UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
WICHITA FALLS DIVISION

THE STATE OF FLORIDA, *et al.*, *Plaintiffs*, *v.* U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*.	Civil Action No. 7:25-cv-00126-O

BRIEF IN SUPPORT OF GENBIOPRO, INC.'S MOTION TO INTERVENE

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GenBioPro, Inc. respectfully submits this Memorandum of Law in Support of its Motion for Leave to Intervene pursuant to Rule 24 of the Federal Rules of Civil Procedure.

INTRODUCTION

This is one of three lawsuits filed by states seeking to vacate—on a nationwide basis—regulatory actions by the Food and Drug Administration ("FDA") related to mifepristone. In the other two cases, GenBioPro has already been granted intervention to protect the availability of the generic mifepristone it manufactures—a product that is foundational to its business and critical to healthcare for many Americans. GenBioPro has held an FDA-approved Abbreviated New Drug Application ("ANDA") to market generic mifepristone since 2019, and is one of only two U.S. manufacturers holding that generic approval. Sales of mifepristone represent the majority of the company's revenue.

In this Complaint, like in the other two cases, Plaintiffs Texas and Florida seek an order vacating various FDA actions that control the conditions under which mifepristone can be marketed, sold, prescribed, and distributed to patients, threatening serious harm to GenBioPro and the many Americans it serves. Plaintiffs specifically ask the Court to rescind FDA's 2019 approval of GenBioPro's generic mifepristone as safe and effective for its intended use. GenBioPro's stake in these issues is thus self-evident, as these other two courts—including one in this district—have recognized by granting intervention. *See All. for Hippocratic Med. v. FDA*, 2023 WL 11840559 (N.D. Tex. Feb. 6, 2023); *Missouri v. FDA*, 2025 WL 1223581, at *1 (N.D. Tex. Apr. 28, 2025); *Louisiana v. FDA*, No. 6:25-cv-01491-DCJ-DJA, at 1 (W.D. La. Feb. 24, 2026), ECF No. 229.

Here, GenBioPro meets all of the requirements for intervention as of right under Rule 24(a) in this lawsuit that seeks to void the ANDA that GenBioPro holds. This motion is timely; GenBioPro has a paradigmatic and clear interest in defending the approval of and regulatory regime governing its primary product; GenBioPro's interests would be impaired by Plaintiffs'

requested relief; and the existing parties will suffer no prejudice from intervention. Defendants also do not adequately protect GenBioPro's interests, as their request for a stay (or alternatively for dismissal) in this case amply illustrates. Specifically, in response to Plaintiffs' Complaint, Defendants have moved to stay the litigation based on a recently announced administrative review of what they call the "safety risks of mifepristone." ECF No. 20-1 at 3. In the related litigation, in response to Louisiana's motion to enjoin certain of FDA's actions challenged here, Defendants have declined to defend the merits of these actions at all.

At a minimum, permissive intervention under Rule 24(b) is appropriate. As Judge Kacsmaryk correctly found in one of the two predecessor cases, "GenBioPro's claim [had] a question of law or fact in common with the main action," as "GenBioPro seeks to protect its product's FDA approval" whereas "Plaintiffs challenge GenBioPro's product's FDA approval." *Missouri*, 2025 WL 1223581, at *6. Moreover, "intervention [would] not 'unduly delay or prejudice' [the State Plaintiffs'] rights" because it would "change nothing in the existing case schedule." *Id.* Each of those propositions is equally true in this case, and the Court should grant GenBioPro's motion.[1]

BACKGROUND

Approved by FDA as safe and effective for performing medical abortions up to ten weeks of gestation, mifepristone has been marketed and prescribed under the brand name Mifeprex for more than a quarter of a century, since 2000. Mifepristone's approval is subject to a set of distribution and administration conditions known as a "Risk Evaluation and Mitigation Strategy" or "REMS," which FDA has periodically revised and updated, including most recently in 2023.

[1] GenBioPro has conferred with the existing parties regarding their positions on this motion. Plaintiffs take no position on intervention, but reserve the right to oppose once they have reviewed the motion and accompanying Rule 24(c) pleading. Defendants take no position on intervention.

