DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-516/S-021

McNeil Consumer Healthcare
Attention: John F. Hauser
Associate Director, Global Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Mr. Hauser:

Please refer to your supplemental new drug application dated October 28, 2008, received October 29, 2008, 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 April 3, 24, and 29, 2009.

This supplemental new drug application (NDA) provides for the revised cardiovascular warning statement "When using this product the risk of heart attack or stroke may increase if you use more than directed or for longer than directed" and the addition of the warning statement "Ask a doctor before use if you have asthma" to the Drug Facts label in response to the September 19, 2008 supplemental labeling request letters.

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

Submit final printed labeling for all represented stock keeping units, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labels (Children's Motrin berry-flavored 2 oz (representative of the berry-flavored 1 oz and 2 oz) carton label, and berry-flavored 4 oz immediate container and carton labels submitted October 28, 2008, and the dye-free berry and tropical punch-flavored 4 oz carton and immediate container labels, grape and bubble gum-flavored 4 oz (representative of the grape and bubble gum-flavored 1 oz and 4 oz) carton labels, and the grape and bubble gum-flavored 4 oz immediate container labels submitted April 24, 2008), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 20-516/S-021**." Approval of this submission by FDA is not required before the labeling is used.

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

MedWatch
Food and Drug Administration
Suite 12B05
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

Enclosure

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

/s/

Andrea Segal

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