DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018052/S-032

SUPPLEMENT APPROVAL

Schering-Plough HealthCare Products, Inc.
Attention: Michal Sienko, Associate
Regulatory Affairs
56 Livingston Avenue
Roseland, NJ 07068-1733

Dear Mr. Sienko:

Please refer to your supplemental new drug application dated October 13, 2009, received October 14, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gyne-Lotrimin 7 (1% clotrimazole) vaginal cream.

This "Changes Being Effected" supplemental new drug application provides for the following labeling revisions:

- Placement of a trademark, logo or picture on the cream tube that will provide a clearly identifying characteristic which, when breached or missing will provide visible evidence to consumers that tampering has occurred per the regulation at 21 CFR 211.132(b)(1).
- Identification of the tamper-evident feature (of the cream tube) on the carton, on the immediate container (tube), and in the educational brochure per the regulation at 21 CFR 211.132(c) (1) and (2).
- Addition of verbiage to the educational brochure to identify the tamper-evident feature of the immediate container (tube) to be consistent with the carton label.
- Revision of the Drug Facts label in order to be consistent with the most recently approved label for other marketed vaginal antifungal drug products except for the product specific differences.

We have completed our review of this application. This supplement 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 (carton and immediate container (tube) labels, and consumer information leaflet (educational brochure) submitted October 13, 2009). It 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 18-052/S-032**." Approval of this submission by FDA is not required before the labeling is used.

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

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 Lewis, Regulatory Project Manager at (301) 796-0941.

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

Enclosures:
Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-18052	SUPPL-32	SCHERING PLOUGH HEALTHCARE PRODUCTS INC	GYNE-LOTRIMIN

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
04/12/2010