DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-281 **NDA APPROVAL**

Schering-Plough Healthcare Products, Inc.
Attention: William Cochran
Senior Manager, Regulatory Affairs
56 Livingston Avenue
Roseland, NJ 07068

Dear Mr. Cochran:

Please refer to your new drug application (NDA) dated March 10, 2008, received March 10, 2008, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for Zegerid OTC™ (20 mg omeprazole & 1100 mg sodium bicarbonate) capsules.

We acknowledge receipt of your amendments dated April 24, May 5, June 23, July 2, 9 and 11, August 19 and 21, September 25 and 28, October 8, 16, 22, 23, 27 and 30, and December 11, 2008; and January 21, February 16, March 25, June 6, July 29, September 23 and 30, October 22, and November 5, 2009.

The June 6, 2009 submission constituted a complete response to our January 6, 2009 action letter.

This new drug application provides for the use of Zegerid OTC™ (20 mg omeprazole & 1100 mg sodium bicarbonate) capsules for the treatment of frequent heartburn (occurs 2 or more days per week).

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.

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 (14-count bottle label and 14-count, 28- and 42-count carton labels submitted October 22, 2009), 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 22-281**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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.

We are waiving the pediatric study requirement for this application because there is evidence suggesting that OTC omeprazole would be unsafe in all pediatric age groups. Children with symptoms of gastroesophageal reflux and heartburn should be evaluated by physicians, the treatment of frequent heartburn in the pediatric population should be under the direction of a physician, and children should be examined for possible complications**.**

In addition, we request that you submit one copy of the introductory promotional materials you propose to use for this product to this division.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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) 786-4150.

Sincerely,

{See appended electronic signature page}

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

Enclosure

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22281	ORIG-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
12/01/2009