



NDA 19771/S-40

SUPPLEMENT APPROVAL

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

Dear Ms. McManus:

Please refer to your Supplemental New Drug Application (sNDA) dated September 28, 2016, received September 28, 2016, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil[®] Cold & Sinus (ibuprofen 200 mg, pseudoephedrine hydrochloride 30mg) tablets (coated caplet).

This “Changes Being Effected” supplemental new drug application provides for the addition of the “Heart attack and stroke warning” in accordance with the “Changes Being Effected” (CBE-0) Request Letter from the Agency dated August 18, 2016.

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 for Advil[®] Cold & Sinus tablets (coated caplet) 40-count and 20-count 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 40-count representative labeling submitted on September 28, 2016; and, the label (strip attaching the two 40-count cartons (i.e., “club pack”) submitted on January 25, 2017. The labeling must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

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 19771/S-040.**” 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 CAPT Janice Adams-King, Safety Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
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/

VALERIE S PRATT
03/23/2017