DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 14, 2020

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

Sent via email to: mike@asepsismedical.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA amend the children's over-the-counter dosage schedule and directions of single-ingredient acetaminophen for the 2 to under 4 years of age group as published within the TFM, and as described and illustrated herein in Section 6, (Figure 17a & 17b). In addition, requests the FDA to 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.

Your submission was received by this office on 12/1/2020 and assigned docket number FDA-2020-P-2296. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.12.14 17:55:59 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)