DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19012/S-056 & S-057

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer, Inc.
McNeil Consumer Healthcare Division
Attention: Doris Roberts
Manager, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Ms. Roberts:

Please refer to your Supplemental New Drug Applications (sNDAs) for NDA 19012/S-056 and S-057 dated and received September 16 and November 23, 2016, respectively, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Motrin® IB (ibuprofen) tablets, 200 mg.

Each "Prior Approval" supplemental new drug application provides to update its respective labeling with safety-related information to warn consumers of the risks of cardiovascular events (i.e., increased chance of heart attack or stroke) associated with the use of nonsteroidal anti-inflammatory drugs (NSAIDS).

We have completed our review of these applications, as amended. These are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling, with the revisions listed above, 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 following:

NDA 19012/S-056

Submitted Labeling	Submission Date
50-count immediate container and outer carton	January 20, 2017
100-count (NDCs 50580-110-01 and -110-10) immediate container and carton	January 20, 2017
225-count immediate container	January 20, 2017
300-count (NDC 50580-110-38) immediate container	January 20, 2017

and outer carton	
60-count immediate container and carton (Hospital and Government)	January 20, 2017
2-count pouch	January 20, 2017
100-count (50 x 2-count pouch) dispenser	January 20, 2017

NDA 19012/S-057

Submitted Labeling	**Submission Date**
500-count (Hospital and Government) immediate container and outer carton	January 20, 2017

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 19012/S-056 & S-057**." 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 and this page is the manifestation of the electronic signature.

/s/

KAREN M MAHONEY
03/16/2017