

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

THE STATE OF MISSOURI, <i>et al.</i> ,	§	
	§	
<i>Intervenor Plaintiffs,</i>	§	
	§	Case No. 4:25-cv-01580-CMS
v.	§	
	§	
U.S. FOOD AND DRUG	§	
ADMINISTRATION, <i>et al.</i> ,	§	
	§	
<i>Defendants.</i>	§	

MOTION FOR LEAVE TO SUPPLEMENT  
THE AMENDED COMPLAINT

Pursuant to Federal Rule of Civil Procedure 15(d), the State of Missouri, the State of Kansas, and the State of Iowa (“Plaintiffs”) respectfully move the Court for leave to file their First Supplemental Complaint “setting out . . . event[s] that happened after the date of the [original] pleading . . . .” Fed R. Civ. P. 15(d). Plaintiffs respectfully request that the attached proposed Supplemental Complaint be accepted and docketed as filed, and Defendants be ordered to “plead to the supplemental pleading within a specified time.” *Id.* The grounds for this motion are set forth in the attached memorandum in support.

## MEMORANDUM IN SUPPORT OF THE PLAINTIFFS' MOTION FOR LEAVE TO SUPPLEMENT THE AMENDED COMPLAINT

### INTRODUCTION

In 2019, the U.S. Food and Drug Administration (“FDA”) approved GenBioPro Inc.’s (“GenBioPro”) amended new drug application (“ANDA”) for a generic form of mifepristone (“2019 ANDA Approval”). Am. Compl. ¶ 164, ECF No. 217; Ex. 30. This was the FDA’s first approval of a generic version of mifepristone. Am. Compl. ¶ 164, ECF No. 217. The FDA’s approval subjected GenBioPro’s generic drug to the same labeling and REMS requirements as its reference drug, Mifeprex which is produced by Danco Laboratories, LLC (“Danco”). *Id.*; Ex. 30. At the same time, the FDA approved a single, shared risk evaluation and mitigation strategy (“REMS”) for all mifepristone products (“Mifepristone REMS Program”). *Id.* ¶ 165; Ex. 31. Along with other actions by Defendants, these approvals form the basis of this lawsuit.

Six years after the 2019 ANDA Approval and eight months after Plaintiffs filed their Amended Complaint, the FDA approved Evita Solutions, LLC’s (“Evita”) ANDA for its generic version of Mifeprex (“2025 ANDA Approval”).<sup>1</sup> Like GenBioPro’s generic drug, Evita’s generic mifepristone is subject to the same labeling and REMS requirements as Mifeprex, which Plaintiffs challenge as being unlawful and arbitrary and capricious.<sup>2</sup> In addition, Evita’s generic mifepristone is chemically identical to Danco’s Mifeprex and GenBioPro’s generic mifepristone, meaning it poses the same

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<sup>1</sup> 2025 FDA ANDA Approval Letter to Evita Solutions, LLC p. 1 (September 30, 2025), [https://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2025/216616s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2025/216616s000ltr.pdf) (“2025 FDA ANDA Approval Letter”).

<sup>2</sup> *See id.*

health risks to pregnant woman that the FDA ignored when first approving the chemical abortion drug.

The 2025 ANDA Approval, in short, represents a continuance of the underlying case brought by Plaintiffs—one that must be addressed if Plaintiffs are to obtain complete and speedy relief from the FDA’s illegal actions. For these reasons, as well as for the sake of judicial economy, Plaintiffs respectfully request leave to supplement their Amended Complaint to update their claims to reflect the FDA’s approval of a second generic mifepristone.

### **BACKGROUND**

This lawsuit originated in 2022, when several doctors and four medical associations (“Original Plaintiffs”) filed a complaint against the FDA; Robert M. Califf, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; Janet Woodcock, M.D., in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration; Patrizia Cavazzoni, M.D., in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; the U.S. Department of Health and Human Services; and Xavier Becerra, in his official capacity as Secretary, U.S. Department of Health and Human Services (“Original Defendants”)<sup>3</sup> in the Northern District of Texas. ECF No. 1. In their complaint, the Original Plaintiffs challenged the FDA’s 2000 approval of name-brand mifepristone, its 2019 approval of generic mifepristone,

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<sup>3</sup> This list of defendants reflects the list of parties at the initiation of this lawsuit. Since that time, the office of Principal Deputy Director of the FDA has been dropped and pursuant to Federal Rule of Civil Procedure 25(d), the current occupants of the official positions have been substituted for those no longer in office.

