

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
FROM: Lemrey “Al” Carter, Executive Director/Secretary
DATE: December 19, 2024
RE: FDA Issues Declaratory Order Confirming Tirzepatide Shortage Resolution

On December 19, 2024, Food and Drug Administration’s (FDA’s) Center for Drug Evaluation and Research issued a [declaratory order](#) confirming its determination that the tirzepatide shortage has been resolved.

The order states that the agency does not intend to take action against compounders for violations of the Food, Drug, and Cosmetic Act (FD&C Act) arising from conditions that depend on the inclusion of tirzepatide injection products on FDA’s drug shortage list:

- For a state-licensed pharmacy under Section 503A of the FD&C Act compounding, distributing, or dispensing tirzepatide injections within 60 calendar days from FDA’s announcement, until February 18, 2025.
- For outsourcing facilities under Section 503B compounding, distributing, or dispensing tirzepatide injections within 90 calendar days from FDA’s announcement, until March 19, 2025.

FDA may still take action regarding violations of any other statutory or regulatory requirements, such as to address findings that a product may be of substandard quality or otherwise unsafe.

cc: NABP Executive Committee