U.S. FOOD & DRUG ADMINISTRATION

October 17, 2024

Scott Brunner, CAE
Chief Executive Officer
Alliance for Pharmacy Compounding
100 Daingerfield Road, Suite 401
Alexandria, Virginia 22314
scott@a4pc.org

Dear Mr. Brunner-

On October 7, 2024, FDA was sued by a compounder and a trade association regarding removal of tirzepatide injection from FDA's drug shortages list. On October 11, upon FDA's motion, a court order remanded the decision to the Agency for reevaluation. *See Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-953, ECF Nos. 27, 28 (N.D. Tex.).

In that litigation, FDA stated in its motion that during the reevaluation and until 2 weeks after the Agency makes its decision (and if the plaintiffs file a motion for preliminary injunction, until the court resolves such a motion), FDA does not intend to take action against the plaintiffs in the case for violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act) arising from conditions that depend on tirzepatide's inclusion on the FDA drug shortage list (see section 506E of the FD&C Act) [*i.e.,* section 503A(b)(1)(D) (compounded drugs that are essentially a copy of a commercially available drug product) or sections 503B(a)(2)(A) (bulk drug substances used in compounding) and (a)(5)) (compounded drugs that are essentially a copy of an FDA-approved drug product)]. Neither FDA's statement nor the court's order prevents FDA from taking action for violations of any other statutory or regulatory requirements, such as to address findings that the product may be of substandard quality or otherwise unsafe.

Given these circumstances, FDA intends to treat compounders consistently at this time, meaning that FDA does not intend to take action against compounders for violations arising from the conditions above, for the same duration of time and subject to all the same limitations as described in FDA's motion and the court's order.

Sincerely,

Frances G. Bormel -S

Digitally signed by Frances G. Bormel -S
Date: 2024.10.17 19:00:19 -04'00'

Gail Bormel
Office Director
Office of Compounding Quality and Compliance
Center for Drug Evaluation and Research