



NDA 20812/S-017

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 8, 2010, received March 8 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Infants' Advil[®] (ibuprofen) oral suspension, 50 mg/ 1.25 mL.

We acknowledge receipt of your amendments dated October 29, 2010, February 2, April 5, and April 15, 2011.

Your October 29, 2010, submission constituted a complete response to our September 3, 2010, action letter.

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 and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Infants' Advil[®] (ibuprofen) oral suspension, (white grape flavor) submitted March 8, 2010:

- 15 mL (0.5 fl oz) peel-back Drug Facts label for the carton label

Infants' Advil[®] (ibuprofen) oral suspension, (white grape flavor) submitted April 15, 2011:

- 15 mL (0.5 fl oz) carton
- 15 mL (0.5 fl oz) immediate container (bottle) 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 020812 S-017.**” Approval of this submission by FDA is not required before the labeling is used.

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 LT James Lee, Regulatory Project Manager, at (301)796-5283.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D., M.S.
Division Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosures: Carton and Container Labeling

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

/s/

ANDREA LEONARD SEGAL
04/26/2011