Compl. ¶ 188. When FDA approved GenBioPro's generic mifepristone ANDA in 2019, FDA subjected generic mifepristone to a single, shared REMS with Mifeprex. *See* 2019 FDA ANDA Approval Letter to GenBioPro (Apr. 11, 2019), ECF No. 1-6 at 694-700.

In November 2022, several individuals and organizations sued FDA and the U.S. Department of Health and Human Services in the Northern District of Texas challenging regulatory actions relating to mifepristone, dating back to the 2000 approval of Mifeprex. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 372-77 (2024). Mifeprex's manufacturer Danco intervened in the case without opposition. *See All. for Hippocratic Med.*, 2023 WL 11840559, at *1. Those plaintiffs sought a preliminary injunction or a stay of the effective dates of the challenged FDA actions. The district court entered the requested relief, which the Fifth Circuit largely affirmed, but the Supreme Court barred that order from taking effect. *Danco Lab'ys, LLC v. All. for Hippocratic Med.*, 143 S. Ct. 1075 (2023) (staying case pending resolution of petition for certiorari, and if granted, until judgment of the Court). Ultimately, the Supreme Court unanimously held that the plaintiffs lacked Article III standing. *All. for Hippocratic Med.*, 602 U.S. at 374.

While the appeal in that case was pending, the States of Missouri, Kansas, and Idaho intervened in the district court in an effort to bolster standing. On remand following the Supreme Court's ruling, the State plaintiffs amended their complaint; GenBioPro then moved to intervene to defend the challenged FDA actions, which Judge Kacsmaryk permitted under Rule 24(b). *Missouri*, 2025 WL 1223581, at *6.[2] In "a belated attempt to establish venue," Texas and Florida also sought intervention, which the Texas court denied. *Missouri v. FDA*, 2025 WL 2825980, at

[2] Although the *Missouri* court denied mandatory intervention under Rule 24(a)(2), the court ultimately granted GenBioPro permissive intervention under Rule 24(b), *see Missouri*, 2025 WL 1223581, at *4-6; Section II, *infra*.

*11-12 (N.D. Tex. Sept. 30, 2025). The court held that venue was improper and transferred the case to the Eastern District of Missouri. *Id.* at *12-13. Louisiana has also filed a similar challenge to FDA's current REMS framework; on February 24, 2026, the court there granted GenBioPro and Danco leave to intervene. *Louisiana v. FDA*, No. 6:25-cv-01491-DCJ-DJA, at 1 (W.D. La. Feb. 24, 2026), ECF No. 229.

On December 9, 2025, Texas and Florida filed this lawsuit against FDA challenging many of the same regulatory actions at issue in *Missouri*. Among other things, Plaintiffs allege that FDA acted arbitrarily and capriciously by approving Mifeprex in 2000, adopting labeling and regimen changes in 2016, approving GenBioPro's ANDA in 2019, and modifying mifepristone's dispensing and use conditions through the 2023 REMS. Plaintiffs seek declaratory and injunctive relief, asking the Court to permanently set aside, rescind, and vacate the challenged approvals and regulatory actions.

ARGUMENT

I. GenBioPro Is Entitled to Intervene As of Right Under Federal Rule 24(a)(2)

A party must be permitted to intervene in an action if it shows by "timely motion" that (a) "it has a protectable 'interest' in the action," (b) "the 'disposing of the action' could 'impair' its ability to protect that interest," and (c) "existing parties do not 'adequately represent' that interest." *Louisiana v. Burgum*, 132 F.4th 918, 922 (5th Cir. 2025) (quoting Fed. R. Civ. P. 24(a)(2)). Courts "should liberally construe the test for mandatory intervention" and should "allow intervention where no one would be hurt and the greater justice could be attained." *Rotstain v. Mendez*, 986 F.3d 931, 937 (5th Cir. 2021) (cleaned up); *see Entergy Gulf States La., L.L.C. v. EPA*, 817 F.3d 198, 203 (5th Cir. 2016) ("doubts resolved in favor of the proposed intervenor"); *Wal-Mart Stores, Inc. v. Tex. Alcoholic Beverage Comm'n*, 834 F.3d 562, 569 (5th Cir. 2016) (emphasizing "broad policy favoring intervention"). GenBioPro easily meets that standard here.

