DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021698/S-023
NDA 020520/S-033

SUPPLEMENT APPROVAL

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

Dear Ms. Doyle:

Please refer to your supplemental New Drug Applications (sNDA) dated and received February 4, 2016, and your amendments dated February 18, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following sNDAs:

NDA 021698/S-023 Maximum Strength Zantac 150 (ranitidine) tablets, 150 mg

NDA 020520/S-033 Zantac 75 (ranitidine) tablets, 75 mg

These Prior Approval sNDAs propose a 90-degree rotation of the Drug Facts labeling for the 3-count (NDA 021698/S-023) blister carton labeling and the 4-count (NDA 020520/S-033) blister carton labeling to add a hang tab.

We have completed our review of these applications, as amended. These are 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 following submitted labeling and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

NDA 021698/S-023 (Maximum Strength Zantac 150)	NDA 020520/S-033 (Zantac 75)	Submission Date
3-count immediate container (blister)	4-count immediate container (blister)	February 18, 2016
3-count blister carton (hanger tab)	4-count blister carton (hanger tab)	February 4, 2016
consumer information leaflet (universal)	consumer information leaflet (universal)	February 18, 2016

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 these submissions "**Final Printed Labeling for approved NDA 021698/S-023**" and "**Final Printed Labeling for approved NDA 020520/S-033.**" Approval of these submissions 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 applications, 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 Jung Lee, Regulatory Project Manager, at (301) 796-3599.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
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
07/27/2016