DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Barbara A. Kochanowski, PhD
Vice President, Regulatory & Scientific Affairs
Consumer Healthcare Products Association
1625 Eye Street, NW, Suite 600
Washington, DC 20006

Re: Docket No. FDA-2013-P-0999/CP1

Dear Dr. Kochanowski:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issue raised in your citizen petition received on August 15, 2013. Your petition requests that the Agency publish a statement of enforcement policy expressly permitting manufacturers of single-ingredient acetaminophen over-the-counter (OTC) drugs subject to the ongoing internal analgesic, antipyretic and antirheumatic monograph proceedings to include labeling on products that provides instructions for use in children aged 6 months to 2 years. The petition requests that this statement of policy recommend use of a single, standardized dosing chart, as provided in section II.D. of your request.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research