



NDA 18989/S-091

SUPPLEMENT APPROVAL

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

Dear Ms. Thomas:

Please refer to your Supplemental New Drug Application (sNDA) dated and received, May 23, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil® (ibuprofen) tablet, 200 mg.

This “Prior Approval” supplemental new drug application provides for instantly redeemable coupons (IRCs) to be affixed to previously approved count sizes (see supplement 088 approved on August 23, 2017).

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 identical to the labeling in the table below, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
“Save \$2.00 on Advil® 160ct or 200ct” IRC to be affixed to 200-ct EZ Open Advil Tablets stand-alone bottle (D000060606)	May 23, 2018
“Save \$1.00 on Advil® 160ct or 200ct” IRC to be affixed to 200-ct EZ Open Advil Tablets stand-alone bottle (D000060607)	May 23, 2018
“Save \$1.00 on any Advil® 20ct or larger” IRC to be affixed to 50-ct Advil gelatin-coated capsule-shaped tablets (Gel-Caplets) Carton (D000063735)	September 20, 2018
“Save \$2.00 on any Advil® 40ct or larger” IRC to be affixed to 50- & 100-ct Advil tablets carton; 50- & 100-ct Advil capsule-shaped tablets (Caplets) carton; and 50 & 100-ct Advil Gel-Caplets carton (D000063736)	September 20, 2018
“Save \$3.00 on any Advil® 80ct or larger” IRC to be affixed to 200-ct EZ Open Advil tablets stand-alone bottle and 200-ct Advil tablets carton (D000063737)	September 20, 2018

The FPL should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (April 2017, Revision 4)*. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 18989/S-091.**” 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 Sensie, 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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

KAREN M MAHONEY
11/14/2018

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