DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022565/S-002

SUPPLEMENT APPROVAL

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

Dear Ms. Chirdo:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 3, 2014 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil Sinus Congestion & Pain (ibuprofen 200 mg; phenylephrine hydrochloride 10 mg) tablets.

We acknowledge receipt of your amendments dated January 28, February 10, and March 11, 2015.

This "Prior Approval" sNDA proposes to change the proprietary name from Advil Congestion Relief to Advil Sinus Congestion & Pain.

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 but with the following revisions:

> Replace the term "pill" in the statement "1 PILL DOSAGE" with the term "tablet," on the Principal Display Panel of the 10-count, 20-count, 50-count carton, and 50-count dispenser outer container carton labeling. Include these changes when you submit the Final Printed Labeling (FPL).

LABELING

Submit FPL, with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The FPL, except for the agreed upon revisions, must be identical to the enclosed labeling, submitted on February 10, 2015, for the following stock keeping units (SKUs) and must be in the Drug Facts labeling format (21 CFR 201.66), where applicable.
:

- 10-count immediate container (blister card)
- "Piggy-back" peel-back type with Drug Facts
- 10-count, 20-count, and 50-count outer container cartons

- 1-count immediate container (pouch)
- 50-count outer container dispenser carton

Your submission dated February 10, 2015, states that the 10-count outer container carton labeling is intended to serve as representative labeling for the 20-count and 50-count outer carton container labeling. We remind you that any changes approved for the 10-count outer container carton labeling must be incorporated onto the 20-count and 50-count outer container carton labeling, which are identical to the 10-count outer container carton labeling with the exception of the count size.

The FPL 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 022565/S-002**." Approval of this submission by FDA is not required before the labeling is used.

MARKET PACKAGE

Please submit one market package of the drug product when it is available.

If sending via USPS, please send to:

Sherry Stewart
Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 5494
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

If sending via any carrier other than USPS (e.g., UPS, DHL), please send to:

Sherry Stewart
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 5494
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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/

CHARLES J GANLEY
03/30/2015
signing letter for Dr. Michele