DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020520/S-030

SUPPLEMENT APPROVAL

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Judy Doyle
Director, Drug Regulatory Affairs
900 Ridgebury Road, P.O. Box 368
Ridgefield, CT 06877

Dear Ms. Doyle:

Please refer to your Supplemental New Drug Application (sNDA) dated May 19, 2015, received May 19, 2015 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zantac 75® (ranitidine) tablets, 75 mg.

This "Prior Approval" supplement provides for the following:

- Adds "Regular Strength" product descriptor and other labeling revisions
- Revises labeling for the following SKUs: 4-, 10-, 30-, 60-, 80-, and 100-count
- Adds 2-, 40-, 90-, and 96-count SKUs and associated labeling
- Revises 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 (FPL), with the revisions listed above, 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.

Submit FPL identical to the following labeling submitted on May 19, 2015:

- 4 one-count immediate containers as 4-count blistercard
- 4-count carton (contains 4-count blistercard)
- 10 one-count immediate counters as 10-count blistercard
- 10-count carton (contains 10-count blistercard)
- 30-count carton (contains three 10-count blistercards)
- 40-count carton (contains four 10-count blistercards)
- 60-count immediate container (bottle)
- 60-count carton (contains bottle)
- 80-count carton (contains bottle)
- 90-count carton (contains 80-count bottle and 10 one-count pouches)
- 96-count immediate container (bottle)
- 96-count carton (bottle)
- 100-count dispenser carton (pouches)

Submit FPL identical to the following the labeling submitted on September 8, 2015:

- 2-count carton (holds two 1-count pouches)
- Consumer Information Leaflet

Submit FPL identical to the following the label submitted on November 6, 2015:

- 1-count immediate container (1-count pouch)

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 020520/S-030**." 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.

REQUIRED PEDIATRIC ASSESSMENTS

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.

Because none of these criteria apply to your application, you are exempt from this requirement.

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}

Karen Murry Mahoney, MD
Deputy 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/

KAREN M MAHONEY
11/20/2015