There is no question that GenBioPro's motion is timely. Plaintiffs filed this suit in December 2025, and the Court thereafter granted Defendants' unopposed motion to extend their response deadline to Plaintiffs' Complaint until March 13, 2026. ECF No. 19. Defendants have not answered the Complaint, the administrative record has not been produced, and no substantive activity has occurred in this case other than the near-contemporaneous filing of Defendants' motion to stay and motion to dismiss.

GenBioPro's filing easily qualifies as timely under the Fifth Circuit's standards. *See Sierra Club v. Espy*, 18 F.3d 1202, 1205-06 (5th Cir. 1994) (intervention was timely even though motion to intervene was filed eight years after suit commenced and two months after preliminary injunction was issued); *see also Edwards v. City of Houston*, 78 F.3d 983, 1001 (5th Cir. 1996) ("[M]ost of our case law rejecting petitions for intervention as untimely concern motions filed after judgment was entered in the litigation."); *Missouri*, 2025 WL 1223581, at *5 (finding GenBioPro's motion to intervene timely because it was filed less than two months after amended complaint implicating GenBioPro's distinct interests).

Having filed a timely motion, GenBioPro meets each of the Rule 24(a)(2) requirements laid out in *Burgum*, as described below.

A. GenBioPro Has a Protectable Interest in This Action

GenBioPro clearly has "direct, substantial, and legally protectable" interests in this action. *John Doe No. 1 v. Glickman*, 256 F.3d 371, 379 (5th Cir. 2001) (cleaned up). Courts routinely recognize that litigation against FDA affecting a drug approval implicates the interests of the holder or potential holder of the approval for Rule 24 purposes. *See, e.g.*, *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1075-76 (D.C. Cir. 1998) (reversing denial of a motion to intervene as of right of New Drug Application ("NDA") holder in litigation concerning FDA's approval of an ANDA); *Eagle Pharms., Inc. v. Price*, 322 F.R.D. 48, 49-50 (D.D.C. 2017) (manufacturer with a

pending ANDA permitted to intervene as of right because plaintiff's requested relief would prevent intervenor "from marketing its generic product"); *Apotex Inc. v. FDA*, 508 F. Supp. 2d 78, 80 n.2 (D.D.C. 2007) (manufacturer permitted to intervene as of right because plaintiff sought to "set aside the FDA's decision as to its approval status" for its generic version of the intervenor's drug).

GenBioPro has a direct interest as "the intended beneficiar[y] of the challenged federal policy," namely FDA's 2019 ANDA approval, *Texas v. United States*, 805 F.3d 653, 660 (5th Cir. 2015), and a "legally protectable interest in the regulatory scheme," *Wal-Mart*, 834 F.3d at 566. The States' Complaint seeks to vacate the 2019 ANDA approval and other agency actions governing the marketing, sale, and distribution of GenBioPro's primary product. Decl. of Evan Masingill ("Masingill Decl.") ¶¶ 4-6. Accordingly, whether GenBioPro "will or will not be" able to market generic mifepristone under the current FDA conditions of use "depend[s] on the outcome of this case." *Texas*, 805 F.3d at 660. GenBioPro thus has a direct stake in the outcome of the litigation that is "sufficiently concrete and specific to support" intervention. *Id.* at 660-61.

It is also "obvious that the economic interests of [GenBioPro] are at stake" in this lawsuit. *See Espy*, 18 F.3d at 1207. "[E]conomic interests can justify intervention when they are directly related to the litigation." *Wal-Mart*, 834 F.3d at 568. GenBioPro is one of just two entities granted ANDA approvals for generic mifepristone in the United States, Compl. ¶ 198, and sales of mifepristone are the company's majority source of revenue, Masingill Decl. ¶ 5. The States' requested relief thus "threatens a 'prospective interference'" with GenBioPro's ability to market its product in the United States, presenting a direct, concrete, and particularized threat to GenBioPro's economic interests that justifies intervention. *Brumfield v. Dodd*, 749 F.3d 339, 343 (5th Cir. 2014); *see Wal-Mart*, 843 F.3d at 567-68 (collecting cases "permitting intervention based on economic interests").

