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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Lemrey "Al" Carter, Executive Director/Secretary

DATE: June 1, 2023

RE: FDA Provides Updated Drug Shortage and Compounding Information for Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss

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Food and Drug Administration (FDA) has provided updated information about FDA-approved semaglutide products, which are marketed for type 2 diabetes or weight loss, and its concerns about compounding semaglutide products.

Semaglutide is a glucagon-like peptide-1 receptor agonist, and there are currently three FDA-approved semaglutide products: Ozempic® injection, Rybelsus® tablets, and Wegovy® injection. These three medications are available by prescription only, and there are no approved generic versions. As of May 2023, Ozempic and Wegovy are on FDA's Drug Shortages List, which may allow compounders to prepare a compounded version of these drugs if they meet certain requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The active pharmaceutical ingredient in Ozempic and Wegovy is semaglutide in its base form. FDA is aware, however, that in some cases compounders may be using salt forms of semaglutide, including semaglutide sodium and semaglutide acetate. The salt forms are different active ingredients than what is used in the approved drugs. FDA is not aware of any basis for compounding using the salt forms that would meet the FD&C Act requirements for types of active ingredients that can be compounded.

FDA has received adverse event reports after patients used compounded semaglutide. Health care professionals and patients should understand that FDA does not review compounded versions of these drugs for safety, effectiveness, or quality, and are reminded to not use a compounded drug if an approved drug is available. FDA encourages health care professionals, compounders, and patients to report adverse events or quality problems to its MedWatch Adverse Event Reporting Program.

The full semaglutide update may be viewed at *https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss*.

NABP encourages you to distribute this information to licensees in your state.

cc: NABP Executive Committee