Michael A. Creaturo
Managing Director
Parenteral Technologies, LLC
1584 Independence Blvd.
Sarasota, FL 34234

October 9, 2024

Re: Docket No. FDA-2024-P-2150

Dear Mr. Creaturo:

This letter responds to your citizen petition dated April 24, 2024 (Petition). Your Petition requests that the Food and Drug Administration (FDA or the Agency):

- "publish a statement of enforcement expressly prohibiting the further use of misleading, confusing and inadequate directions for over-the counter (OTC) single-ingredient acetaminophen products for 2-3 year of age, 24-35 lb Infants"; and

- more specifically, "issue a notice of compliance and publish a statement of enforcement requiring the removal and further use of specific labeling and directions, explicitly; '***if possible, use weight to dose;***'…from all Infant's [over-the-counter] OTC single-ingredient acetaminophen liquid drug formulations for 2-3 year of age, 24-35 lb" (Petition at 1).

In the Petition, you contend as grounds for your requests that the directions for use of such OTC liquid acetaminophen products for "infants" are:

A) Misleading, confusing and are inadequate, thus should be removed or amended pursuant to section 502 of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. § 352);
B) Contrary to the FD&C Act requirements at 21 U.S.C. § 352(a) and 21 U.S.C. § 352(f), in addition to 21 CFR § 201.5; and
C) Contrary to the format and content requirements for OTC drug product labeling under 21 CFR §§ 201.66(a) and 201.66(c)(6).

(See Petition at 1).

Decisions on initiating enforcement action are generally made by the Agency on a case-by-case basis and are within the discretion of the Agency. Requests for the Agency to initiate enforcement actions are not within the scope of FDA's citizen petition procedures (see 21 CFR

10.30(k)). Accordingly, your request is not the appropriate subject of a citizen petition. Therefore, the Petition is denied.[1]

We nevertheless appreciate the information that you provided. Such information is often helpful for us to identify issues with marketed products and possible violations of the laws and regulations that we enforce. We take such matters seriously.

Moreover, as you may already know, in March 2020 Congress enacted section 505G of the FD&C Act, which reformed and modernized the regulation of OTC monograph drugs.[2] Pursuant to authority under section 505G, FDA intends to propose updates regarding pediatric acetaminophen dosing, in the form of changes to labeling conditions in the Over-the-Counter Monograph M013: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use.[3] Specifically, FDA intends to issue a proposed safety-related order on pediatric acetaminophen dosing that addresses dosage strengths of oral, single-ingredient pediatric acetaminophen products, and will propose adding weight- and age-based dosing for children under the age of 12. The Agency has included the proposed safety order on its publicly available Annual Forecast for Planned Monograph Activities which covers a three-year horizon.[4]

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
Date: 2024.10.09 13:49:36 -04'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

[1] You also submitted a citizen petition dated November 21, 2020, requesting that FDA amend the children's OTC dosage schedule and directions of single-ingredient acetaminophen for the 2 to under 4 years of age group (Docket No. FDA-2020-P-2296). This response does not address that citizen petition, which remains pending with the Agency.

[2] Section 505G of the FD&C Act was added by the "Coronavirus Aid, Relief, and Economic Security Act" (or the "CARES Act"), Public Law No. 116-136. See also https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act.

[3] https://dps.fda.gov/omuf/ordersearch/order_otc000027.

[4] https://dps.fda.gov/omuf/forecast.