DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-516/S-012
NDA 21-128/S-003

McNeil Consumer & Specialty Pharmaceuticals
Attention: Paula J. Oliver
Senior Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Oliver:

Please refer to your supplemental new drug applications dated June 19, 2003, received June 20, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Motrin (100mg/5mL ibuprofen) Suspension and Children's Motrin Cold (100mg/5mL ibuprofen and 15mg/5mL pseudoephedrine HCl) Suspension.

We acknowledge receipt of your submissions dated July 22 (NDA 20-516) and 24 (NDA 21-128), August 11 (NDA 20-516) and 13, November 11, and December 5, 2003.

These supplemental new drug applications add dosing in mL, in addition to the current teaspoon dosing, to the Dosing Chart of the Drug Facts panel and on the dosing cup.

We have completed our review of these applications, as amended. These applications are 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 draft labeling (immediate container and carton labels submitted June 19, 2003, and proposed dosing cup submitted November 11, 2003), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-516/S-012" and "FPL for approved supplement NDA 21-128/S-003". Approval of these submissions 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 acetaminophen and/or NSAIDs in the future.

In addition, we recommend the following revisions to this approved labeling to be implemented at the time of the next printing:

1. Revise the teaspoon designation, to be either "tsp" (as indicated on the carton and container labels) or "TSP" (as indicated on the dosing cup), so that it will appear the same throughout all components of the labeling.

2. Include the complete allergy alert statements for the 1 oz. bottle, if you choose to include an allergy alert warning. These statements should be identical to the allergy statements on the 4 oz. bottle.

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 these NDAs and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, call Walt Ellenberg, Ph.D., Regulatory Project Manager for NDA 20-516, at (301) 827-2279, or Elaine Abraham, R.Ph., Regulatory Project Manager for NDA 21-128, at (301) 827-2276.

Sincerely,

{See appended electronic signature page}

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