DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22565/S-003

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Wendy McManus
Sr. Manager, US Regulatory Strategy
Worldwide Regulatory Strategy
One Giralda Farms
Madison, NJ 07940

Dear Ms. McManus:

Please refer to your Supplemental New Drug Application (sNDA) dated September 29, 2016, received September 29, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil® Sinus Congestion & Pain (ibuprofen 200 mg, phenylephrine hydrochloride 10 mg) tablet.

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; introduction of a 30-count stock-keeping unit (SKU) (i.e., 10-count and 20-count combined with a clear adhesive label); a change to the list of symptoms relieved on the principal display panel; and, changes to style and layout.

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 Advil® Sinus Congestion & Pain tablet labeling as described and submitted on the respective dates in the table below. The labeling must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submission Date	Submitted Labeling	Represented Labeling
29 Sep 2016	20-count carton (outer container)	None
16 Dec 2016	10-count carton (outer container)	None
16 Dec 2016	30-count bonus carton (outer container)	None
29 Sep 2016	50-count dispenser (outer container)	None

16 Dec 2016	10-count blister (immediate container)	None
29 Sep 2016	1-count pouch (immediate container)	None
16 Dec 2016	$1 IRC (coupon)	None
16 Dec 2016	$2 IRC (coupon)	None

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 22565/S-003**." 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

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