DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-516/S-020

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 February 21, 2006, received February 22, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Motrin (100 mg/5 mL ibuprofen) suspension.

We acknowledge receipt of your submissions dated March 29, May 22, and June 19 and 21, 2006.

This supplemental application provides for the use of four new flavoring systems (cherry, bubblegum, apple, and strawberry flavor crystals) with Children's Motrin 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 enclosed labeling (Children's Motrin Grape-flavored 4 oz immediate container and inner carton labels submitted March 29, 2006, Children's Motrin with Flavor Creator outer carton label, inner pouch containing flavor packets, and individual flavor packets submitted May 22, 2006), 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 20-516/S-020**". Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the flag "New" from the principal display panel six months after introduction into the marketplace.

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 Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Charles Ganley
6/22/2006 03:55:04 PM
signing for Dr. Leonard Segal