DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21394/S-021

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 30, 2016, received September 30, 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 citrate 38 mg) tablets.

This "Prior Approval" supplemental new drug application proposes a mandatory safety related labeling change to 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.

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 Advil® PM (ibuprofen 200 mg and diphenhydramine citrate 38 mg) tablet labels listed below by submission date, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Submission Date
2-count immediate container (pouch) front and back	September 30, 2016
20-count immediate container (bottle) and outer carton	September 30, 2016
4-count outer carton (with peel-back Drug Facts)	September 30, 2016
50x 2-count (pouch) dispenser	September 30, 2016
120-count immediate container ("Easy Open") "stand-alone" without an outer carton)	September 30, 2016
40-count immediate container (bottle) and outer carton	December 20, 2016
50-count immediate container (bottle) and outer carton	December 20, 2016
80-count immediate container (bottle) and outer carton	December 20, 2016
120-count immediate container (bottle) and outer carton	December 20, 2016
200-count immediate container (bottle) and outer carton	December 20, 2016
12-count carton (trial size)	December 20, 2016
30-count (20-count +10-count) immediate container (bottle) and outer carton - 50% free	December 20, 2016
140-count (120-count + 20-count) immediate container (bottle) and outer carton - 20 free	December 20, 2016
*50-count (40-count + 10-count (25% free)) outer carton *immediate container is the same as that of the 50-count immediate container submitted on September 30, 2016	December 20, 2016

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 21394/S-021**." 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
03/30/2017