DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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August 28, 2013

Barbara A. Kochanowski, Ph.D.
Vice President, Regulatory & Scientific Affairs
Consume Healthcare Products Association
900 19th St, NW, Suite 700
Washington, D.C. 20009

Dear Dr. Kochanowski:

Your petition to the Food and Drug Administration requesting that the Agency publish a statement of enforcement policy expressly permitting manufacturers of single-ingredient acetaminophen 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 six months to two years, was received by this office on 8/15/2013. It was assigned docket number FDA-2013-P-0999/CP1, and it was filed on 8/15/2013. 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,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)