DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020958/S-018

SUPPLEMENT APPROVAL

MSD Consumer Care, Inc.
Attention: Samuel Herald, M.S
Associate Director, CMC Regulatory Affairs
7050 Camp Hill Road, Mailbox #111
Fort Washington, PA 19034-2299

Dear Mr. Herald:

We have received your Supplemental New Drug Application (sNDA) dated and received January 31, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pepcid Complete (famotidine/calcium carbonate/ magnesium hydroxide) Tablets.

We also acknowledge receipt of your amendments dated May 14, June 17 and 20, 2013.

This "Changes Being Effected" Supplemental New Drug Application provides for the following:

- Removed the (b) (4) from the principal display panel (PDP).
- Changed the tamper evident statement on the label from (b) (4) to "Do not use if foil seal under bottle cap printed "SAFETY SEAL®" is open or torn."
- Changed the "Distributed by" portion of the label from "Johnson & Johnson • Merck Consumer Pharmaceuticals Co." to "McNeil Consumer Pharmaceuticals Co." to reflect change in ownership.
- Changed the storage statement in the Drug Facts label, ***Other information*** section, from "store at 20°-30°C (68°-86°F)" to "store at 20°-25°C (68°-77°F)".
- Added another bulleted statement that reads [bullet] "do not use if foil seal under bottle cap printed "SAFETY SEAL®" is open or torn" in the Drug Facts label, ***Other information*** section.
- Removed the Spanish toll-free phone number and added a "Call Collect" phone number to the Drug Facts label, "***Questions and Comments?***" section.
- Other minor modifications to the 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 and with the revisions listed below/indicated in the enclosed Drug Facts label.

Under the subheading "***Active ingredients***" replace the word "chewable" in the descriptor "***(in each tablet)***" so that the statement now reads "***(in each chewable tablet)***".

We also remind you of your June 20, 2013 commitment that this change will be made to the label at the time of next printing or within six months of this approval letter, whichever is sooner.

LABELING

Submit final printed labeling, with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the 25-, 50- and 100-count berry flavor and 25-count mint flavor bottle labels submitted on January 31, 2013, the 25- and 50-count tropical fruit flavor bottle labels submitted on May 14, 2013, and the 50-count mint flavor bottle label submitted on June 17, 2013, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling 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 020958/S-018**." 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 Daniel Reed, Regulatory Project Manager, at (301) 796-2220.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE:
Labeling

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

/s/

JOEL SCHIFFENBAUER
07/30/2013