DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20325/S-030

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer Inc.,
McNeil Consumer Healthcare Division
Attention: Patrice B. Wright, PhD
Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Dr. Wright:

Please refer to your Supplemental New Drug Application (sNDA) dated December 8, 2015, received December 8, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Original Strength Pepcid AC® (famotidine 10 mg) and Maximum Strength Pepcid AC® (famotidine 20 mg) tablets.

This supplemental new drug application proposes graphical revision to the principal display panel and the addition of the Poison Control Center telephone number to the Drug Facts 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 agreed-upon labeling text.

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 10-count 10 mg and the 5- and 8-count 20 mg blisters that were submitted on February 26, 2016, and to the labeling identified in the tables below. The labeling must also be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Original Strength PEPCID-AC 10 mg tablets

Submitted Labeling	Representative of Following SKUs	Date Submitted
30-count carton (blister)	None	June 3, 2016
90-count carton (bottle)	None	June 3, 2016
90-count carton (bottle) - *Alternative*	None	June 3, 2016
90-count immediate container (bottle)	None	June 3, 2016
90-count immediate container (bottle) - *Alternative*	None	June 3, 2016

Maximum Strength PEPCID-AC 20 mg tablets

Submitted Labeling	Representative of Following SKUs	Date Submitted
8-count carton (blister)	None	June 3, 2016
25-count carton (blister)	None	June 3, 2016
50-count carton (bottle)	None	June 3, 2016
50-count carton (bottle) - *Alternative*	None	June 3, 2016
50-count immediate container (bottle)	None	June 3, 2016
50-count immediate container (bottle) - *Alternative*	None	June 3, 2016

The FPL should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 20325/S-030**." 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 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

ENCLOSURES:
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VALERIE S PRATT
06/08/2016