DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20601/S-021

SUPPLEMENT APPROVAL

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

Dear Ms. Roberts:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 6, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Motrin® (ibuprofen) chewable tablets, 100 mg.

This "Prior Approval" supplemental new drug application provides for the following revisions to the principal display panel and Drug Facts labeling:

Principal Display Panel

1. Changes the proprietary name from "Motrin® Junior Strength" to "Children's Motrin®"
2. Revises the statement of identity to reflect current compendial established name dosage form nomenclature for this specific drug product to read as:

   Ibuprofen Chewable Tablets, 100 mg
   Pain Reliever / Fever Reducer **(NSAID)**

4. Revises the tablet graphic image and adds the phrase "actual size"
5. Removes the "See New Warnings" flag
6. Revises the background graphic on the principal display panel

Drug Facts Labeling

Adds as the first bulleted directions statement: "[bullet] chew or crush tablets completely before swallowing"

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.

We also have the following recommendations:

Revise the dosage form under Drug Facts Active ingredient from "(in each tablet)" to "(in each chewable tablet)". This revision may be submitted in final printed labeling or in your annual report, whichever is submitted first.

Establish a compendial monograph for "ibuprofen chewable tablets".

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 below with the change noted above and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Dates Submitted
24-ct grape-flavored immediate container (bottle), with "Chew or crush tablets completely before swallowing," displayed on PDP	September 25, 2018
24-ct grape-flavored outer container (carton)	September 14, 2018

The final printed labeling 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 20601/S-021**." 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
10/02/2018