DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22113/S-005

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Tania Thomas
Director, Regulatory Strategy
One Giralda Farms
Madison, NJ 07940

Dear Ms. Thomas:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 10, 2018, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil Allergy & Congestion Relief and Advil Multi-Symptom Cold & Flu (ibuprofen 200 mg, phenylephrine hydrochloride 10 mg, chlorpheniramine maleate 4 mg) tablets.

This "Prior Approval" supplemental new drug application adds a new 2-count carton, peel-back booklet type Drug Facts label, and a new coupon "Save $2 off on Any Advil Cold, Sinus or Allergy Product"). The coupon will be inserted into both Advil Multi-Symptom Cold & Flu and Advil Allergy & Congestion Relief cartons.

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 (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling described in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. Also submit labeling for the two pouches for these SKUs with your FPL to ensure a complete record.

Submitted Labeling	Date of Submission
2-count carton (Allergy & Congestion Relief)	8/10/2018
2-count carton (Multi-Symptom Cold & Flu)	8/10/2018
Drug Facts label peel-back booklet type (Allergy & Congestion Relief)	8/10/2018
Drug Facts label peel-back booklet type (Multi-Symptom Cold & Flu)	8/10/2018
Coupon	8/10/2018

The FPL 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 (April 2017, Revision 4).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 22113/S-5**." 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 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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

THERESA M MICHELE
01/25/2019 04:16:23 PM