NDA 20801/S-020

SUPPLEMENT APPROVAL

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

Dear Mr. Morra:

Please refer to your supplemental new drug application (sNDA) dated and received May 3, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pepcid AC® EZ Chews (famotidine) 20 mg tablet.

This "Changes Being Effected" supplemental new drug application provides for modification of the kidney disease warning and addition of drug-drug interaction warning on the Principal Display Panel (PDP) in accordance with FDA's requests on June 29 and August 10, 2018.

APPROVAL & LABELING

We have completed our review of this application. 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 25-count carton (bottle) *Berries 'n' Cream Flavor* enclosed labeling submitted May 3, 2019, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

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 20801/S-020**." Approval of this submission by FDA is not required before the labeling is used.

[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.

While we note your assertion that you are not currently marketing this product, if you decide to market it in the future, submit a supplement to address the following:

1. Increase the prominence of the statement of identity (SOI) on all carton labeling (PDP) in relation to the proprietary name in bold font (See 21 CFR 201.61). Ensure that SOI and pharmacological category are distinct from the "EZ CHEWS" descriptor on the PDP.

2. Consistent with 2018 FDA Guidance "Quality Attribute Considerations for Chewable Tablets, change the dosage form in the SOI from "tablets" to "chewable tablets". To help prevent patients from swallowing the drug intact, include the following statement on the PDP of the container label and the carton label:

   Chew or crush tablets completely before swallowing.

3. Submit any coupon/money saving offer indicated on the outer carton of your current approved labeling and designate if this is printed on the inside panel of the carton, or if it is a leaflet inside the carton, if applicable.

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).

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

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

ENCLOSURE:

- Carton 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/

VALERIE S PRATT
10/29/2019 01:50:32 PM