DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020520/S-028

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 July 30, 2014, received July 30, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zantac (ranitidine hydrochloride) 75 mg tablets.

We acknowledge receipt of your amendments dated September 26, 2014, January 13, and January 16, 2015.

This sNDA provides for revisions to the Drug Facts label (DFL) including non-DFL-related revisions to the immediate container label, carton labeling, and consumer information leaflet labeling as follows:

- Revises Drug Facts label (DFL) Warnings and Other Information sections
- Changes color and background design of the principal display panel (PDP)
- Removes the national drug code (NDC) number from the PDP
- Adds country of origin statements
- Replaces the swirl graphic with a graphic of a shield with the letter “Z”
- Changes other graphics and moved the statement “PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach”
- Adds a tablet graphic near the net quantity of contents statement
- Revises the distributor information to reflect Boehringer Ingelheim ownership
- Reintroduces previously approved efficacy claim to the consumer information leaflet

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, 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-ct immediate container (pouch), 4-ct and 10-ct immediate container (blister), 60-ct and 80-ct immediate container

(bottle) labels and consumer information leaflet submitted on July 30, 2014; the 10-ct and 30-ct blister cartons, the 60-ct and 80-ct bottle cartons and the 100-ct pouch dispenser carton labels submitted on January 13, 2015 and the 4-ct blister carton label submitted on January 16, 2015, 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 020520 /S-028**." 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, MD
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
01/30/2015