DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-516/S-016

McNeil Consumer & Specialty Pharmaceuticals
Attention: Ms. Carolyn Zlogar
Manager, CMC Regulatory
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Zlogar:

Please refer to your supplemental new drug application dated October 5, 2004, received October 7, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Motrin (100 mg ibuprofen) oral suspension.

We acknowledge receipt of your submissions dated October 5, 2004 and November 19, 2004.

This supplemental new drug application provides the manufacturing, formulation, and labeling changes associated with the addition of two new flavor versions (tropical punch and green apple) of Children's Motrin Oral Suspension.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (outer carton label and immediate container, submitted on October 5, 2004 for the 1 fl oz and 4 fl oz package sizes), and must be formatted in accordance with the requirements of 21 CFR 201.66.

We have the following additional recommendations for your consideration to be incorporated at the next printing:

> In order to maintain uniformity among all flavors of Children's Motrin Oral Suspension, include the Spanish tool-free number under the ***Questions and comments*** section of the Drug Facts label.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-516/S-016**." Approval of this submission by FDA is not required before the labeling is used.

The Agency is concerned about the need for organ-specific warnings for OTC drug products containing analgesic/antipyretic active ingredients. We will provide guidance on wording and placement of organ-specific warnings in the labeling of drug products containing ibuprofen in the future.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Walter Ellenberg, Ph.D., Regulatory Project Manager, at (301) 827-2241.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Center for Drug Evaluation V
Office of Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Curtis Rosebraugh
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