



FDA U.S. FOOD & DRUG
ADMINISTRATION

Michael Creaturo
Parenteral Technologies, LLC
10604 Technology Terrace #106
Lakewood Ranch, FL 34211

Re: Docket No. FDA-2025-P-4513

APR 02 2026

Dear Mr. Creaturo:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated September 17, 2025 and received on September 29, 2025. Your petition requests that the Agency "amend and/or remove specific labeling and directions, explicitly; *'if possible, use weight to dose;'* ...from all Infant's OTC single-ingredient acetaminophen liquid drug formulations for 2-3 year of age, 24-35 lb."

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

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Date: 2026.04.02 10:37:04
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research