NDA 19012/S-058

SUPPLEMENT APPROVAL

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

Dear Ms. Haque:

Please refer to your supplemental new drug application (sNDA) dated and received October 10, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Motrin IB (ibuprofen) tablet, 200 mg.

We acknowledge receipt of your amendment dated September 10, 2020, which constituted a complete response to our February 4, 2020, action letter.

This Prior Approval supplemental new drug application provides for a new formulation and 24-count presentation.

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

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 enclosed labeling, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
24-count immediate container	October 10, 2019
50-count immediate container	October 10, 2019
60-count immediate container (For Hospital and Government Use Only)	October 10, 2019
100-count immediate container	October 10, 2019
225-count immediate container (non-child resistant packaging)	October 10, 2019
300-count immediate container	October 10, 2019

500-count immediate container (For Hospital and Government Use Only)	October 10, 2019
2-count pouch	October 10, 2019
24-count outer carton	October 10, 2019
50-count outer carton	October 10, 2019
60-count outer carton (For Hospital and Government Use Only)	October 10, 2019
100-count outer carton	October 10, 2019
225-count outer carton (non-child resistant packaging)	October 10, 2019
300-count outer carton	October 10, 2019
500-count outer carton (For Hospital and Government Use Only)	October 10, 2019
100-count (50 x 2-count pouch) dispenser	October 10, 2019

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 19012/S-058**." 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 FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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).

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

If you have any questions, call LCDR Sally Doan, Regulatory Project Manager, at (301) 796-8025.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Deputy Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
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/

NUSHIN F TODD
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