DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 20325/S-033

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer, Inc.
McNeil Consumer Healthcare Division
Attention: Cindy Abraham
Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2210

Dear Ms. Abraham:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 9, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pepcid AC® (famotidine) tablets, 10 mg and 20 mg.

This "changes being effected" supplemental new drug application provides for "**Ask a doctor or pharmacist before use if you are** taking a prescription drug. Acid reducers may interact with certain prescription drugs." This supplemental new drug application also provides for a modification of the Drug Facts label to include "**Ask a doctor before use if you have**" subheading, add "[bullet] kidney disease" to the bottom of the list. These warnings are in response to the Agency's communications of June 29 and August 10, 2018.

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 and with the minor editorial revision and recommendation listed below.

1. Update the copyright date by replacing "20XX" with an actual date.

2. Remove the new warning flag six months after marketing.

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 listed in the below table and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	**Date Submitted**
30-count carton (blister),10 mg *Original Strength*	February 5, 2019
90-count carton (bottle),10 mg *Original Strength*	February 5, 2019
90-count immediate container (bottle),10 mg *Original Strength*	February 5, 2019
90-count carton (bottle) - *Alternative*, 10 mg *Original Strength*	March 6, 2019
90-count immediate container (bottle) - *Alternative*, 10 mg *Original Strength*	March 6, 2019
8-count carton (blister), 20 mg *Maximum Strength*	February 5, 2019
25-count carton (blister), 20 mg *Maximum Strength*	February 5, 2019
50-count carton (bottle), 20 mg *Maximum Strength*	February 5, 2019
50-count immediate container (bottle), 20 mg *Maximum Strength*	February 5, 2019
50-count carton (bottle) – *Alternative,* 20 mg *Maximum Strength*	March 6, 2019
50-count immediate container (bottle) – *Alternative,* 20 mg *Maximum Strength*	March 6, 2019

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 20325/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 Janice Adams-King, Safety Regulatory Health 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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

VALERIE S PRATT
04/09/2019 02:45:17 PM