DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201803/S-009

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 and received March 30, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil® Menstrual Pain (ibuprofen sodium) tablets, 256 mg.

This "Prior Approval" supplemental new drug application provides for new labeling for the Advil Menstrual Pain line extension: a 2-count immediate container (pouch) with 100-count (50x2) dispenser, and an 8-count immediate container (vial) to be packaged in two different cartons - a tall backer card carton, and a short backer card carton with peel-back Drug Facts label that will be dispensed in a 12-count shelf tray. The supplement provides for a "Purse Pack" descriptor and icon for all submitted cartons, and the descriptors "Home", "Office", "Travel" on the 8-count tall backer card carton.

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 must be identical to the labeling in the table below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Submitted Labeling	Submission date
2-count immediate container (pouch), front	May 1, 2017
2-count immediate container (pouch), back	March 30, 2017
100-count (50x2-count) pouch dispenser	March 30, 2017

8-count immediate container (vial)	July 20, 2017
8-count short backer card carton with peel-back Drug Facts label	March 30, 2017
8-count tall backer card carton	May 1, 2017
12-count shelf tray for 8-count short backer card carton	May 1, 2017

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 201803/S-009**." 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
08/22/2017