DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20944/S-011

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Wendy A. McManus, MS, RAC
Senior Manager Worldwide Safety and Regulatory
One Giralda Farms
Madison, NJ 07940

Dear Ms. McManus:

Please refer to your Supplemental New Drug Application (sNDA) dated September 27, 2016, received September 27, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Junior Strength Advil® Chewables (ibuprofen) chewable tablets, 50 and 100 mg.

This "Prior Approval" supplemental new drug application provides for the following labeling revisions:

- Changes to the Drug Facts labeling (DFL) in accordance with the Agency's supplement request letter dated August 18, 2016
- Increase font size of statement of identity
- Reverse indications on principal display panel from "Fever Reducer/Pain Reliever" to "Pain Reliever/Fever Reducer"
- Update distributor information

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, with the revisions listed above as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be in the "Drug Facts" format (21 CFR 201.66), where applicable, and be identical to the following submitted labels:

Submitted Labeling	Date Submitted
24-count carton (bottle) 100 mg, *Grape Flavor* 24-count immediate container (bottle) 100 mg, *Grape Flavor*	January 19, 2017

Peel-back Drug Facts label, 100 mg	September 27, 2016
24-count carton (blister) 50 mg, *Grape Flavor*	February 8, 2017
Peel-back Drug Facts label, 50 mg	January 19, 2017

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 20944/S-011**." 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 Tinya Sensie, Regulatory Project Manager, at (240) 402-4230.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

KAREN M MAHONEY
03/27/2017