DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20402/S-043

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 February 6, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil® Liqui-Gels® and Advil® Migraine (ibuprofen) capsules, 200 mg.

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

- the addition of heart attack and stroke warning information to all Advil® LIQUI-GELS® and Advil® Migraine labels
- the addition of medication overuse headache warning information to the Advil® Migraine labels
- updates to the graphics on the principal display panel
- updates to the net quantity statement on the 2-count immediate container (pouch) label
- minor revisions to immediate container and carton labels (e.g., inactive ingredients revisions, update copyright and patent information)
- new bonus labeling (e.g., 100-, 180- child resistant, 180- non-child resistant count sizes)
- the addition of two instantly redeemable coupons for the Advil® Migraine 20- and 80-count cartons
- the removal of the 4-count carton (hang card), 8-count carton, 120-count carton, and 240-count immediate container (standalone bottle) labels approved in Supplement 025

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 following revisions listed below:

Delete light mineral oil as a listed inactive ingredient within the Drug Facts labeling because it is not part of the final drug product.

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

Submitted Labeling	Date Submitted
Advil® LIQUI-GELS®	
2-count immediate container (front side of pouch)	April 28, 2017
2-count immediate container (back side of pouch)	October 3, 2016
4-count carton (hang carton)	April 28, 2017
4-count peel-back Drug Facts (3 part piggy back)	April 28, 2017
20-count immediate container (bottle) with peel-back Drug Facts	February 6, 2017
20-count carton	February 6, 2017
30-count immediate container (bottle) with peel-back Drug Facts	February 6, 2017
30-count carton ('50% MORE FREE'/ '10 Free' flags)	February 6, 2017
40-count immediate container (bottle)	February 6, 2017
40-count carton	February 6, 2017
80-count immediate container (bottle)	October 3, 2016
80-count carton	October 3, 2016
100-count (50x2ct) carton (pouch dispenser)	October 3, 2016
100-count immediate container (bottle)	February 6, 2017
100-count carton ('20 FREE' flag)	February 6, 2017

120-count immediate container (bottle)	February 6, 2017
160-count immediate container (bottle)	February 6, 2017
160-count carton	February 6, 2017
160-count non-child resistant immediate container (standalone bottle)	October 3, 2016
180-count (‘20 FREE’ flag) non-child resistant immediate container (standalone bottle)	February 6, 2017
180-count immediate container (bottle)	February 6, 2017
180-count carton (‘20 FREE’ flag)	February 6, 2017
200-count carton (standalone bottle with ‘GREAT VALUE!’ flag)	February 6, 2017
240-count (120x2ct) carton	February 6, 2017
Advil® Migraine	
20-count immediate container (bottle) with peel-back Drug Facts	April 21, 2017
20-count carton	April 21, 2017
40-count immediate container (bottle)	April 21, 2017
40-count carton	April 21, 2017
80-count immediate container (bottle)	April 21, 2017
80-count carton	April 21, 2017
Instantly Redeemable Coupon (IRC) with 20-count principal display panel (PDP) image	February 6, 2017
IRC with 80-count PDP image	February 6, 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 20402/S-043**.” 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).

ADDITIONAL INFORMATION

Based on our review of your application, your drug product may have packaging that is subject to the requirements of the Poison Prevention Packaging Act (PPPA) (codified at 15 U.S.C. §§ 1471−1477), as well as its implementing regulations (Code of Federal Regulations, Title 16, Part 1700). Under section 502(p) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a drug that has packaging or labeling that is in violation of a regulation issued pursuant to section 3 or 4 of the PPPA is deemed misbranded. We encourage you to consult the PPPA, as well its implementing regulations, in order to ensure the compliance of your drug product with respect to applicable special packaging (also known as child-resistant packaging) standards. If you have questions regarding compliance with the PPPA, please contact the U.S. Consumer Product Safety Commission (CPSC).

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
08/08/2017