DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-012/S-55

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 Application (sNDA) dated February 29, 2016, received February 29, 2016, and your amendments, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Motrin® IB (ibuprofen) 200 mg, tablets.

This "Prior Approval" supplemental new drug application proposes the following changes:

1) Modifies the Warnings **Do not use** section on carton and immediate containers:
   - Allergy alert: Do not use if you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
2) Changes corporate name on carton and immediate containers
3) Adds "Actual Size" and a picture of the product on the principal display panels to comply with California slack fill regulations
4) Revises inactive ingredient corn starch to modified starch

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 and with the minor editorial revisions listed below.

- The tablet imprint will be added to the tablet images in the labeling
- The statement "Total 100 coated caplets*" will appear on the PDP of the pouch dispenser labeling, below the statement "50 pouches of 2 coated caplets* each"

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 (FPL) must be identical to the 50-count carton and 50-count immediate container (bottle), 100-count carton (110-01 and

110-10) and 100-count immediate container (110-01 and 110-10) (bottle), 225-count immediate container (bottle), 300-count carton (110-37 and 110-38) and 300-count immediate container (110-37 and 110-38) (bottle), 60-count carton and 60-count immediate container (bottle) (Hospital/Government), 2-count immediate container (pouch), and 100-count (50 x 2-count pouch) carton (dispenser) submitted February 29, 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 19012/S-55**." 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, Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, M.D.
Deputy Director for Safety
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/

VALERIE S PRATT
08/18/2016