



NDA 20-602/S-008

McNeil Consumer & Specialty Pharmaceuticals  
Attention: Hina S. Harlow, Pharm.D.  
Manager, Regulatory Affairs  
7050 Camp Hill Road  
Fort Washington, PA 19034

Dear Dr. Harlow:

Please refer to your supplemental new drug application dated November 10, 2005, received November 14, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Junior Strength Motrin (100 mg ibuprofen) tablets.

We also acknowledge receipt of your submission dated December 27, 2005.

This supplemental new drug application provides for revisions to the Drug Facts label and Principal Display Panel for the Junior Strength Motrin 24-count package size in response to the June 14, and July 15, 2005 supplemental labeling request letters.

We have completed our review of this application. This application is approved for the Junior Strength Motrin 24-count package size, 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 submitted labeling (24-count carton and immediate container labels submitted November 10, 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 20-602/S-008**". 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 December 27, 2005, to make the following revisions to the labeling for Junior Strength Motrin at the time of next printing in March 2006:

*a. Principal Display Panel*

Move the word "(NSAID)" from its current location to immediately follow the name of the NSAID ingredient "Ibuprofen Tablets" or the pharmacological category

statement “Pain Reliever/Fever Reducer” as stated in the July 15, 2005 supplemental labeling request letter.

b. *Drug Facts Panel (Carton)*

Under the warning “**Keep out of reach of children**”, relocate the toll-free number for Poison Control Center after the required text (see 21 CFR 330.1(g)) to read “**Keep out of reach of children**. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)”.

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  
Food and Drug Administration  
WO 22, Room 4447  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 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  
Acting 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/

-----  
Andrea Segal  
2/27/2006 11:00:19 AM