B. Disposition of This Action May Impair GenBioPro's Ability to Protect Its Interests

GenBioPro also easily clears the second Rule 24(a)(2) criterion: There is far more than a mere "possibility that [GenBioPro's] interest could be impaired or impeded" as a result of this litigation. *La Union del Pueblo Entero v. Abbott*, 29 F.4th 299, 307 (5th Cir. 2022). Plaintiffs seek an order that "[d]eclares unlawful and preliminarily and permanently sets aside, rescinds, and vacates" a host of regulatory actions that allow GenBioPro to market and distribute mifepristone—including the original "2000 NDA of Mifeprex" and "the 2019 ANDA and consolidated REMS program." Compl., Prayer for Relief, § A. Granting their requested relief would prevent GenBioPro from marketing generic mifepristone. Masingill Decl. ¶ 6.

C. GenBioPro's Interests Are Not Adequately Represented by Defendants

The existing Defendants do not adequately represent GenBioPro's interests. "The inadequate-representation factor typically 'is satisfied if the [movant] shows that the representation of his interest may be inadequate.'" *Missouri*, 2025 WL 1223581, at *2 (quoting *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10 (1972)). That burden is "minimal" unless "one of two presumptions of adequate representation appl[ies]." *Burgum*, 132 F.4th at 922 (quotation marks omitted); *accord Missouri*, 2025 WL 1223581, at *2. The first presumption "arises when the intervenor has the same ultimate objective as a party to the lawsuit." *Burgum*, 132 F.4th at 922 (quotation marks omitted). "The second presumption arises when the existing party is a governmental body or officer charged by law with representing the interests of the movant." *Id.* (quotation marks omitted).

Neither presumption applies here. The first is inapplicable because the existing Defendants do not have "the same ultimate objective" as GenBioPro. *See Burgum*, 132 F.4th at 922. GenBioPro's ultimate objective is to defend the challenged FDA actions—including on the merits,

as necessary—to ensure that both GenBioPro's ANDA and the existing REMS remain in effect. Defendants are instead undertaking what they call a "study" of the safety of the current REMS, in order to "determine whether modifications are necessary." ECF No. 20-1 at 7-8 (quoting Letter from Secretary Robert F. Kennedy, Jr. to State Attorneys Generals describing FDA's mifepristone study). Whereas GenBioPro intends to robustly defend FDA's actions on the merits, Defendants in related litigation have declined to do so, instead seeking primarily to *stay* the litigation out of deference to its ongoing review. Defs.' Mem. Supp. Mot. to Stay at 3, Louisiana v. FDA, No. 6:25-cv-1491-DCJ-DJA (Jan. 27, 2026), ECF No. 50-1. Defendants have even invoked "concerns" raised by the Fifth Circuit regarding mifepristone's safety record—the same concerns identified in Plaintiffs' Complaint. *See* ECF No. 20-1 at 1; Compl. ¶ 141. GenBioPro's goal of defending FDA's regulation of mifepristone on the merits—while Defendants fail to do so—is dispositive on this element.

Even if the "ultimate objective" presumption of adequate representation somehow applied (it does not), Defendants' failure to affirmatively defend their prior actions concerning mifepristone on the merits, coupled with their repetition of statements cited in the Complaint, would be sufficient to overcome it. *See Burgum*, 132 F.4th at 922 (first presumption can be overcome "by showing adversity of interest, collusion, or nonfeasance on the part of the existing party") (quotation marks omitted). Defendants' litigation positions and public statements discussed above are textbook examples of "specific conduct showing that the party at issue inadequately represent[s] [the proposed intervenor's] interests, notwithstanding that it share[s] an ultimate objective." *Id.* at 923; *see La Union del Pueblo Entero*, 29 F.4th at 308-09 (finding inadequate representation prong satisfied because, even assuming presumptions applied, state

officials "prefer[red] to not resolve th[e] case on the merits at all" and moved for dismissal only on standing and sovereign immunity grounds).

The second presumption of adequate representation—arising when "the existing party is a governmental body or officer charged by law with representing the interests of the movant," *Burgum*, 132 F.4th at 922 (quotation marks omitted)—does not apply here either. FDA of course is not charged by law with representing the interests of the drug companies it regulates. *See Missouri*, 2025 WL 1223581, at *3 ("The second presumption does not apply."). Indeed, Defendants' express statement that they are investigating a change in the REMS, shows that they are *not* bound to represent GenBioPro's interests in maintaining the status quo.

