



NDA 201803

NDA APPROVAL

Pfizer Consumer Healthcare
Attention: Kevin N. Hibbert, MD, MPH
Director, North American Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Dr. Hibbert:

Please refer to your New Drug Application (NDA) dated July 1, 2010, received July 1, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Advil (sodium ibuprofen) tablet, 256 mg.

We acknowledge receipt of your amendments dated July 12, and 27, September 30, October 13, 29, and 31 2010, and January 14, 18, and 25, February 3, 11, 15, and 25, March 1, 2, and 21, and April 1, 15, and 22, June 15, and December 16, 2011, March 8, March 23, and May 23, 2012.

The December 16, 2011, submission constituted a complete response to our April 29, 2011, action letter.

This new drug application provides for the use of Advil (sodium ibuprofen) tablet, 256 mg, for (1) the temporary relief of minor aches and pains due to: headache, toothache, backache, menstrual cramps, the common cold, muscular aches, and minor pain of arthritis, and for (2) the reduction of fever.

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 submitted on April 15, 2011

Advil[®] round tablet

- 8-count immediate container (vial) label
- 8-count loose vial label
- 8-count outer container (small blister card with peel-back Drug Facts) label
- 20-, 40-, and 80-count immediate container (bottle) label
- 20-, 40-, and 80-count outer carton label
- 100-count (50 X 2-count) pouch dispenser
- 240-count immediate container (bottle) label

Advil[®] capsule-shaped tablet (caplet)

- 20-, 40-, and 80-count immediate container (bottle) label
- 20-, 40-, and 80-count outer carton label

Labeling submitted on April 22, 2011

Advil[®] round tablet

- 2-count immediate container (pouch) label
- 8-count outer carton (long hang card)

We remind you to remove the “NEW” flag from all pieces of labeling after 6 months of marketing.

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 201803.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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.

Your application for Advil (sodium ibuprofen) tablet, 256 mg, was not referred to an FDA advisory committee for the following reasons:

- A) This drug is not the first in its class.
- B) The safety profile is acceptable for the indications: (1) temporarily relieves minor aches and pains due to headache, toothache, backache, menstrual cramps, the common cold, muscular aches, and minor pain of arthritis, and (2) the reduction of fever.

- C) The clinical study design is acceptable.
- D) The application did not raise significant safety or efficacy issues in the intended population.
- E) The application did not raise significant public health questions on the role of the drug in the diagnosis, cure, mitigation, treatment, or prevention of a disease.
- F) Outside expertise was not necessary; there were no controversial issues that would benefit from advisory committee discussion.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric study because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

- 1042-1 The applicant currently proposes to develop a liquid pediatric formulation and then perform a pharmacokinetic (PK) study in adults comparing the pediatric formulation to an approved pediatric ibuprofen product. The proposed PK study is a single-dose, randomized, open-label, two-way crossover PK study. Approximately 30 healthy male and female subjects, 18 to 45 years of age, will be enrolled. The treatment groups will be:
- 10 ml of currently marketed Children's Advil Suspension (equivalent to ibuprofen 200 mg)
 - 10 ml of sodium ibuprofen solution (equivalent to ibuprofen 200 mg)

The statistical hypothesis to be tested is that sodium ibuprofen pediatric solution is bioequivalent to Children's Advil suspension in the fasted state.

Final Protocol Submission: July, 2013
Study/Trial Completion: February, 2014
Final Report Submission: April 2014

Submit final reports to this NDA. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated “**Required Pediatric Assessment(s).**”

We are waiving the pediatric study requirement for ages 0 to 6 months of age for the following reasons:

- Necessary studies are impossible or highly impracticable. This is because the causes of pain for which this medication is indicated should not be treated by a parent in the over-the-counter environment.

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}

Joel Schiffenbauer, M.D.
Deputy 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/

JOEL SCHIFFENBAUER
06/12/2012