DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022281/S-003

SUPPLEMENT APPROVAL

Schering-Plough Healthcare Products, Inc.
Attention: Laureina Greenberg
Associate, Regulatory Affairs
556 Morris Avenue
Summit, NJ 07901

Dear Ms. Greenberg:

Please refer to your Supplemental New Drug Application (sNDA) S-003 dated September 10, 2010, received September 13, 2010 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zegerid OTC (omeprazole 20mg and sodium bicarbonate 1100 mg) capsules.

We acknowledge receipt of your amendments dated November 3, 2010 and December 14, 2010

This "Changes Being Effected" supplemental new drug application provides for the revision of the current bulleted statement, "warfarin (blood-thinning medicine)," under the Drug Facts Warnings subheading, "Ask a doctor or pharmacist before use if you are taking" to read:

"**Ask a doctor or pharmacist before use if you are** taking
- warfarin or clopidogrel (blood-thinning medicine)"

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 enclosed labeling (the 42-count "Club Pack" SKU carton label submitted on November 3, 2010), 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 (October 2005).* 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 022281/ S-003**." 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.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Mary Vienna, Regulatory Project Manager, at (301) 796-4150.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure
Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOEL SCHIFFENBAUER
12/20/2010