



NDA 19-012/S-043

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 Motrin IB (200 mg ibuprofen) tablets.

We acknowledge receipt of your correspondences dated March 23, and April 3, 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 (Motrin IB 50-count tablet (representative of the 24-, 50-, 50+15, and 50+25-count tablet) carton labels, 100-count tablet (representative of the 100-, 100+25-, and 100+50-count tablet) carton and immediate container labels, 2-count caplet front and back pouch labels, 3 x 2-count caplet (representative of the 3 and 50 x 2-count caplet) pouch dispenser, 50-count caplet (representative of the 24-, 24+6-, 50-, 50+15-, 50+25-, and 60-count caplet) carton label, 100-count (representative of the 100-, 100+25-, 100+50-, and 165-count caplet) carton and immediate container labels, 225-count caplet immediate container label, and the 300-count caplet carton and immediate container labels submitted October 28, 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 19-012/S-043.” Approval of this submission by FDA is not required before the labeling is used.

We remind you of your commitment, stated in your submission dated March 23, 2008, to revise the labeling for the discontinued Motrin Migraine Pain product in response to the July 14, and July 15, 2005, September 26, 2006, and September 19, 2008 supplemental labeling request letters prior to re-introduction into the marketplace.

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}

Joel Schiffenbauer, MD
Deputy 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/

Joel Schiffenbauer
4/24/2009 12:02:38 PM