



NDA 20812/S-023

**SUPPLEMENT APPROVAL**

Pfizer Inc.  
Attention: Christine Chirido  
Director, Worldwide Safety and Regulatory  
1 Giralda Farms  
Madison, NJ 07940

Dear Ms. Chirido:

Please refer to your Supplemental New Drug Application (sNDA) dated September 26, 2016, received September 26, 2016, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Infants' Advil<sup>®</sup> Concentrated Drops (ibuprofen) oral suspension, 50 mg/1.25 mL.

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 as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be in the "Drug Facts" format (21 CFR 201.66), where applicable, and identical to the Infants' Advil<sup>®</sup> Concentrated Drops (ibuprofen) oral suspension, 50 mg/1.25 mL labeling as submitted on January 6, 2017:

- 1 fluid ounce (fl. oz.) carton, *White Grape Flavor* (bottle)
- 1 fl. oz. immediate container, *White Grape Flavor* (bottle)
- 3/4 fl. oz. carton, *White Grape Flavor* (bottle)
- 3/4 fl. oz. immediate container, *White Grape Flavor* (bottle)
- 1/2 fl. oz. carton, *White Grape Flavor* (bottle)
- 1/2 fl. oz. carton, *White Grape Flavor* (bottle) [Walmart]
- 1/2 fl. oz. immediate container, *White Grape Flavor* (bottle)
- 1/4 fl. oz. carton, *White Grape Flavor* (bottle)
- 1/4 fl. oz. immediate container, *White Grape Flavor* (bottle)
- 1/4 fl. oz. peel-back Drug Facts carton label

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 20812/S-023.**” 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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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VALERIE S PRATT  
03/24/2017