and its subsequent 2016 and 2021 loosening of federal regulations pertaining to mifepristone. *Id.*

In February 2023, the court granted Danco leave to intervene. ECF No. 33. GenBioPro was granted leave to intervene in February 2025 (together with Danco and the Original Defendants “Defendants”). Plaintiffs, meanwhile, intervened in this lawsuit in 2024 and filed their initial complaint that same month. ECF Nos. 175, 176. In January 2025—after the Supreme Court decided *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024) and the original plaintiffs voluntarily dismissed from the lawsuit, ECF No. 203—Plaintiffs filed an amended complaint (“Amended Complaint”), ECF No. 217. The Amended Complaint brought Administrative Procedure Act (“APA”) challenges against the FDA’s decisions in 2016, 2021, and 2023 to loosen federal regulations of mifepristone related to labeling and REMS; its 2019 issuance of the Mifepristone REMS Program; and its 2019 ANDA Approval. *Id.* Defendants have not filed an answer in response to the Amended Complaint and discovery has not commenced in relation to the Amended Complaint.

On September 30, 2025, the Northern District of Texas court issued an order transferring this case to the Eastern District of Missouri. ECF No. 273. The case was officially transferred to this Court on October 23, 2025 and assigned a judge the same day. ECF No. 274. Neither the Court nor the Parties have taken any since. Plaintiffs now move to supplement their Amended Complaint in order to incorporate events that occurred after Plaintiffs filed the Amended Complaint and are directly

related to the existing controversy and necessary to achieve orderly, fair, and complete relief.

### LEGAL STANDARD

Under Rule 15(d), “the court may, on just terms, permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented.” Fed. R. Civ. P. 15(d). Rule 15(d) “is designed to cover matters subsequently occurring but pertaining to the original cause.” *Weeks v. Birch*, No. 1:17-CV-00022 AGF, 2020 WL 33089, at \*2 (E.D. Mo. Jan. 2, 2020) (quoting *Schreier v. Drealan Kvilhaug Hoefker & Co. P.A.*, 018-CV-02310-DSDKMM, 2019 WL 1923111, at \*1 (D. Minn. Apr. 30, 2019) (citing *U.S. v. Vorachek*, 563 F.2d 884, 886 (8th Cir. 1977))).

Rule 15(d) “gives the trial court, in the exercise of its sound discretion, the right to determine whether or not leave should be granted to file a supplemental pleading,” *Minn. Min. & Mfg. Co. v. Superior Insulating Tape Co.*, 284 F.2d 478, 481 (8th Cir. 1960), and “is intended to give district courts broad discretion in allowing supplemental pleadings.” *In re Bankamerica Corp. Sec. Litig.*, No. 4:99-MD-1264 CEJ, 2010 WL 4622530, at \*1 (E.D. Mo. Nov. 5, 2010) (quoting Fed. R. Civ. P 15, 1963 Amendment notes).

“Supplemental complaints stating claims against new parties are acceptable, so long as the claims are a continuation of the underlying case and the supplemental complaint is necessary ‘to achieve an orderly and fair administration of justice.’” *Id.* (quoting *Griffin v. Cnty. Sch. Bd. Of Prince Edward Co.*, 377 U.S. 218, 226 (1964)). “However, when claims are separate and distinct from the underlying case, the claims

‘are more appropriately brought in a separate suit.’” *Id.* (quoting *Paige v. Harper*, No. 4:99-MD-1264 CEJ, 2010 WL 4622530 (E.D. Mo. Nov. 5, 2010).

While the Eighth Circuit has not articulated a standard that applies “to the Court’s exercise of discretion concerning a motion for leave to file a supplemental pleading under Rule 15(d),” this Court has consistently applied the same liberal principles that apply to amended pleadings under Rule 15(a). *Riggs v. City of Owensville*, No. 4:10-CV-793 CAS, 2011 WL 1576723, at \*2 (E.D. Mo. Apr. 26, 2011); *see, e.g., Weeks v. Birch*, No. 1:17-CV-00022 AGF, 2020 WL 33089, at \*2 (E.D. Mo. Jan. 2, 2020); *Raineri Const., LLC v. Taylor*, No. 4:12-CV-2297 CEJ, 2013 WL 6050772, at \*2 (E.D. Mo. Nov. 15, 2013).

