

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
SOUTHEASTERN DIVISION

THE STATE OF MISSOURI, *et al.*,

Intervenor Plaintiff,

v.

U.S. FOOD AND DRUG
ADMINISTRATION, *et al.*,

Federal Defendants,

and

DANCO LABORATORIES, *et al.*,

Intervenor Defendants.

No. 4:25-cv-01580-CMS

**FEDERAL DEFENDANTS' RESPONSE TO MOTION FOR LEAVE TO
SUPPLEMENT THE AMENDED COMPLAINT**

On November 19, 2025, Intervenor Plaintiffs filed a Motion for Leave to Supplement the Amended Complaint. ECF No. 277. The proposed supplemental complaint asserts two claims challenging the U.S. Food and Drug Administration's September 30, 2025 approval of a new generic mifepristone drug product. ECF No. 277-1. Intervenor Plaintiffs request that the Court order Defendants to plead to the supplemental complaint within a specified time. ECF No. 277, at 1.

Without waiving any defense they might assert in a motion to dismiss or a responsive pleading, Federal Defendants do not oppose Intervenor Plaintiffs' Motion for Leave to Supplement the Amended Complaint, but Federal Defendants do not

believe that any response to the Supplemental Complaint is necessary until after the Court resolves the pending motion to dismiss this case on threshold grounds.

Before the United States District Court for the Northern District of Texas, Federal Defendants moved to dismiss the Amended Complaint (ECF No. 217) on several grounds. ECF No. 219. In addition to challenging venue, *id.* at 3-7, Federal Defendants argued that the court lacked subject matter jurisdiction, *id.* at 7-12, Intervenor Plaintiffs failed to administratively exhaust their claims, *id.* at 12-14, and certain claims were barred by the statute of limitations, *id.* at 14-15. Although the Northern District of Texas granted Federal Defendants' alternative request to transfer the case, ECF No. 273, at 1, 27, that court did not rule on whether the Amended Complaint should be dismissed based on non-venue grounds, including for lack of subject-matter jurisdiction, *see id.* at 8-10 (concluding that the court could rule on venue without addressing subject matter jurisdiction). Federal Defendants' arguments regarding subject matter jurisdiction and exhaustion would also pertain to the Supplemental Complaint.

Federal Defendants' motion to dismiss therefore remains pending. Indeed, while the Northern District of Texas determined that some pending motions should be denied as moot due to the pending transfer, *id.* at 1, 27, the court did not deny (as moot or otherwise) Federal Defendants' motion insofar as it requested dismissal. It would be premature for Federal Defendants to answer or otherwise respond to the Supplemental Complaint before the Court has resolved threshold grounds for dismissal of this entire case.

If, however, this Court determines that the motions to dismiss are no longer

pending (or should be refiled for any other reason), Federal Defendants respectfully request that the Court permit Federal Defendants to file a consolidated response to the Amended Complaint and Supplemental Complaint at least 60 days after the Supplemental Complaint is docketed.

December 3, 2025

Respectfully submitted,

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