DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201803/S-007

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Christine D. Chirdo
Director, US Regulatory Strategy
One Giralda Farms
Madison, NJ 07940

Dear Ms. Chirdo:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 4, 2015, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil (ibuprofen sodium) 256 mg, tablets.

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

- Adds the proprietary name "Advil Menstrual Pain" under the same NDA
  - Adds 20- and 40-count stock keeping units (SKUs) and associated labeling
  - Changes the order of the symptoms under "Uses" in the Drug Facts label for the new 20- and 40-count SKUs

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 (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable, and identical to the Advil Menstrual Pain 20- and 40-count immediate container labels submitted on December 4, 2015 and 20- and 40-count outer carton labels submitted on May 6, 2016.

We note that the principal display panel contains a new tablet image. We remind you that images should represent the actual tablet and should reflect the true size, color and imprint of the tablet. We refer you to the draft guidance for industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors.*

The FPL 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/S-007**." 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
06/03/2016