Accordingly, courts are encouraged to grant a motion for leave to supplement under Rule 15(d), “when doing so will promote the economic and speedy disposition of the entire controversy between the parties, will not cause undue delay or trial inconvenience, and will not prejudice the rights of any of the other parties to the action.” *Harris v. Adams*, No. 4:17-CV-00842 PLC, 2021 WL 5823885, at \*6 (E.D. Mo. Dec. 8, 2021) (quoting *U.S. ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1, 4 (1st Cir. 2015). “[A]bsent any suggestion of bad faith or dilatory motive,” *Weeks*, 2020 WL 33089, at \*3, “[f]actors to be considered include the futility of the supplementation, prejudice to the opposing party, unreasonable delay in the request to supplement, and whether the supplementation would ‘unduly delay resolution of the case.’” *Harris*, 2021 WL 5823885, at \*6 (quoting *PharMerica Corp.*, 809 F.3d at 7). Plaintiffs’ motion for leave satisfies the above standard.

## ARGUMENT

This Court should grant the Plaintiffs' motion to supplement their Amended Complaint because the supplemental complaint is directly related to the existing controversy and supplementation is necessary to ensure complete relief. Moreover, granting Plaintiffs' motion to supplement will not cause undue delay nor will it prejudice the parties but instead will help promote judicial economy by allowing Plaintiffs' APA claims against the 2019 ANDA Approval and the 2025 ANDA Approval be heard simultaneously.

As a preliminary matter, Rule 15(d) is the proper mechanism for adding a cause of action necessary to afford Plaintiffs complete relief based on events that occurred after the underlying pleading. Plaintiffs' filed their Amended Complaint in January 2025. ECF No. 217. Over eight months later, on September 30, 2025, the FDA approved Evita's ANDA. *See* 2025 FDA ANDA Approval Letter. This event provides the basis for Plaintiffs' supplemental complaint. Thus the events giving rise to the supplement "happened after the date of the pleading to be supplemented" and Rule 15(d) is appropriate. Fed. R. Civ. P. 15(d); *see United States ex rel. Kenny v. Stoltz*, 327 F.3d 671, 674 n.4 (8th Cir. 2003) ("[S]upplemental pleadings, not amended pleadings, are intended to cover matters occurring after the original complaint is filed.").

Plaintiffs' motion should be granted because their supplemental complaint "is merely a continuation" of the Amended Complaint. *See Gen. Bronze Corp. v. Cupples Prods. Corp.*, 9 F.R.D. 269, 270 (E.D. Mo. 1949). Plaintiffs' supplemental complaint does not present a cause of action "separate and distinct" from the controversy. *In re*

*Bankamerica Corp. Sec. Litig.*, 2010 WL 4622530, at \*1. Rather, the supplement “justif[ies] further relief with respect to the same subject matter as the controversy referred to in the complaint.” *Gen. Bronze Corp.*, 9 F.R.D. at 270–71 (E.D. Mo. 1949). The underlying Amended Complaint alleges violations of the APA by the Defendants related to the FDA’s decisions regarding Mifeprex and generic mifepristone. ECF No. 217. In the Amended Complaint, Plaintiffs’ assert two causes of action against the FDA’s 2019 ANDA Approval. *Id.* at ¶¶ 763–767, 783–88. Building on this foundation, Plaintiffs’ supplemental complaint contains two causes of action challenging the FDA’s 2025 ANDA Approval on the *same legal grounds* that it challenges the FDA’s 2019 ANDA Approval. *See id.* The causes of action and prayer for relief in Plaintiffs’ supplemental complaint mirrors claims already alleged in the Amended Complaint and therefore does not present distinct new causes of action.

Supplementation is further appropriate because it “promote[s] the economic and speedy disposition of the entire controversy between the parties.” *Harris*, 2021 WL 5823885 at \*6. Generic drugs are inextricably linked to their reference drug. *See* Am. Compl. ¶ 88, ECF No. 217. And under the 2019 Mifepristone REMS Program, generic and brand drugs are subject to the same labeling requirements. *Id.* at ¶¶ 20, 165. Thus, Evita’s generic drug is subject to the same labeling and REMS requirements as Danco’s Mifeprex and BioGenPro’s generic mifepristone. *See* 2025 FDA ANDA Approval Letter. These labeling requirements and REMS scheme are at the core of the controversy. *See* Am. Compl. ¶¶ 757–88, ECF No. 217. Moreover, the parties are already litigating the FDA’s 2019 ANDA Approval which is nearly

identical to its 2025 FDA ANDA Approval. *Compare* Ex. 30, Am. Compl., ECF 217, and 2025 ANDA Approval Letter. Without supplementation, Plaintiffs will be required to seek complete relief by bringing these claims in a separate case and manage a separate trial, ultimately duplicating efforts. Thus, Plaintiffs should be allowed to supplement their complaint to “achieve an orderly and fair administration of justice,” *In re Bankamerica Corp. Sec. Litig.*, 2010 WL 4622530, at \*1 (quoting *Griffin*, 377 U.S. at 226 (1964)).

