



Paula J. Oliver  
Senior Director, Regulatory Compliance  
McNeil Consumer Healthcare  
7050 Camp Hill Road  
Fort. Washington, Pennsylvania 19034

Food and Drug Administration  
Rockville MD 20857

APR 18 2001

4976 02 15-9 09:13

Re: Docket No. 77N-0094  
Comment No. CP14

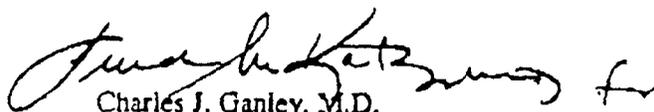
Dear Ms. Oliver:

This letter is sent in reference to your citizen petition dated February 1, 1999. The petition is filed as CP14 in Docket No. 77N-0094 in FDA's Dockets Management Branch. The petition requests that the agency amend the Tentative Final Monograph for Over-the-Counter Internal Analgesic, Antipyretic, and Antirheumatic Drug Products (53 FR 46204, November 16, 1988) to expand the proposed dosing directions for children to include children under 2 years of age. Specifically, the petition seeks expansion of the proposed dosing directions to include: (1) Dosing down to 2 months of age for concentrated infant acetaminophen products (80 mg/ 0.8 mL); (2) dosing down to 4 months of age for less concentrated acetaminophen products (160 mg/teaspoon); (3) weight and age based dosing for these products; and (4) a statement in the directions of concentrated products that states: Always call doctor for fever in children under age 4 months. Your petition further requests that FDA promptly publish an enforcement policy in the FEDERAL REGISTER to permit the marketing of OTC acetaminophen drug products bearing expanded pediatric labeling pending establishment in the final monograph.

In a telephone conversation with representatives of your company dated September 22, 2000, the agency noted that the petition's proposed weight ranges are too low for the accompanying age ranges, and raised the concern that this could lead to dosing errors. In response to this concern, McNeil representatives agreed to look into the issue and formulate a proposal for discussion. To date, we have not received your proposal. We would like to complete our evaluation of your petition and request that you provide your proposal or a response to our request within the next 30 days.

Your proposal should be submitted as an amendment to your petition to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All correspondence regarding this matter should reference the docket and comment number noted above and be submitted to the Dockets Management Branch.

Sincerely yours,

  
Charles J. Ganley, M.D.  
Director  
Division of OTC Drug Products

77N-0094

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M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

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DATE: AUG 8 2002

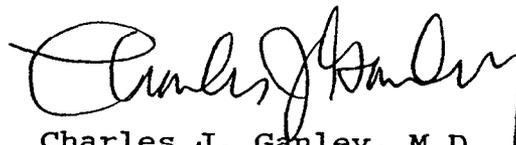
FROM: Director  
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 77N-0094

TO: Dockets Management Branch, HFA-305

The attached material should be placed on public display under the above referenced Docket No.

This material should be cross-referenced to Comment No. CP14

  
Charles J. Ganley, M.D.

Attachment