U.S. FOOD & DRUG ADMINISTRATION
Human Foods Program

January 14, 2025

Peter Lurie, MD, MPH
Laura MacCleery, JD
Sarah Sorscher, JD, MPH
James Kincheloe, DVM, MPH
Eva Greenthal, MS, MPH
Center for Science in the Public Interest
1250 I Street NW, Suite 500
Washington, DC 20005-5979

Re: Docket Number FDA-2021-P-0168

Dear Dr. Lurie, et al.:

This letter responds to your citizen petition requesting that the Food and Drug Administration (FDA or we) coordinate with the Drug Enforcement Administration (DEA) and Customs and Border Protection (CBP) to:

1. "Issue regulations and guidance establishing a maximum permissible threshold of opiate alkaloid contamination of poppy seeds sold in the United States and describing current good manufacturing practices to reduce the presence of opiate alkaloids in poppy seeds; and
2. Issue import requirements and conduct testing of imports to ensure the safety of imported seeds, including an import alert specifying steps to ensure that imported seeds do not exceed the maximum threshold of opiate alkaloid contamination."

See Citizen Petition from Peter Lurie, MD, MPH, President and Executive Director, Laura MacCleery, JD, Policy Director, Sarah Sorscher, JD, MPH, Deputy Director, Regulatory Affairs, James Kincheloe, DVM, MPH, Food Safety Campaign Manager, and Eva Greenthal, MS, MPH, Senior Science Policy Associate, Center for Science in the Public Interest, sent to the Division of Dockets Management, Food and Drug Administration, dated February 5, 2021, ("petition") at page 1.

We have reviewed your petition and the comments and information submitted to the docket. In accordance with 21 CFR 10.30(e)(2), and for the reasons stated below, we are denying your petition.

A. Discussion

Requested Actions

1. Request to Issue Regulations and Guidance Establishing Maximum Opiate Alkaloid Contamination Levels and Describing Current Good Manufacturing Practices

Your petition requests that FDA "[i]ssue regulations and guidance establishing a maximum permissible threshold of opiate alkaloid contamination of poppy seeds sold in the United States and describing current good manufacturing practices to reduce the presence of opiate alkaloids in poppy seeds" (petition at 1). We are denying this request.

Based on our review of the available information, including the information provided in your petition, there is insufficient evidence to issue regulations or guidance "describing current good manufacturing practices to reduce the presence of opiate alkaloids in poppy seeds." Currently, there is limited publicly available information about agricultural, industry, manufacturing, and supply chain practices that reduce the presence of opiate alkaloids on poppy seeds. This information is needed to recommend best practices for poppy seed growers, manufacturers, distributors, and sellers of poppy seeds. FDA is issuing a request for information (RFI), which will publish in the *Federal Register* of January 15, 2025, to better understand the agricultural, industry, manufacturing, and supply chain practices currently being used, and whether certain practices increase or reduce the presence of opiate alkaloids on poppy seeds. Based on the comments submitted to the RFI docket, FDA intends to consider which actions, if any, it might pursue to help reduce the presence of opiate alkaloids on poppy seeds and in poppy seed products, as appropriate.

Although we have taken several important steps to expand our understanding of opiate alkaloids in poppy seeds and consumer behaviors related to poppy seed consumption (which we discuss in greater detail below), we are still in the process of gathering additional information regarding poppy seeds. Gathering and assessing this information will take additional time. Furthermore, given the breadth of FDA's foods program, we must balance multiple public health and regulatory priorities. For example, we have been advancing work on our "Closer to Zero" project to reduce dietary exposure to contaminants to as low as possible while also maintaining access to nutritious foods, as well as our efforts to reduce sodium intake. We also have had to expend considerable resources recently on strengthening the resiliency of the supply of safe and nutritious infant formula. As noted in the December 2022 Reagan-Udall Report entitled "Operational Evaluation of the FDA Human Foods Program," the FDA's Human Foods Program is significantly under-resourced.[1]

[1] Reagan-Udall Foundation, "Operational Evaluation of the FDA Human Foods Program," December 2022, available at https://reaganudall.org/sites/default/files/2022-12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf.

Finally, we note that your petition does not include the wording of the proposed regulation, as required by 21 CFR 10.30(b)(3). Further, your petition does not propose a specific level for "a maximum permissible threshold of opiate alkaloid contamination of poppy seeds sold in the United States" (petition at 1) or "a maximum safe level for opiates in poppy seeds" (petition at 7).

2. Request to Issue Import Requirements and Conduct Testing to Ensure the Safety of Imported Poppy Seeds

Your petition requests that FDA "[i]ssue import requirements and conduct testing of imports to ensure the safety of imported seeds, including an import alert specifying steps to ensure that imported seeds do not exceed the maximum threshold of opiate alkaloid contamination" (petition at 1). Your petition requests that the import alert specify "the conditions under which poppy seeds that appear to be contaminated may be detained at the border for violation of FDA and DEA rules" and could specify the forms of documentation to avoid detention, for example product testing results (petition at 8). We are denying this request.

First, the import alert contemplated by your petition depends on our establishing a "maximum permissible threshold of opiate alkaloid contamination of poppy seeds." In other words, we cannot issue "an import alert specifying steps to ensure that imported seeds do not exceed the maximum threshold of opiate alkaloid contamination" unless we have first established a "maximum threshold of opiate alkaloid contamination." For the reasons noted above, we are denying your request to establish a "maximum permissible threshold of opiate alkaloid contamination of poppy seeds." Accordingly, we are also denying your request to issue such import alert.

