CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

022283Orig1s000

Trade Name:	Zegerid OTC® (Omeprazole, 20 mg, and Sodium Bicarbonate, 1680 mg)
Generic Name:	Omeprazole
Sponsor:	MSD Consumer Care, Inc.
Approval Date:	June 17, 2013
Indications:	Provides for the Use of Zegerid OTC® (Omeprazole, 20 mg, and Sodium Bicarbonate, 1680 mg) Powder for Oral Suspension For the Treatment of Frequent Heartburn

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022283

NDA APPROVAL

MSD Consumer Care, Inc.
Attention: Verna Mecadon
Executive Director, Regulatory Affairs
556 Morris Avenue, Mail Stop S4-2-216A
Summit, NJ 07901-1330

Dear Ms. Mecadon:

Please refer to your New Drug Application (NDA) dated March 19, 2008, received March 20, 2008, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zegerid OTC® (omeprazole, 20 mg, and sodium bicarbonate, 1680 mg) powder for oral suspension.

We acknowledge receipt of your amendments dated March 20, April 24, May 5 (two), June 6 and 9, July 2, 11 and 16, August 19 and 27, September 25 (three) and 28, October 8, 16, 22, 27 and 30, November 19, and December 18, 2008; January 13 (complete response), June 11, 22 and 25, August 5 and October 21, 2010; April 5 and 12, June 14 and 29 (complete response), September 23 and 30, October 13, November 22, 29 and 30, and December 15, 2011; December 14, 2012 (complete response); and January 25 and May 8, 2013. The December 14, 2012 submission constituted a complete response to our December 28, 2011 action letter.

This new drug application provides for the use of Zegerid OTC® (omeprazole, 20 mg, and sodium bicarbonate, 1680 mg) powder for oral suspension for the treatment of frequent heartburn.

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; however, we remind you that the "New" flag must be removed from the label and labeling, wherever it appears, 6 months following introduction of the label into the over-the-counter (OTC) marketplace.

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 (FPL) must be identical to the 1-count immediate container (1-dose packet), the 2-count sample carton, and the 14-count carton labels, as submitted December 14, 2012, 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 022283**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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.

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because there is evidence suggesting that Zegerid would be unsafe in all pediatric age groups. Children with symptoms of gastroesophageal reflux and heartburn should be evaluated by physicians, the treatment of frequent heartburn in the pediatric population should be under the direction of a physician, and children should be examined for possible complications**.**

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, contact 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

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/

JOEL SCHIFFENBAUER
06/17/2013