DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022281/S-006

SUPPLEMENT APPROVAL

MSD Consumer Care, Inc.
Attention: Joanna Fleming
Associate, Regulatory Affairs
556 Morris Avenue
Mailstop S4-2-2161A
Summit, NJ 07901-1330

Dear Ms. Fleming:

Please refer to your Supplemental New Drug Application (sNDA) dated March 20, 2012, received March 21, 2012, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zegerid OTC® (omeprazole, 20 mg, and sodium bicarbonate, 1100 mg) capsules.

We acknowledge receipt of your amendment dated May 30, 2012.

This "Changes Being Effected" supplemental new drug application proposes the following change to the Warnings section of the "Drug Facts" label:

Following the subheading "**Stop use and ask a doctor if**," add a bullet that reads

- you get diarrhea

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 a minor editorial revision. In your email communication to a representative of the DNCE on August 14, 2012, MSD Consumer Care committed to implement the following minor editorial revision at the next printing or no later than January 17, 2013:

Revise the proposed warning under Drug Facts so that the "[bullet] you get diarrhea" becomes the fourth-bulleted statement under the subheading "**Stop use and ask a doctor if**."

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: 2-count (sample) carton, 14-count immediate container (bottle), 14-count carton and

42-count Club Pack carton labels submitted March 20, 2012, and 42-count carton label submitted May 30, 2012, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Although no revisions were made to the 2-count (sample) immediate container (bottle) labeling as part of this supplement, MSD Consumer Care should submit the 2-count (sample) immediate container (bottle) label as part of the FPL for this supplement in order to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement.

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 022281/S-006**." 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 questions, call Jeff Buchanan, Regulatory Project Manager, at (301) 796-1007.

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(S):
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/

JOEL SCHIFFENBAUER
09/18/2012