DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22113/S-001

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Christine D. Chirdo
US Regulatory Strategy
1 Giralda Farms
Madison, NJ 07940

Dear Ms. Chirdo:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 30, 2016, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil Multi-Symptom Cold & Flu (ibuprofen 200 mg / phenylephrine hydrochloride 10 mg / chlorpheniramine maleate 4 mg), tablet.

This "Prior Approval" supplemental new drug application proposes the addition of a line extension product for NDA 22113 using the identical drug product (other than unique tablet embossing) under the proprietary name Advil Multi-Symptom Cold & Flu, with revised labeling related to cold and flu symptoms.

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.

We remind you to remove the "NEW!" flag from the labeling 6 months after the marketing start date.

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 enclosed labeling as listed in Table 1, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Table 1: Labeling to be Submitted as Final Printed Labeling

Submission Date	Submitted Labeling
28 Feb 2017	10-count carton (outer container)
28 Feb 2017	20-count carton (outer container)

04 Apr 2017	Drug Facts Label (affixed to 10-count and 20-count outer containers)
26 Apr 2017	50-count dispenser (outer container)
04 Apr 2017	1-count pouch (immediate container)
28 Feb 2017	10-count blister (immediate container)

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 22113/S-001**." 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

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 Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
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/

THERESA M MICHELE
04/28/2017