NDA 22113/S-8

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention Lisa Miller
Senior Manager, Worldwide Safety and Regulatory
One Giralda Farms
Madison, NJ 07940

Dear Ms. Miller:

Please refer to your supplemental new drug application (sNDA) dated and received March 8, 2019, and your amendment, 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) tablets.

This "Prior Approval" supplemental new drug application provides for a new package configuration for Advil Multi-Symptom Cold & Flu, consisting of a 40-count carton.

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

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 below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Labeling: Multi-Symptom Cold & Flu, 40-count carton, submitted June 14, 2019

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 22113/S-8.**" 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 FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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).

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

If you have any questions, call Sherry Stewart, Senior 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 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
09/06/2019 12:12:51 PM