DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 22283/S-002

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Joanna Fleming
Associate Director, Regulatory Affairs
100 Bayer Boulevard, PO Box 915
Whippany, NJ 07981

Dear Ms. Fleming:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 1, 2017 and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zegerid OTC® (omeprazole 20 mg and sodium bicarbonate 1680 mg) powder for suspension.

This "Changes Being Effected" (CBE-0) supplemental new drug application provides for the addition of a new warning to inform consumers to stop use and ask doctor if they develop a rash or joint pain in accordance with the Agency's CBE-0 Request Letter dated April 6, 2017.
We have completed our review of this application. 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, 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 table below. The final printed labeling must also be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Submission Date
1-count immediate container (sachet)	May 1, 2017
2-count sample outer carton	May 1, 2017
14-count outer carton	May 1, 2017

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 (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 22283/S-002**." Approval of this submission by FDA is not required before the labeling is used. Remove the "New" flag from the 2-count sample and 14-count package size product labeling after 6 months of marketing.

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. 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
10/30/2017