DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021698/S-018

SUPPLEMENT APPROVAL

Boehringer Ingelheim
Attention: Judy Doyle
Director, Regulatory Affairs Consumer Health Care
900 Ridgebury Road, P.O. Box 368
Ridgebury, CT 06877

Dear Ms. Doyle:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 12, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zantac (ranitidine) 150 mg tablets.

We acknowledge receipt of your amendment dated February 10, 2015.

This sNDA provides for the following labeling revisions:

- Change in color and background design of the regular and cool mint flavor principle display panels (PDPs)
- Replacement of the (b) (4) with a graphic resembling that of a shield with the letter "Z"
- Change in graphics and placement of the statement "PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach"
- Addition of a tablet graphic near the declaration of net quantity of contents
- Revisions to the distributor information to reflect Boehringer Ingelheim ownership
- Changes to the "**Uses**", "**Do not use**" and "**Ask a doctor before use if**" sections of the Drug Facts label to make the marketed label consistent with the Drug Facts label changes identified in the November 5, 2003 supplement request letter for NDA 020520 and approved in S-003.
- Additional information added to the "**Questions?**" section of the Drug Facts label
- Addition of a "Sodium Free" claim to the "**Other Information**" section of the Drug Facts label of the regular flavor tablet
- Removal of the inactive ingredient (b) (4) from the "**Inactive Ingredients**" section of the cool mint flavor tablet 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 labels as listed below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Labels submitted on September 12, 2014:

- 1-ct immediate container (pouch), regular flavor
- 3-ct and 8-ct immediate container (blister), regular flavor
- 8-ct immediate container (blister), cool mint flavor
- 50-ct and 65-ct immediate container (bottle), regular flavor
- Consumer Information Leaflets, regular and cool mint flavors

Labels submitted on February 10, 2015:

- 50-ct and 65-ct immediate container (bottle), cool mint flavor
- 3-ct, 8-ct, and 24-ct blister cartons, regular flavor
- 8-ct and 24-ct blister cartons, cool mint flavor
- 50-ct and 65-ct bottle cartons, regular and cool mint flavors
- 80-ct pouch dispenser carton, regular flavor

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 021698/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}

Theresa Michele, M.D.
Director
Division of Nonprescription Drug Products
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/

THERESA M MICHELE
03/12/2015