DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-128/S-006

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

Dear Ms. Zlogar:

Please refer to your supplemental new drug application dated January 14, 2005, received January 18, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Motrin Cold (100mg/5mL ibuprofen and 15mg/5mL pseudoephedrine HCl) Suspension.

This supplemental new drug application provides for the addition of two new flavored versions (tropical punch and green apple) of Children's Motrin Cold Suspension.

We have completed our review of this supplemental application. This supplement 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 draft labeling (carton and bottle labels submitted on January 14, 2005) and must be formatted in accordance with the requirements of 21 CFR 201.66.

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 21-128/S-006**." Approval of this submission by FDA is not required before the labeling is used.

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 the requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Elaine Abraham, R.Ph., Regulatory Project Manager, 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
4/20/05 07:28:16 AM