DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18989/S-088

SUPPLEMENT APPROVAL

Pfizer Inc.
Wendy A. McManus, MS, RAC
Sr. Manager, US Regulatory Strategy
One Giralda Farms
Madison, NJ 07940

Dear Ms. McManus:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 23, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil® (ibuprofen) tablets, 200 mg.

This "Prior Approval" supplemental new drug application provides for a labeling change to inform consumers of the risks of cardiovascular events associated with the use of nonsteroidal anti-inflammatory drugs (NSAIDs).

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 table below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Component Type	Component	Submission Date	Component #
TABLETS			
Dispenser	50-ct. Dispenser for 2-ct. pouches	*3 October 2016*	PAA080243
Pouch (front) Pouch (back)	2-ct. pouch – front 2-ct. pouch – back	*3 October 2016* *3 October 2016*	PAA080241 PAA080242
Carton Carton Piggyback Short Backer Card Long Backer Card Backer Card Vial	6-ct. (3 x 2-ct. pouch) 6-ct. 10-ct. (10-ct. vial) 10-ct. (10-ct. vial) 20-ct. (2 x 10-ct.)	*23 February 2017* *23 February 2017* *3 October 2016* *23 February 2017* *23 February 2017*	PAA070720 D000057831 PAA080189 PAA083442 PAA083445

Vial (loose)	10-ct. vial	*3 October 2016*	PAA080244
Vial (non-loose)	10-ct. vial	*3 October 2016*	PAA080190
Carton	100-ct. 24-ct. 50-ct. 130-ct. 200-ct.	*3 October 2016* *23 February 2017* *23 February 2017* *23 February 2017* *23 February 2017*	PAA080141 PAA082490 PAA082582 PAA085127 PAA083160
Bonus Carton	36-ct. (24 + 12) 115-ct. (100 + 15) 225-ct. (200 + 25)	*23 February 2017* *23 February 2017* *23 February 2017*	PAA085129 PAA083083 PAA085431
Bottle	100-ct. 24-ct. 50-ct. 130-ct. 200-ct.	*3 October 2016* *23 February 2017* *23 February 2017* *23 February 2017* *23 February 2017*	PAA080142 PAA082581 PAA082583 PAA085128 PAA083161
Bonus Bottle	36-ct. (24 + 12) 115-ct. (100 + 15) 225-ct. (200 + 25)	*23 February 2017* *23 February 2017* *23 February 2017*	PAA085130 PAA083084 PAA085432
Standalone EZ Open Bottle	200-ct. EZ Open	*3 October 2016*	PAA080143
Standalone Bottle	300-ct. Standalone 360-ct. Standalone	*23 February 2017* *23 February 2017*	PAA083046 PAA085433
IRC Carton	100ct. $2 IRC – directly over PDP 24ct. $1 IRC – directly over PDP 50ct. $1 IRC – directly over PDP	*23 February 2017* *23 February 2017 and 19 May 2017* *23 February 2017 and 19 May 2017*	D000057345 D000056703 D000056705
CAPLETS			
Carton	24-ct. 50-ct. 100-ct. 200-ct.	*23 February 2017* *23 February 2017* *3 October 2016* *23 February 2017*	PAA083047 PAA083394 PAA080147 PAA083396
Bonus Carton	36-ct. (24 + 12) 115-ct. (100 + 15) 225-ct. (200 + 25)	*23 February 2017* *23 February 2017* *23 February 2017*	PAA085436 PAA085434 PAA085438

Bottle	24-ct. 50-ct. 100-ct. 200-ct.	*23 February 2017* *23 February 2017* *3 October 2016* *23 February 2017*	PAA083048 PAA083395 PAA080148 PAA083397
Bonus Bottle	36-ct. (24 + 12) 115-ct. (100 + 15) 225-ct. (200 + 25)	*23 February 2017* *23 February 2017* *23 February 2017*	PAA085437 PAA085435 PAA085439
IRC Carton	24-ct. $1 IRC 50-ct. $1 IRC	*23 February 2017 and 19 May 2017* *23 February 2017 and 19 May 2017*	D000056704 D000056706
GEL CAPLETS			
Carton	100-ct. 24-ct. 50-ct. 200-ct.	*3 October 2016* *23 February 2017* *23 February 2017* *23 February 2017*	PAA080250 PAA083162 PAA085440 PAA085442
Bottle	100-ct. 24-ct. 50-ct. 200-ct.	*3 October 2016* *23 February 2017* *23 February 2017* *23 February 2017*	PAA080251 PAA083163 PAA085441 PAA085443

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 18989/S-088**." 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
08/23/2017