DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21393/S-014

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 September 29, 2016, received September 29, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil® PM (ibuprofen 200 mg and diphenhydramine HCl 25 mg) capsules.

This "Prior Approval" supplemental new drug application proposes a safety labeling change to further inform consumers of the risks of cardiovascular events associated with the use of NSAIDs (i.e., increase chance of heart attack or stroke).

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.

Make the following editorial changes to all immediate container labels at the next printing:

> In the "When using this product" subheading, include the statement "take with food or milk if stomach upset occurs" and revise the order of listed items in the "When using this product" subheading, to be consistent with the approved "When using this product" subheading for the Drug Facts label.

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

Submitted Labeling	Date Submitted
20-count immediate container (bottle with peel pack Drug Facts)	January 10, 2017
20-count carton	November 21, 2016
30-count immediate container (bottle with peel-back Drug Facts)	January 10, 2017
30-count (20+10 bonus) carton with "50% MORE FREE 10 Free LIQUI-GELS®" flag	January 10, 2017
40-count immediate container (bottle)	January 10, 2017
40-count carton	November 21, 2016 Revised February 7, 2017
50-count immediate container (bottle)	January 10, 2017
50-count (40 + 10) carton with "25% MORE FREE 10 Free LIQUI-GELS®" flag	January 10, 2017
80-count immediate container (bottle)	September 29, 2016
80-count carton with "Great Value" flag	September 29, 2016
100-count immediate container (bottle)	January 10, 2017
100-count (80 + 20) carton with "20 Free LIQUI-GELS®" and "80+ 20 Free" flags	January 10, 2017 Revised March 2, 2017

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)." 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 21393/S-014**." 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
03/29/2017