DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-899/S-015

McNeil Consumer and Specialty Pharmaceuticals
Attn: Paula J. Oliver
Senior Director, Medical and Regulatory Affairs
7050 Camp Hill Rd
Fort Washington, PA 19034

Dear Ms. Oliver:

Please refer to your supplemental new drug application dated June 3, 2003, received June 4, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Motrin Sinus/Headache (200mg ibuprofen/30mg pseudoephedrine HCl) Caplet.

We acknowledge receipt of your submissions dated June 24 and July 16, 2003.

This supplemental new drug application provides for a change in the tradename from Motrin Sinus/Headache to Motrin Cold & Sinus.

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 enclosed labeling (20- and 40-count carton and blister pack labels) submitted on June 24 and July 16, 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, this submission should be designated "FPL for approved supplement NDA 19-899, S-015." 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 827-2301.

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

Enclosure

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
7/29/03 04:28:58 PM