DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20402/S-042

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Christine D. Chirdo
Director, US Regulatory Strategy
1 Giralda Farms
Madison, NJ 07940

Dear Ms. Chirdo:

Please refer to your Supplemental New Drug Application (sNDA) dated November 9, 2016, received November 9, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil® Liqui-Gels® (ibuprofen) capsules, 200 mg.

This "Prior Approval" supplemental new drug application proposes a new line extension product for a smaller liquid-filled capsule (identified as minis) as compared to the currently approved Advil® Liqui-Gels®.

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.

We remind you to remove the 'NEW' flag from the statement "NEW Smaller Capsule" on the principal display panel 6 months after introduction to the marketplace.

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 20-count immediate container (bottle) and carton, 80-count immediate container (bottle) and carton, 120-count immediate container (bottle), 200-count immediate container (standalone bottle with the GREAT VALUE! flag), 240-count immediate container (standalone bottle with the GREAT VALUE! flag), and 2x120-count carton labels submitted on November 9, 2016; and the 40-count immediate container (60 cc bottle) and carton, 40-count immediate container (100cc bottle) and carton, 160-count immediate container (150 cc bottle) and carton, 160-count immediate container (200cc bottle) and carton, 160-count non-child-resistant immediate container (156 cc standalone bottle), and the160-count non-child-resistant immediate container (225 cc standalone bottle) labels submitted on December 20, 2016, 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 20402/S-042**." 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 Tinya, Regulatory Project Manager, at (240) 402-4230.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
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/

KAREN M MAHONEY
03/08/2017