Further, the balance of the remaining factors weighs in favor of granting the Plaintiffs’ motion. First, supplementation is not futile. Typically, courts review whether an amendment is futile based on whether it is meritorious and “would withstand a motion to dismiss under Rule 12(b)(6).” *Prowell v. OM Fin. Life Ins. Co.*, No. 4:09-CV-529 CAS, 2009 WL 1833463 (E.D. Mo. June 23, 2009). As discussed above, the courts apply similar standards to supplemental pleadings. The claims alleged in the supplemental complaint are part of a justiciable controversy between the parties. The claims rest on the same legal basis as claims already properly plead in the Amended Complaint. *See* Am. Compl. ¶¶ 763–767, 783–88, ECF No. 217. Plaintiffs are not “attempt[ing] to gain an advisory opinion.” *Furminator, Inc. v. Ontel Prods. Corp.*, 246 F.R.D. 579, 596 (E.D. Mo. 2007).

Second, Plaintiffs do not seek to supplement their Amended Complaint out of “bad faith” or “dilatory motive,” nor have they filed this motion with “undue delay.” *Weeks*, 2020 WL 33089 at \*3. Instead, Plaintiffs have filed this supplement in direct response to the FDA’s decision to double down on its failure to protect women from

an unsafe abortion drug. As explained above, the FDA has only approved two generic forms of mifepristone. Plaintiffs challenged the approval of the first generic variant in their Amended Complaint. The supplement addresses the second. Moreover, Plaintiffs have acted with due diligence. This motion comes less than a month after this case was transferred and before any substantive steps were taken on the Amended Complaint. *See Daughters of Charity Nat'l v. Am. Int'l Grp., Inc.*, No. 4:04-CV-754 CAS, 2005 WL 8176860, at \*1 (E.D. Mo. May 31, 2005) (finding no undue delay, bad faith, dilatory motive, or prejudice where plaintiffs brought a claim prior to the discovery completion deadline and in advance of trial

Third, Defendants are not prejudiced by the timing of this motion. *See Equal Emp. Opportunity Comm'n v. Convergys Customer Mgmt. Grp., Inc.*, No. 4:04-CV-846 CAS, 2005 WL 8176815, at \*1 (E.D. Mo. Oct. 5, 2005) (“Delay in seeking to amend, alone, is a [sic] insufficient justification to deny leave. Prejudice to the nonmovant must also be shown.”). Plaintiffs are pursuing a nearly identical claim in this litigation against the FDA’s 2019 ANDA Approval. Defendants could have foreseen that Plaintiffs would seek to bring a claim for their nearly identical 2025 ANDA Approval. *Cf. Equal Emp. Opportunity Comm'n v. Convergys Customer Mgmt. Grp., Inc.*, No. 4:04-CV-846 CAS, 2005 WL 8176815 at \*2 (E.D. Mo. Oct. 5, 2005) (finding no bad faith, dilatory motive, undue delay or prejudice even where the court determined the plaintiff should have filed an amendment sooner, but the amendment “was not a surprise that would prejudice” the defendants).

Finally, supplementation does not prejudice any of the Defendants because Plaintiffs' supplemental complaint "does not posit a new theory of recovery." *Weeks*, 2020 WL 33089 at \*3. Instead, the causes of action against the FDA and prayer for relief mirror those already included in the Amended Complaint. Granting this motion would not require the FDA to brief new legal claims or factual defenses. Additionally, the supplemental complaint adds no new claims against GenBioPro or Danco and will not inhibit their ability to fully litigate their positions or even necessitate additional briefing on their part. Defendants will not be able to meet their burden of demonstrating prejudice.

Supplementation of the Plaintiffs' Amended Complaint will advance judicial economy for the benefit of the parties and the Court. Specifically, it will streamline the adjudication of the controversy and ensure order in litigating this controversy. Thus, this Court should utilize its broad discretion to grant Plaintiffs' motion to supplement their Amended Complaint.

## CONCLUSION

For the reasons set forth above, Plaintiffs respectfully ask this Court for leave to file the attached supplemental complaint under Rule 15(d).

Date: November 19, 2025

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on November 19, 2025, a true and accurate copy of the foregoing was electronically filed by using the Court's CM/ECF system to be served on all counsel of record entered in the case.

*/s/ Louis J. Capozzi, III*