ATTORNEYS GENERAL OF THE STATE OF ARIZONA AND THE DISTRICT OF COLUMBIA

Via Electronic Submission on Regulations.gov

June 23, 2025

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services, rm. 1-23
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Attn: Dr. Martin A. Makary, FDA Commissioner
Attn: Kyle Diamantas, FDA Deputy Commissioner for Human Foods
Attn: Dr. Donald A. Prater, FDA Principal Deputy Director for Human Foods

Cc: Robert F. Kennedy Jr., Secretary of the U.S. Dep't of Health & Human Services

Letter in Support of the Petition for Reconsideration Requesting FDA Actions on Toxic Heavy Metals in Food Intended for Babies and Young Children
Docket Number FDA-2021-P-1144

Dear Commissioner Makary, Deputy Commissioner Diamantas and Dr. Prater:

The undersigned Attorney Generals support the relief sought in the multistate Petition for Reconsideration[1] dated June 1, 2022 in the above-referenced proceeding ("Reconsideration Petition") for the reasons stated therein and also supplied in the subsequent letters from the petitioners dated August 18, 2022, February 14, 2024 and May 1, 2025. In particular, the undersigned Attorneys General strongly urge the FDA to issue guidance on finished product testing on lead and other toxic heavy metals without further delay. Such testing is a preventive control crucial to ensuring the safety of babies and young children from exposure to toxic elements in their food. Had the FDA issued guidance on finished product testing years ago as requested in the Reconsideration Petition, the recent nationwide recalls of popular baby food purees due to elevated levels of lead may have been avoided.

This letter is submitted pursuant to 21 CFR 10.30(d) which allows interested persons to submit comments on a filed and pending petition to become part of the docket file.

The State of Arizona and the District of Columbia have a concrete and vital interest in protecting babies and young children from exposure to dangerous levels of toxic heavy metals in

[1] *Petition for Reconsideration from Office of the Attorney General of the State of New York* Regulations (June 2, 2022), https://www.regulations.gov/document/FDA-2021-P-1144-0012.

commercially available baby foods. In Arizona alone, 78,355 babies were born in 2022.[2] As babies transition to solid foods, parents rely on baby and toddler foods available to them in local grocery stores. Arizona's interest in protecting young children from potential harm from elements found in food is further demonstrated by recent state legislative actions. Recently, Arizona Governor Katie Hobbs signed into law HB2164,[3] a bill designed to reduce ultra-processed foods in school lunches. The legislation affirms that childhood obesity, morbidity, and wellness are matters of statewide concern. Concern over potential harms resulting from heavy metal exposure by babies and infants from commercially-marketed foods reflects a similar interest in ensuring children have a safe and healthy diet.

The June 1, 2022 Reconsideration Petition was filed in response to FDA's denial of the Attorneys Generals' October 25, 2021 rulemaking petition.[4] This original petition, which, among other issues, called upon FDA to issue industry guidance on the testing of finished baby food products for lead, inorganic arsenic, cadmium and mercury, was filed in the wake of two U.S. House of Representatives Oversight Committee reports[5] highlighting findings regarding the dangers of even low-level exposures of inorganic arsenic, lead, cadmium, and mercury to the health of vulnerable populations, especially infants. As discussed in the congressional reports, peer-reviewed studies had found such dangers to include permanent decreases in IQ, diminished future economic productivity, and increased risk of future criminal and antisocial behavior.[6] In their 2021 petition, the coalition of state Attorneys General asserted that finished product testing guidance constitutes a "preventive control" under 21 C.F.R. § 117.3 and requested FDA issue such guidance to assist baby food manufacturers and distributors in limiting concentrations of these toxic elements in their products. In their Reconsideration Petition, the Attorneys General demonstrate that not only does FDA's own definition of "preventive control" reasonably encompasses finished product testing, but FDA's prior practice is to consider finished product testing as a form of preventive control.

