

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
Fort Worth Division**

Outsourcing Facilities Association, *et al.*,

Plaintiffs,

v.

U.S. Food and Drug Administration, *et al.*,

Defendants.

Case No. 4:24-cv-00953-P

**DEFENDANTS' UNOPPOSED MOTION FOR VOLUNTARY REMAND AND STAY**

Defendants respectfully request that the Court remand this matter to the United States Food and Drug Administration (FDA) to give the agency the opportunity to reevaluate the decision at issue in this case. A remand would conserve the resources of the parties and the Court by avoiding unnecessary briefing and consideration of motions that may become moot in light of subsequent administrative proceedings. Defendants request that the Court enter an order remanding the matter to the agency, staying this litigation pending proceedings on remand, and canceling the hearing scheduled for Tuesday, October 15, 2024.

Congress requires FDA to “maintain an up-to-date list of drugs that are determined . . . to be in shortage in the United States.” 21 U.S.C. § 356e. Appearing on FDA’s shortage list provides certain drugs with a temporary exemption from certain statutory requirements, such as the requirement for premarket review, when several criteria are met. *See id.* §§ 353a(b)(1)(D), 353b(a)(2)(A) and (a)(5). In December 2022, FDA identified a nationwide shortage of tirzepatide and added that drug to the shortage list. FDA updated the status of the tirzepatide shortage to “resolved” on October 2, 2024, based on its determination that there was no longer a shortage.

Plaintiffs challenge Defendants' decision to remove tirzepatide from the drug shortage list under the Administrative Procedure Act (APA), arguing that the action was a substantive rule issued without notice and comment and thus contrary to law, and contrary to record evidence and thus arbitrary and capricious, among other arguments. Defendants wish to reevaluate the challenged decision.

"[I]n the absence of a specific statutory limitation, an administrative agency has the inherent authority to reconsider its decision." *Macktal v. Chao*, 286 F.3d 822, 825–26 (5th Cir. 2002). "The reasonableness of an agency's reconsideration implicates two opposing policies: 'the desirability of finality on one hand and the public's interest in reaching what, ultimately, appears to be the right result on the other.'" *Id.* at 826 (quoting *Civil Aeronautics Bd. v. Delta Air Lines, Inc.*, 367 U.S. 316, 321 (1961)).

"Courts have long recognized the propriety of voluntarily remanding a challenged agency action without judicial consideration of the merits, with or without admission of agency error." *Frito-Lay, Inc. v. U.S. Dep't of Labor*, 20 F. Supp. 3d 548, 552 (N.D. Tex. 2014) (citation omitted). Granting such a motion "allow[s] agencies to cure their own mistakes rather than wasting the courts' and the parties' resources." *Ethyl Corp. v. Browner*, 989 F.2d 522, 524 (D.C. Cir. 1993). Accordingly, "[a]n agency's motion to remand for reconsideration of its own decision is usually granted." *Am. Wild Horse Pres. Campaign v. Salazar*, 115 F. Supp. 3d 1, 3 (D.D.C. 2012).

Those standards are satisfied here. First, a remand would permit Defendants to reevaluate the decision in light of Plaintiffs' challenges to it. *See Citizens Against Pellissippi Parkway Extension, Inc. v. Mineta*, 375 F.3d 412, 416 (6th Cir. 2004) (it may be "an abuse of discretion to prevent an agency from acting to cure the very legal defects asserted by plaintiffs challenging federal action").

Second, granting a voluntary remand and staying this litigation while further administrative proceedings are ongoing "would preserve the Court's scarce judicial resources by providing [Defendants] the opportunity to cure" any legal errors that may

exist. *Frito-Lay, Inc.*, 20 F. Supp. 3d at 554 (alterations and citation omitted); *see id.* at 554–55 (surveying cases and noting that courts “often rely on the principle of judicial economy” in granting motions for voluntary remand); *Sierra Club v. Van Antwerp*, 560 F. Supp. 2d 21, 23, 25 (D.D.C. 2008) (“an agency wishing to reconsider its action should move the court to remand or hold the case in abeyance pending the agency’s reconsideration,” in part because remand “will serve the interest of allowing [the agency] to cure its own potential mistake rather than needlessly wasting the Court’s and the parties’ resources”).

Third, Defendants’ proposed remand order would ensure that Plaintiffs are not prejudiced during the remand period. Defendants represent that, during the time period specified below, they will not take action against Plaintiffs and their members for violations of the Federal Food, Drug, and Cosmetic Act arising from conditions that depend on tirzepatide’s inclusion on the drug shortage list (*i.e.*, compounding that does not meet the applicable conditions in 21 U.S.C. §§ 353a(b)(1)(D) or 353b(a)(2)(A)(ii) and (a)(5)), which is effectively the relief that Plaintiffs sought in their motion for a temporary restraining order. Defendants represent that the exercise of enforcement discretion will extend from the date of the Court’s remand order to two weeks beyond Defendants’ reconsideration of the decision. Should Plaintiffs file a motion for preliminary injunction from the new decision, the exercise of enforcement discretion would continue through the Court’s resolution of that motion. However, nothing in the above or the proposed remand order would affect Defendants’ ability to take action on any other statutory or regulatory requirements, such as addressing findings that the product may be substandard or otherwise unsafe, for example in circumstances of adulteration (*e.g.*, insanitary conditions in a compounding facility that could result in contamination of drug products or products that are superpotent, which could lead to overdose).

Defendants further represent that Plaintiffs may submit additional information regarding tirzepatide's availability for Defendants' consideration during the remand period. Defendants encourage Plaintiffs to submit any such information expeditiously.

Finally, Defendants' proposed remand order would instruct the parties to file a joint status report by November 21, 2024, and cancel the hearing currently scheduled for October 15, 2024.

On October 11, 2024, Defendants conferred with counsel for Plaintiffs. Counsel for Plaintiffs indicated by email that Plaintiffs do not oppose Defendants' motion.

#### CONCLUSION

The challenged decision should be remanded to the agency consistent with the attached proposed order.

DATED: OCT. 11, 2024

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### CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

October 11, 2024

/s/ Oliver McDonald  
OLIVER MCDONALD

### CERTIFICATE OF CONFERENCE

Pursuant to Local Rule CV-7(i), the undersigned hereby certifies that on October 11, 2024, the undersigned conferred with Andrew Grossman and Richard Raile, counsel for Plaintiffs. Counsel for Plaintiffs indicated by email that Plaintiffs do not oppose Defendants' motion.

October 11, 2024

/s/ Oliver McDonald  
OLIVER MCDONALD