DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201803/S-008

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 October 3, 2016, received October 3, 2016, and your amendments, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil® (ibuprofen sodium) tablets, 256 mg.

This "Prior Approval" supplemental new drug application proposes a mandatory safety related labeling change to inform consumers of the risks of cardiovascular events associated with the use of NSAIDs (i.e., increase chance of heart attack or stroke), and proposes new bonus cartons for the Advil round tablet and coupons for the Advil round and capsule-shaped tablets.

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 and with the minor editorial labeling revisions listed below.

Change the uppercase "E" to a lowercase "e" on the Other Information drug facts statement "each tablet contains: **sodium 22mg**" for the following immediate container (bottle) labels: the 20-, 100-, and 160-count round tablet bottles, the 20- and 40-count capsule-shaped tablet (caplet) bottles, and the 20-count Advil Menstrual Pain bottle.

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

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)." For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 201803/S-008**." Approval of this submission by FDA is not required before the labeling is used.

Advil round tablets:

- 2-count immediate container (pouch), 8-count immediate container (non-loose vial), 80-count immediate container (bottle) and 80-count carton (representative of 20- and 40-count cartons) labels submitted October 3, 2016
- 20-count immediate container (bottle), 100-ct (80+20) "Bonus" immediate container (bottle), 160-count immediate container (bottle), 160-count carton, $1.00 instantly redeemable coupon (IRC) for the 20-, 40- and 80-count cartons, and $1.00 "shelf-talker" IRC submitted January 18, 2017
- $2.00 IRC for 80- and 160-count cartons submitted April 14, 2017
- 8-count immediate container (loose vial with peel-back Drug Facts label), 8-count club pack with backer card carton, 100-count (50x2-ct) pouch dispenser carton, 100-count (80+20) "Bonus" carton and 180-count (160+20) "Bonus" carton submitted May 12, 2017

Advil capsule-shaped tablets:

- 80-count immediate container (bottle) and 80-count carton submitted October 3, 2016
- 20- and 40-count immediate containers (bottles), 20- and 40-count cartons and $1.00 IRC for the 80-count carton submitted January 18, 2017

Advil Menstrual Pain (tablets):

- 40-count immediate container (bottle) and 40-count carton submitted October 3, 2016
- 20-count immediate container (bottle) and 20-count carton submitted January 18, 2017

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
06/12/2017