U.S. FOOD & DRUG ADMINISTRATION

Michael A. Creaturo
Parenteral Technologies, LLC
4315 Mangrove Place
Siesta Key, FL 34234

February 2, 2023

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

Dear Mr. Creaturo:

I am writing in response to your correspondence dated January 25, 2023 regarding your December 1, 2020 citizen petition requesting that the Food and Drug Administration (FDA or Agency) "amend and expand the single-ingredient acetaminophen [over-the-counter (OTC)] consumer children's dosage schedule and directions for the 2-4 year of age group, as published within the [Tentative Final Monograph for Over-the-Counter Internal Analgesic, Antipyretic and Antirheumatic Drug Products as published, November 16, 1988 (TFM)]".

As noted in your January 25, 2023 correspondence, we previously sent a May 27, 2021 interim response to inform you that FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. We continue to work on your petition and will respond to your petition as soon as we have reached a decision on your request.

We also refer you to FDA's Annual Forecast for Planned Monograph Activities, a nonbinding list, issued each year, of planned monograph activities that FDA intends to address over the ensuing 3 years. The most recent forecast, posted September 30 2022, and available at https://www.fda.gov/media/161835/download, has pediatric acetaminophen dosing listed as one of the Agency's planned proposed safety orders. The proposed safety order would address dosage strengths of oral, single ingredient pediatric acetaminophen products, and propose the addition of weight- and age-based dosing for children under age 12 years.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
Date: 2023.02.01 16:41:33 -05'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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