DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22283/S-001

SUPPLEMENT APPROVAL

Bayer Healthcare, LLC
Consumer Care
Attention: Monica Hug
Associate Director, Regulatory Liaison
100 Bayer Boulevard
P.O. Box 915
Whippany, NJ 07981-0915

Dear Ms. Hug:

Please refer to your Supplemental New Drug Application (sNDA) dated December 11, 2014, received December 12, 2014, 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 oral suspension.

We acknowledge receipt of your amendment dated April 24, 2015. We also reference our October 31, 2014 CBE-0 supplement request letter.

This "Prior Approval" sNDA provides for changes to the carton and Drug Facts label to include the addition of the following label warnings requested in the October 31, 2014 CBE-0 supplement request letter:

> Under the Drug Facts Warnings heading "**Ask a doctor or pharmacist before use if you are taking**", adding the new bulleted statement:
>
> - methotrexate (arthritis medicine)
>
> and by revising the existing immunosuppressant drug interaction warning by adding mycophenolate mofetil:
>
> - tacrolimus or mycophenolate mofetil (immune system medicines).

This supplement also provides for the addition of the Bayer logo, changes to the carton design, revised distributor information, and changes to the "***Questions or Comments?***" section of the Drug Facts label.

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 Zegerid OTC 1-count immediate container (powder packet) label, the 2-count sample carton label and the 14-count carton label submitted April 24, 2015, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

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 22283/S-001**." Approval of this submission by FDA is not required before the labeling is used.

MARKET PACKAGE

Please submit one market package of the drug product when it is available.

If sending via USPS, please send to:

Mr. Jeffrey Buchanan
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 5461
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

If sending via any carrier other than USPS (e.g., UPS, DHL), please send to:

Mr. Jeffrey Buchanan
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 5461
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

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, M.D.
Acting 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
06/11/2015