Today, over three years after the Attorneys General submitted their 2022 Reconsideration Petition, the record supporting the need for FDA finished product testing has only become stronger. In addition to the evidence contained in their August 18, 2022 and February 15, 2024 supplemental submissions, on May 1, 2025 the Attorneys General brought to FDA's attention

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[2] *TABLE 5B-3 NUMBER OF BIRTHS BY YEAR AND COUNTY OF RESIDENCE, ARIZONA, 2012-2022* Arizona Department of Health Services http://pub.azdhs.gov/health-stats/menu/info/trend/index.php?pg=births.
[3] H.R. 2164, 57 Leg., 1st Reg. Sess. (Ariz. 2025).
[4] *Citizen Petition from State of New York Office of The Attorney General* Regulations, (Oct. 25, 2021), https://www.regulations.gov/document/FDA-2021-P-1144-0001.
[5] February 4, 2021 House Subcommittee Report https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf.
[6] *See, e.g. Miguel* Rodríguez-Barranco et al., *Association of Arsenic, Cadmium and Manganese Exposure with Neurodevelopment and Behavioural Disorders in Children: A Systematic Review and Meta-Analysis* (Apr. 9, 2013) (www.sciencedirect.com/science/article/abs/pii/S0048969713003409?via%3Dihub).

three recent FDA documents, each of which lend critical additional support to their Reconsideration Petition: (1) FDA's record of a March 12, 2025 nationwide recall of a Target private-brand baby food product due to elevated lead levels,[7] (2) FDA's January 2025 Final "Guidance for Industry on Action Levels for Lead in Food Intended for Babies and Young Children",[8] and (3) FDA's November 4, 2024 "Warning Letter" to Wanabana USA LLC for its violations of federal law and regulations resulting from the massive nationwide recall of apple cinnamon fruit puree in October 2023.[9]

These three FDA records highlight the critical role that finished product testing could play in protecting babies and infants from exposure to dangerous levels of toxic heavy metals. Had the FDA issued such guidance back in 2022, two recent significant and nationwide baby food recalls may have been avoided: the recall of Wanabana Apple Cinnamon Fruit Puree in October 2023 and the more recent March 12, 2025 nationwide recall of a Target private-label brand baby food product, "Good & Gather" Pea, Zucchini, Kale and Thyme Vegetable Puree. In issuing its 2025 lead action levels guidance and formally warning Wanabana USA LLC in November 2024 for failing to ensure its supplier performed finished product testing of its apple cinnamon fruit puree for lead prior to distribution, the FDA has laid the foundation to proceed with the relief sought by the Attorneys General in their Reconsideration Petition: the FDA's prompt issuance of finished product testing guidance. Such guidance would assist baby food manufacturers and distributors in developing preventive controls to maintain lead levels in their finished products within the agency's existing and future action levels for toxic elements.

In their Reconsideration Petition, the state Attorneys General urged the FDA take immediate action to issue guidance on finished product testing to prevent further harm to babies and young children from exposure to elevated levels of toxic elements in commercially-available food products. That was over three years ago. Since that time, the evidence in support of the critical role that such testing could play in avoiding such exposure as well food product recalls has continued to mount. FDA regulations provide that "[t]he Commissioner shall *promptly* review a petition for reconsideration." 21 CFR §10.33(d) (emphasis added). It is past time that that review take place.

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[7] *Attachment A (FDA Recall Record from March 12, 2025 re "Good & Gather" Pea, Zucchini, Kale & Thyme Vegetable Puree)* Regulations (May 6, 2025), https://www.regulations.gov/document/FDA-2021-P-1144-0021.

[8] *Attachment B (FDA Final Guidance for Industry on Action Levels for Lead in Food Intended for Babies and Young Children)* Regulations (May 6, 2025), https://www.regulations.gov/document/FDA-2021-P-1144-0022.

[9] *Attachment C (Nov 2024 FDA Warning Letter to Wanabana USA LLC)* Regulations (May 6, 2025), https://www.regulations.gov/document/FDA-2021-P-1144-0023.

In conclusion, we, the undersigned state Attorneys General submit this letter in support of the Reconsideration Petition and likewise urge FDA to issue finished product testing guidance to protect our childrens' health.

Respectfully submitted,

FOR THE STATE OF ARIZONA

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