DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021394/S-023

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Wendy McManus
Sr. Manager, US Regulatory Strategy
1 Giralda Farms
Madison, NJ 07940

Dear Ms. McManus:

Please refer to your supplemental new drug application (sNDA) dated January 31, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil PM (ibuprofen 200 mg / diphenhydramine citrate 38 mg) tablet.

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

- Addition of 4-count outer carton labeling (for 2-count pouches)
- Flag on the principal display panel for an enclosed manufacturer's coupon "save $1.00 on your next purchase of Advil PM 20 ct. or larger"
- Revised Drug Facts labeling to include mandatory safety-related changes 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 in the "Drug Facts" format (21 CFR 201.66), where applicable, and be identical to the following labeling submissions:

Submitted Labeling	Submission Date
4-count outer carton (for 2-count pouches) with coupon (e.g., "SAVE 1^{00}" on your next purchase of Advil PM 20-count or larger)	April 26, 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 021394/S-023**." 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 Laurie Buonaccorsi, Regulatory Project Manager, at (240) 402-6297.

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
07/21/2017