



NDA 21373/S-013

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Christine Chirido
Director, Worldwide Safety and Regulatory
One 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 Children's Advil® Cold (ibuprofen 100 mg/5ml, pseudoephedrine hydrochloride 15 mg/5ml) suspension.

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. The addition of the *Heart Attack and Stroke Warning* is approved, effective on the date of this letter.

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 identical to the Children's Advil® Cold (ibuprofen 100 mg/5ml, pseudoephedrine hydrochloride 15 mg/5ml) grape flavor suspension 4 fl. oz. (carton and container) labeling submitted on September 26, 2016, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

We remind you that updates to labeling after today, may require a prior approval labeling supplement before remarketing this drug product.

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
03/24/2017