From: Bormel, Frances Gail <Frances.Bormel@fda.hhs.gov>
Date: Friday, January 17, 2025 at 2:14 PM
To: Scott Brunner <scott@a4pc.org>, Cosel, Gabrielle <Gabrielle.Cosel@fda.hhs.gov>, Anderson, Kathleen R <Kathleen.Anderson@fda.hhs.gov>
Cc: Tenille Davis <Tenille@a4pc.org>, Bormel, Frances Gail <Frances.Bormel@fda.hhs.gov>
Subject: RE: [EXTERNAL] Request for clarity: Copies of tirzepatide injection

Scott-

In *Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-953, ECF No. 38 (N.D. Tex.), FDA referred to its jointly-proposed preliminary injunction briefing schedule and stated that "If the Court enters the foregoing schedule and it is adhered to, Defendants will continue to exercise the enforcement discretion described in Defendants' unopposed motion for voluntary remand through the Court's resolution of Plaintiffs' motion for a preliminary injunction. See ECF No. 27 at 3." The court proceeded to enter a substantially similar schedule. *See id.*, ECF No. 62. FDA intends to exercise the enforcement discretion described in its filings.

As previously explained in our letter to you dated October 17, 2024, 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 any court 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 litigation filings described here.

In addition to the above-described enforcement discretion, we note the periods of enforcement discretion described in FDA's Declaratory Order: Resolution of Shortages of Tirzepatide Injection Products (Mounjaro and Zepbound) (Dec. 19, 2024), https://www.fda.gov/media/184606/download.

Gail

F. Gail Bormel
Office Director

Office of Compounding Quality and Compliance (OCQC)
Office of Compliance
Center for Drug Evaluation & Research
U.S. Food & Drug Administration

10903 New Hampshire Ave., Bldg. 51, Room 5184
Silver Spring, MD 20993
Tel: 301-796-3263

frances.bormel@fda.hhs.gov