October 29, 2026

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) is writing to share that today we issued a proposed rule that, if finalized, would update infant formula nutrient requirements as part of the agency's first comprehensive review of infant formula nutrition since 1998. The proposed changes would help ensure that infant formula standards reflect the best available science to support infant growth and development.

The comprehensive review and subsequent proposed rule are part of Operation Stork Speed, the HHS/FDA initiative to expand options for safe, reliable, and nutritious infant formula for American families, and support the goals of the Make America Healthy Again initiative.

Infant Formula Nutrient Requirements Proposed Rule

The proposed changes represent the first phase of the FDA's comprehensive review of the 30 nutrients currently required in infant formula sold and marketed in the United States. The FDA is conducting the review in three phases, allowing the agency to advance evidence-based changes as each phase of the review is completed. Subsequent phases will assess the remaining required nutrients, potential new nutrient requirements, and carbohydrate sources. The FDA intends to consolidate final changes to infant formula nutrient requirements into a single comprehensive final rule.

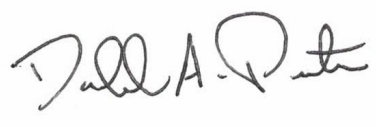
This proposed rule would update requirements for iodine, manganese, vitamin A, and vitamin D, and reaffirm existing requirements for chloride, potassium, selenium, and sodium. It would also change the units of measure for two nutrients. Additionally, the proposed rule requests public input on potential requirements for ingredients that are not presently required in infant formula but are commonly added by manufacturers due to their nutritional value — such as arachidonic acid (ARA), docosahexaenoic acid (DHA), and L-carnitine — which research suggests may play a role in infant development.

The FDA invites the public, including clinicians, doctors, parents, caregivers, the scientific community, industry, and others, to comment on the proposed rule. The comment period is open, and the deadline to submit comments is 120 days from date of publication in the *Federal Register*. Electronic comments may be submitted to www.regulations.gov docket number FDA-2026-56789. Written comments should be submitted to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All written comments should identify the docket number FDA-2026-56789 for "Infant Formula Nutrient Requirements."

U.S. Food & Drug Administration
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Please do not hesitate to reach out if you have any questions. For Tribes in need of assistance with any FDA-related issue, please contact the FDA Intergovernmental Affairs (IGA) team at IGA@fda.hhs.gov.

Sincerely,



Donald A. Prater, DVM
Acting Deputy Commissioner for Food
U.S. Food and Drug Administration