount Prospect, IL 60056

Dear Dr. Carter,

In consideration of several inquiries received, we wish to clarify for state pharmacy regulators that as of today, April 27, 2023, the FDA-approved drugs Wegovy and Ozempic continue to be listed on the FDA Drug Shortage website. If a product is listed on the FDA Drug Shortage website, we still consider the product to be in shortage unless it states that it is resolved. FDA works closely with manufacturers to confirm the accuracy and appropriateness of information before posting publicly on its website.

As you know, depending on the circumstances, compounded drugs can be made and distributed with fewer restrictions when the drug appears on <u>FDA's drug shortages list</u>. Please find more information on drug compounding and drug shortages on FDA's <u>website</u>.

We also wish to ensure you are aware that the active pharmaceutical ingredient in Wegovy and Ozempic is semaglutide in its base form. We are aware that in some cases compounders may be using salt forms of semaglutide, including semaglutide sodium and semaglutide acetate. We are not aware of any basis for compounding a drug using these semaglutide salts that would meet federal law requirements that limit the types of active ingredients that can be used in compounding.

Please let us know if you have additional questions. Thank you.

Sincerely,

F. Gail Bormel, RPh, JD Director CDER Office of Compounding Quality and Compliance <u>frances.bormel@fda.hhs.gov</u>