DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20516/S-033

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 December 18, 2015, received December 18, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Motrin® (ibuprofen 100 mg / 5 mL) oral suspension.

This supplemental new drug application proposes the following:

1) Modifies the current "Do not use" warning to add "ibuprofen or" so that it reads "Do not use if the child has ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer."
2) Metric only units – mL as the only standard unit of measure in the labeling
3) Corporate name change to Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division

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 (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the Children's Motrin® labels listed below, submitted on December 18, 2015. The expiration date and lot numbers must be included on all labels submitted as FPL, as indicated in the representative labels submitted on May 31, 2016, and the FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

- 4 fl. oz. grape flavored carton and bottle
- 4 fl. oz. bubblegum flavored carton and bottle
- 4 fl. oz. berry flavored carton and bottle
- 4 fl. oz. berry dye-free flavored carton and bottle
- 4 fl. oz. berry flavored (Hospital/Government) carton and bottle
- 4 fl. oz. berry flavored (Twin-Pack) panel card

- 1 fl. oz. berry flavored carton and bottle

The FPL 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 20516/S-033**." 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 Regulatory 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
06/16/2016