NDA 22113/S-7
NDA 22565/S-5

**SUPPLEMENT APPROVAL**

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

Dear Ms. Thomas:

Please refer to your supplemental new drug applications (sNDAs) dated and received February 8, 2019, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- NDA 22113/S-7: Advil Allergy & Congestion Relief & Advil Multi-Symptom Cold & Flu (ibuprofen 200 mg, phenylephrine HCl 10 mg, chlorpheniramine maleate 4 mg) tablets

- NDA 22565/S-5: Advil Sinus Congestion & Pain (ibuprofen 200 mg, phenylephrine HCl 10 mg) tablets

These "Prior Approval" sNDAs provide for a new product package configuration, consisting of 30-count (20-ct plus 10-count bonus) carton.

## APPROVAL & LABELING

We have completed our review of these applications. They are 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 in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

| Submitted Labeling – NDA 22113/S-7 | Date of Submission |
|---|---|
| 30-count Allergy & Congestion Relief carton | 4/18/19 |
| 30-count Multi-Symptom Cold & Flu carton | 4/18/19 |

| Submitted Labeling – NDA 22565/S-5 | Date of Submission |
|---|---|
| 30-count Sinus Congestion & Pain carton | 4/18/19 |

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-7**" and **"Final Printed Labeling for approved NDA 22565/S-5."** Approval of these submissions 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

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

ENCLOSURE(S):

- Carton Labeling

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**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.**

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/s/

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