[redacted]

May 27, 2021

Re: Docket No. FDA-2020-P-2296

Dear [redacted]

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on December 1, 2020. Your petition requests that the Agency "amend the children's over-the-counter [OTC] dosage schedule and directions of single-ingredient acetaminophen for the 2 to under 4 years of age group as published within the [tentative final monograph]." In addition, your petition requests that "FDA publish a statement of enforcement policy expressly permitting manufacturers of children's OTC single-ingredient acetaminophen to include labeling on the product that provides for the amended and expanded directions for use."

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 we have reached a decision on your request.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
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Date: 2021.05.26 14:53:47 -04'00'

Carol J. Bennett
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