DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20589/S-029

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Alicia Holsey, M.S., RAC
Manager, Worldwide Safety and Regulatory
Five Giralda Farms
Madison, NJ 07940

Dear Ms. Holsey:

Please refer to your Supplemental New Drug Application (sNDA) dated March 2, 2012, received March 2, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Advil® (ibuprofen) oral suspension, 100 mg / 5 mL.

We also refer to your amendments dated May 22 and September 5, 2013. The September 5, 2013, submission constituted a complete response to our July 2, 2012, action letter.

This "Prior Approval" supplemental new drug application proposes the introduction of two new products: Children's Advil (ibuprofen 100 mg / 5 mL) oral suspension, sugar-free berry flavor and Children's Advil (ibuprofen 100 mg / 5 mL) oral suspension, sugar-free, dye-free berry flavor. In order to address the deficiencies outlined by the Agency in the July 2, 2012 Complete Response letter, you provided the study report for Protocol B34191008 "A Phase I, Randomized, 2-Way Crossover, Open-Label Study to Assess the Bioequivalence of Two Ibuprofen Suspension Formulations in Healthy Volunteers under Fed and Fasted Conditions."

We have completed our review of this application. 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 (FPL) must be identical to the 4 oz Sugar-Free Dye-Free Berry Children's Advil Suspension immediate container (bottle) and carton labels submitted on September 5, 2013, 4 oz Sugar-Free Berry Children's Advil Suspension carton label submitted on September 5, 2013, and 4 oz Sugar-Free Berry Children's Advil Suspension immediate container (bottle) submitted on March 2, 2012, and 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 20589/S-029**." Approval of this submission by FDA is not required before the labeling is used.

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 Jade Pham, Regulatory Project Manager at (301) 796-7031.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

THERESA M MICHELE
12/20/2013