DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022281/S-001 **SUPPLEMENT APPROVAL**

Schering-Plough HealthCare Products, Inc.
Attention: Anna Kalika
Manager, Regulatory Affairs
56 Livingston Avenue
Roseland, NJ 07068

Dear Ms. Kalika:

Please refer to your December 15, 2009 Supplemental New Drug Application (sNDA), received December 16, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zegerid OTC™ (omeprazole 20 mg and sodium bicarbonate 1100 mg) capsules.

We acknowledge receipt of your submissions dated January 7, 2010, March 18 and 26, 2010, and April 7, 2010.

This "Prior Approval" supplemental new drug application provides for the addition of a 2-count consumer sample package size and the associated labeling.

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 and with the minor editorial revisions listed below.

- Delete the periods from the end of each bulleted statement under "Tips for Managing Heartburn" found on the top flap of the carton.

LABELING

Submit final printed labeling, except with the revisions listed above, 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 (2-count carton and immediate container labels submitted April 7, 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-001**." Approval of this submission by FDA is not required before the labeling is used.

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 Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure(s)
Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22281	SUPPL-1	SCHERING PLOUGH HEALTHCARE PRODUCTS INC	ZEGERID OTC CAPSULES

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
04/15/2010