UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

CENTER FOR SCIENCE IN THE PUBLIC INTEREST, Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION and ROBERT M. CALIFF, in his official capacity as Commissioner of Food and Drugs, Defendants.	No. 1:24-CV-01342 **Joint Motion for Stay of Proceedings**

Pursuant to Federal Rule of Civil Procedure 7(b), Plaintiff Center for Science in the Public Interest and Defendants[1] (the Parties) respectfully move for an Order: (1) staying all proceedings in this matter until Friday, February 28, 2025, or until Defendants issue a final decision on the Citizen Petition that is the subject of Plaintiff's Complaint, whichever is earlier; (2) deferring all applicable deadlines in this action pending further order of the Court; and (3) requiring the Parties within 14 days of February 28, 2025 or the date that Defendants issue a final decision on the Citizen Petition, whichever is sooner, to submit a Joint Status Report, proposing next steps in the litigation. For the reasons discussed below, this stay will conserve the resources of the Court and the Parties. Defendants' response to the Complaint is currently due July 22, 2024.

This is an unreasonable delay case under the Administrative Procedure Act, 5 U.S.C. §§ 555(b), 706(1). Plaintiff alleges that FDA has unreasonably delayed

[1] Defendants are the United States Food and Drug Administration (FDA) and Robert M. Califf, in his official capacity as Commissioner of Food and Drugs.

responding to a Citizen Petition that Plaintiff submitted in February 2021.[2] The Petition requested that FDA, "among other things, establish a maximum limit of opiate alkaloid contamination of poppy seeds and set import requirements to ensure that imported seeds do not exceed the maximum threshold." Compl. (ECF No. 1) at 1, ¶3; *see* Citizen Petition, Docket No. FDA-2021-P-0168-0001.

Plaintiff contends that the use of opiate alkaloids, also known as opiates, while an essential pharmaceutical tool in pain management, can lead to a variety of health problems, including overdose resulting in serious injury or death, through consumption of contaminated poppy seeds unwittingly or intentionally for intoxication or claimed health benefits.

Among the relief sought in the Complaint, under 5 U.S.C. § 706(1), Plaintiff asks that the Court order FDA, within 60 days of the Court's order, to grant or deny Plaintiff's Petition and, in the case of a grant of the Petition, to issue at the same time a Notice of Proposed Rulemaking setting a maximum limit of opiate alkaloid contamination of poppy seeds. *See* Compl. at 21-22.

FDA is evaluating the Citizen Petition and, barring unforeseen circumstances, expects to issue its response to the Citizen Petition by February 28, 2025. The Parties request a stay of the proceedings because they believe that this may make it possible to resolve this case without further litigation. A stay of proceedings in this matter until FDA issues its decision will conserve the time and resources of the Court and the Parties by avoiding the need for further litigation that may prove unnecessary.

For these reasons, the Parties respectfully request that the Court grant this Joint Motion for: (1) a stay of all proceedings in this matter; (2) a deferral of all applicable

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[2] Interested persons may submit a Citizen Petition to FDA, requesting that it "issue, amend, or revoke a regulation or order" or "take or refrain from taking any other form of administrative action." 21 C.F.R. §§ 10.25(a)(2), 10.30.

deadlines in this action pending further order of the Court; and (3) the requirement of a Joint Status Report, as provided in the attached [Proposed] Order.

July 15, 2024

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