Since neither presumption applies, GenBioPro's burden of showing inadequate representation is "minimal," and GenBioPro need only show that FDA's representation "may" be inadequate. *Missouri*, 2025 WL 1223581, at *2. GenBioPro easily clears that low threshold. As discussed above, given FDA's and GenBioPro's divergent responses to the Complaint, there can be no question that FDA's representation *is* inadequate to protect GenBioPro's interests.

II. The Court Should Permit GenBioPro to Intervene Under Rule 24(b)

The Court should, at a minimum, permit GenBioPro to intervene under Rule 24(b), as Judge Kacsmaryk did in the other case in this district. "Permissive intervention may be granted if the movant 'has a claim or defense that shares with the main action a common question of law or fact.'" *Missouri*, 2025 WL 1223581, at *4 (quoting Fed. R. Civ. P. 24(b)(1)(B)). The motion must be timely, and intervention must not "unduly delay or prejudice the adjudication of the original parties' rights." *Id.*; *see also Newby v. Enron Corp.*, 443 F.3d 416, 424 (5th Cir. 2006).

Here, as in the recent *Missouri* decision by Judge Kacsmaryk granting permissive intervention, GenBioPro's defenses—including that FDA's approval of the ANDA for generic mifepristone was reasonable, that the agency's modification of the REMS was both reasonable

and reasonably explained, and that all of the challenged agency actions are lawful and should be upheld—clearly share common questions of law and fact with the main action. *See Missouri*, 2025 WL 1223581, at *4-6. Plaintiffs' claims against FDA center on those very same questions. *See id.* at *6 (finding common questions for Rule 24(b) purposes where "GenBioPro seeks to protect its product's FDA approval" whereas "Plaintiffs challenge GenBioPro's product's FDA approval").

GenBioPro thus satisfies all requirements for permissive intervention. As discussed above, this motion is plainly timely, *supra* p. 5, and there is no conceivable way in which GenBioPro's participation could delay or prejudice adjudication of FDA's or Plaintiffs' rights. As in *Missouri*, GenBioPro's intervention "will change nothing in the case schedule." *Missouri*, 2025 WL 1223581, at *6 (quotation marks omitted). "No deadlines will need to be moved, no additional discovery will be necessary, and no delay will occur, and, therefore, the parties will not be prejudiced." *Id.* (quotation marks omitted). The Court should permit GenBioPro to intervene.

III. GenBioPro's Motion to Dismiss Satisfies Rule 24(c)

Rule 24(c) requires that an intervention motion be "accompanied by a pleading that sets out the claim or defense for which intervention is sought." Fed. R. Civ. P. 24(c). The Fifth Circuit "takes a 'lenient approach'" to Rule 24(c), *Missouri*, 2025 WL 1223581, at *2 n.1 (quoting *Liberty Surplus Ins. Co. v. Slick Willies of Am., Inc.*, 2007 WL 2330294, at *1 (S.D. Tex. Aug. 15, 2007)); *see Farina v. Mission Inv. Tr.*, 615 F.2d 1068, 1074 (5th Cir. 1980) (rejecting "excessively technical" interpretation of Rule 24(c) as contrary to Rule 8's policy of flexibility in pleadings).

GenBioPro has attached to this motion a motion to dismiss, which, together with this motion, apprise the Court and all parties of the defenses GenBioPro intends to raise if the motion is granted, serving Rule 24(c)'s purpose to "put the parties on notice of [GenBioPro's] grounds for intervention." *Liberty Surplus*, 2007 WL 2330294, at *2; *see United States ex rel. Hernandez v.*

Team Fin., LLC, 80 F.4th 571, 575 n.1 (5th Cir. 2023) ("proposed motion to unseal, and supporting declaration" submitted with motion to intervene satisfied attachment requirement).

CONCLUSION

For the foregoing reasons, the Court should grant GenBioPro's Motion for Leave to Intervene and accept GenBioPro's Motion to Dismiss for filing on the docket in this action.

Dated: March 13, 2026

Respectfully submitted,

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* Pro hac vice application forthcoming

**Application for admission to the bar of the District Court for the Northern District of Texas pending