FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize

[10/02/2024] The U.S. Food and Drug Administration has determined the shortage of tirzepatide injection, a glucagon-like peptide 1 (GLP-1) medication, has been resolved (https://dps.fda.gov/drugshortages/resolved/tirzepatide-injection). Tirzepatide injection has been in shortage since 2022 due to increased demand.

FDA confirmed with the drug's manufacturer that their stated product availability and manufacturing capacity can meet the present and projected national demand. Patients and prescribers may still see intermittent localized supply disruptions as the products move through the supply chain from the manufacturer and distributors to local pharmacies.

FDA reminds compounders of the legal restrictions on making copies of FDA-approved drugs

Compounded drugs are not approved by FDA. FDA-approved drugs go through FDA's rigorous review for safety, effectiveness, and quality as part of the premarket approval process. Compounded drugs must meet conditions to qualify for exemptions under sections 503A and 503B of the Federal Food, Drug and Cosmetic (FD&C) Act. Among the conditions are:

- Section 503A of the FD&C Act includes restrictions on compounding drugs that are essentially copies of a commercially available drug (/media/98973/download?attachment). When a drug shortage is resolved, FDA generally considers the drug to be commercially available. Certain amounts are permissible under the law as long as the compounding is not done "regularly or in inordinate amounts."
- Section 503B of the FD&C Act restricts outsourcing facilities from making compounded drugs that are essentially a copy of one or more FDA-approved drugs (/media/98964/download?attachment). Among other things, this means the compounded drug may not be identical or nearly identical to an FDA-approved drug unless the approved drug is on FDA's drug shortage list.

Current shortage status of GLP-1 products (as of October 02, 2024):

- Tirzepatide injection: Shortage resolved.
- Dulaglutide injection: In shortage.

- Semaglutide injection: In shortage. Manufacturer has reported all but one of the presentations are available.
- Liraglutide injection: In shortage. Manufacturer has reported 2 presentations are available, and three have limited availability.

The agency will continue to work with manufacturers to help resolve the current shortages, and, as shortages resolve, will closely monitor the situation and provide any assistance we can to help manufacturers ensure an adequate supply. Before determining that a shortage is resolved, FDA considers a variety of factors, including the company's ability to meet current and historical demand, the amount in a manufacturer's stock, affected market share, ability of alternate manufacturers to cover the demand, and confirmed market stabilization. Please visit FDA's Drug Shortages Database (https://dps.fda.gov/drugshortages) for the most recent information on the status of GLP-1 medicines and other drugs in shortage.

For more information:

- Compounding when Drugs are on FDA's Drug Shortages List (/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list)
- Compounding and the FDA: Questions and Answers (/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers)
- FDA Drug Shortage webpage (/drugs/drug-safety-and-availability/drug-shortages)
- FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss (/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss)