IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, *et al.*, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Federal Defendants*, and DANCO LABORATORIES, *et al.*, *Intervenor Defendants.*	No. 6:25-cv-01491-DCJ-DJA

FEDERAL DEFENDANTS' SUPPLEMENTAL BRIEF

On February 24, 2026, the Court directed Federal Defendants "to file a brief within (7) days addressing the FDA's authority to issue interim orders addressing the prescribing or distribution of a drug if confronted with concerning information during its review." ECF No. 229 (Minute Order). The Minute Order followed a hearing in which the Court asked: If "during [FDA's] review process," the agency "sees a public health issue with the 2023 REMS—particularly the . . . in-person dispensing requirement—is there a way for the FDA to take immediate action to change it, to restore it, or to alter the 2023 REMS to meet the public health concern?" Tr. 53:25–54:4; *see also* Tr. 54:21–55:6 (requesting briefing). This brief responds to the Court's inquiry.

Approval Suspension. The provision of the Federal Food, Drug, and Cosmetic Act that specifies the circumstances in which a drug application can be withdrawn, 21 U.S.C. § 355(e), includes authority to suspend an application prior to its withdrawal. In particular, if the Secretary of Health and Human Services[1] finds that a drug presents "an imminent hazard to the public health," he may suspend the approval of the application (including a supplemental application) "immediately." 21 U.S.C. § 355(e). The Secretary then must "give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing" on whether to withdraw approval. *Id.* Approval may be withdrawn if, among other things, "new evidence of clinical experience . . . evaluated together with the evidence available to [FDA] when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved." *Id.* § 355(e)(2).

Apart from the Secretary's suspension authority, there are no "*interim* orders" FDA could issue. However, FDA possesses authority to require a sponsor to propose changes to a drug's conditions of use, including by adding or modifying a REMS requirement related to prescribing or dispensing. The timing of implementation is

[1] Although the Commissioner of Food and Drugs generally "execut[es]" the Secretary's authorities under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 393(d)(2), "the authority . . . to *suspend* approval of an application"—as distinct from withdrawal of approval—"shall not be delegated" and remains with the Secretary, *id* § 355(e) (emphasis added).

influenced by factors outside FDA's control, most notably the degree of cooperation of the drug's sponsor.

Labeling changes. If FDA learns of "new safety information" that it believes "should be included in the labeling of the drug," it may notify the sponsor of that determination and require a response within 30 days. 21 U.S.C. § 355(o)(4)(A), (B).[2] If the sponsor submits a supplemental application seeking the requested change, FDA "shall promptly review and act upon" it. *Id.* § 355(o)(4)(C).

However, if the sponsor responds that it does not believe a labeling change is warranted (or proposes a change that FDA disagrees with), FDA "shall initiate discussions" with the sponsor, *id.*, which "shall not extend for more than 30 days after [the sponsor's] response" to the agency's notice, *id.* § 355(o)(4)(C), (D). Within 15 days after discussions conclude, FDA "may issue an order directing" the sponsor "to make such a labeling change as [FDA] deems appropriate to address" the new safety information. *Id.* § 355(o)(4)(E). The sponsor then has five days to appeal through an administrative process. *Id.* § 355(o)(4)(F). Otherwise, the sponsor must submit a supplement containing the ordered labeling change within 15 days. *Id.* § 355(o)(4)(E).

REMS modification. If FDA determines that a REMS must be modified to, among other things "ensure the benefits of the drug outweigh the risks of the drug," the agency can direct the sponsor to propose appropriate modifications "within 120 days or

[2] The FDCA prohibits a "responsible person" (i.e., the drug's sponsor) from introducing the drug into interstate commerce if the drug is in violation of a requirement established under this process. *Id.* §§ 331(d), 355(o)(1), (2)(A).

within such reasonable time" as the agency determines. *Id.* § 355-1(g)(4)(B). While the statute permits FDA 180 days to act on the proposed changes, *id.* § 355-1(h)(2)(A)(i), the agency could act sooner if circumstances warrant.

However, if the drug's sponsor disagrees with the directive to propose a modification, it may request, in writing, that the dispute be reviewed by FDA's Drug Safety Oversight Board. *Id.* § 355-1(h)(4)(A)(i); *see also id*. § 355-1(j). The Board must hear from the parties in writing or orally, review the dispute, and—within five days of the Board's meeting—make a recommendation. *Id.* § 355-1(h)(4)(D), (F). FDA then has seven days on which to act on that recommendation. *Id.* § 355-1(h)(4)(G).[3]

[3] The Court was correct that there have been "many times" when a safety signal about a drug "comes to the attention of the FDA," and the agency is able to "do something quickly." Tr. 54-55. In such circumstances, to protect the public from drugs the agency believes pose safety concerns, instead of (or in addition to) employing the formal statutory processes outlined above, FDA often relies on less formal measures, such as issuing a Drug Safety Communication or Drug Alert, and/or requesting that a sponsor voluntarily withdraw a product from the market or submit a supplemental application to add a warning to the labeling of its product. *See*, *e.g.*, FDA Requests Removal of All Ranitidine Products (Zantac) from the Market (Apr. 1, 2020) (announcing that FDA "is sending letters to all manufacturers of ranitidine requesting that they withdraw their products from the market"), https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market; FDA to recommend additional, earlier MRI monitoring for patients with Alzheimer's disease taking Leqembi (lecanemab) (Aug. 28, 2025) (announcing that FDA was requiring a change to the prescribing information for Leqembi (lecanemab) and "bring[ing] public attention" to an issue "[i]n the meantime"), https://www.fda.gov/drugs/drug-safety-and-availability/fda-recommend-additional-earlier-mri-monitoring-patients-alzheimers-disease-taking-leqembi-lecanemab.

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Respectfully submitted,

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