DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021393/S-007

SUPPLEMENT APPROVAL

Pfizer Consumer Healthcare
Attention: Yael Gozin, Ph.D.
Manager, Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Dr. Gozin:

Please refer to your Supplemental New Drug Application (sNDA) dated March 3, 2010, received March 3, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil® PM Liqui-Gels (ibuprofen 200 mg/diphenhydramine hydrochloride 25 mg) capsules.

Your October 29, 2010, submission constituted a complete response to our September 1, 2010, action letter. In this submission, you clarified that your designated dosage form has not changed.

This "Changes Being Effected" supplemental new drug application provides for the revised stomach bleeding warning as specified in the Organ-Specific Warnings final rule (21 CFR 201.326) and the removal of the statement "do not take longer than 10 days, unless directed by a doctor (see new warnings)" per the FDA's General Advice letter dated September 4, 2009.

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

LABELING

Submit final printed labeling, 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 following enclosed labeling submitted on March 3, 2010:

- 4-count immediate container (blister card) label (representative of the 8-count immediate container (blister card) label)
- 4-count carton label (with peel-back Drug Facts)
- 16-count carton label (with peel-back Drug Facts
- 32-count carton label (representative of the 40-count carton label)

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 (June 2008)." 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 021393/S-007**." Approval of this submission by FDA is not required before the labeling is used. Please note that representative labeling is not acceptable for Final Printed Labeling.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

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 Sherry Stewart, Regulatory Project Manager, at (301)796-9618.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Division Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosures: Labeling

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
04/20/2011