NDA 20325/S-043

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer, Inc.
McNeil Consumer Healthcare Division
Attention: Neethu Varghese
Manager, Regulatory Affairs CMC
7050 Camp Hill Road
Mail Stop 111
Fort Washington, PA 19034

Dear Neethu Varghese:

Please refer to your supplemental new drug application (sNDA) dated and received August 17, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pepcid AC (famotidine) tablet, 20 mg.

This "Prior Approval" supplemental new drug application provides for the addition of a new formula for Maximum Strength Pepcid AC, Icy Cool Mint Tablets, 20 mg.

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 in the "Drug Facts" format (21 CFR 201.66), where applicable, and identical to the following:

Submitted Labeling	Date Submitted
20–count carton Maximum Strength (20 mg) – Icy Cool Mint (bottle)	October 20, 2023
20–count immediate container Maximum Strength (20 mg) – Icy Cool Mint (bottle)	October 20, 2023
40–count carton Maximum Strength (20 mg) – Icy Cool Mint (bottle)	October 20, 2023
40–count immediate container Maximum Strength (20 mg) – Icy Cool Mint (bottle)	October 20, 2023

In addition, we have the following comments and recommendations:

1. Verify the distributor's name for your product and ensure that the copyright and trademark information on the packaging accurately aligns with the latest details provided in the most recent annual report.

2. Ensure the expiration date follows the format recommended in the information request dated November 20, 2023.

Reminder: Labeling submitted as annual reportable changes in an annual report are not considered approved labeling by the FDA.

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 20325/S-043**." 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 Cynthia Kim, PharmD, BCPS, Regulatory Project Manager, at 301-796-0879.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- 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
12/14/2023 06:41:59 PM