Second, with respect to your request that FDA "conduct testing of imports to ensure the safety of imported seeds," you note that such testing would "inform enforcement activities" (petition at 8). To the extent that your request that FDA conduct such testing is a request that FDA take steps to initiate enforcement action and related regulatory activity, such request is outside the scope of our citizen petition regulations (see 21 CFR 10.30(k)). A citizen petition provides a mechanism for interested persons to request that FDA issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action (see 21 CFR 10.25(a)). However, the definition of "administrative action" does not include enforcement actions. As defined in 21 CFR 10.3(a), "administrative action" includes every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner, except that it does not include the referral of apparent violations to U.S. attorneys for the institution of civil or criminal proceedings or an act in preparation of a referral.

Finally, we note that it is unclear what you mean by "import requirements," which you state includes "an import alert." An import alert is not an import requirement. Rather, an import alert informs FDA field staff and the public that we have enough evidence to support Detention Without Physical Examination (DWPE) of products that appear to be in violation of FDA's laws and regulations. To the extent you are requesting that FDA issue a regulation, your petition does not include the wording of the proposed regulation, as required by 21 CFR 10.30(b)(3).

Although we are denying your request, we note that FDA will continue to consider and, as appropriate, take actions, such as conducting additional testing of poppy seeds and poppy seed products, establishing regulatory limits or guidance levels for poppy seed opiate alkaloid content, and issuing guidance on good manufacturing practices for poppy seeds.

FDA Actions

FDA is committed to helping to ensure that poppy seeds are not harmful when consumed. To that end, FDA's efforts to expand our understanding of opiate alkaloids in poppy seeds and consumer behaviors related to poppy seed consumption include:

- Establishing a Memorandum of Understanding with DEA to effect a more efficient system of communication and information exchange between FDA and DEA, establish collaborations involving food that may contain controlled substances, and clarify and coordinate each agency's responsibilities with respect to food that may be or contain controlled substances.[2]

- Meeting with various stakeholders to help us understand more about opiate alkaloids in poppy seed products and issues related to public health.

- Conducting targeted surveillance sampling and testing of poppy seeds to determine the opiate alkaloid content of 21 samples taken from poppy seeds purchased online. Results showed morphine levels between 1 milligram per kilogram (mg/kg) and 520 mg/kg (median 70 mg/kg; mean 120.4 mg/kg) and codeine levels between 0.8 mg/kg and 255 mg/kg (median 85 mg/kg; mean 113.1 mg/kg).

- Regularly monitoring and following up on adverse event reports that involve poppy seeds and poppy seed-containing products.

- Providing technical assistance on legislative bills pertaining to poppy seeds containing compounds that may render them injurious to health.

- Actively engaging in areas of research related to opiate alkaloids on poppy seeds. Notably, we developed a rapid, low-cost, and portable lateral flow immunoassay for the detection of opiate alkaloids on poppy seeds that was published in the scientific journal *ACS Food Science & Technology*.[3] This work may provide both the food industry and regulatory officials with a simple method for preliminary screening of poppy seed

---

[2] See Memorandum of Understanding Between U.S. Department of Health and Human Services, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition and U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division (June 2023) (MOU 225-23-009), available at https://www.fda.gov/about-fda/domestic-mous/mou-225-23-009.

[3] Moskowitz, J., B.J. Yakes, J.P. Roetting, II, et al. "Rapid, Low-Cost, and Portable Detection of Morphine and Codeine on Poppy Seeds vi a Lateral Flow Immunoassay." *ACS Food Science & Technology,* 4(8): 1829-1833, 2024. Available at https://doi.org/10.1021/acsfoodscitech.4c00364.

products. In addition, in research published in 2020 and 2022, we examined the effect of thermal and rinsing treatments on poppy seeds following our 2020 publication examining thermal and rinsing treatments in their effectiveness on opiate alkaloid reductions on poppy seeds and poppy seed-containing baked muffins.[4,5]

- Developing and publishing an RFI to receive information to better understand the agricultural, industry, manufacturing, and supply chain practices currently being used, and whether certain practices increase or reduce the presence of opiate alkaloids on poppy seeds.

- Performing a multi-laboratory validation according to the FDA's Guidelines for the Validation of Chemical Methods for the FDA Foods Program for a liquid chromatography-tandem mass spectrometry (LC-MS/MS) method developed for the quantification of morphine, codeine, and thebaine on poppy seeds.

B. Conclusion

For the reasons discussed above, we are denying your petition. As stated earlier, FDA is committed to helping to ensure that poppy seed products are not harmful when consumed. We appreciate your interest in food safety.

Sincerely,

Donald Prater, DVM
Principal Associate Commissioner for Human Foods
Human Foods Program

[4] Shetge, S.A., M.P. Dzakovich, J.L. Cooperstone, et al. "Concentrations of the opium alkaloids morphine, codeine, and thebaine in poppy seeds are reduced after thermal and washing treatments but are not affected when incorporated in a model baked product." *Journal of Agricultural and Food Chemistry*, 68(18):5241-5248, 2020. Available at https://doi.org/10.1021/acs.jafc.0c01681.

[5] Shetge, S.A. and B.W. Redan. "Assessment of Dry Heating, Water Rinsing, and Baking on Concentrations of the Opium Alkaloid Noscapine in Poppy Seeds." *ACS Food Science & Technology*, *2*(3), 541-547, 2022. Available at https://doi.org/10.1021/acsfoodscitech.1c00428.