DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-308/S-009

Personal Products Company
Attention: Terry Glass, Esq.
Director, Regulatory Affairs
199 Grandview Road
Room SF101
Skillman, NJ 08558

Dear Ms. Glass:

Please refer to your supplemental new drug application dated December 2, 2003, received December 3, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Monistat 1 Combination Pack (1200 mg miconazole nitrate vaginal insert and 2 % miconazole nitrate cream).

We acknowledge receipt of your submissions dated December 12, 2003, January 16, January 20, February 13, August 11, August 17, August 18 and September 7, 2004.

This supplemental new drug application proposes to change the labeling instructions for Monistat 1 Combination Pack (miconazole nitrate) to allow for daytime administration of the drug product, in addition to the current bedtime administration, to treat vulvovaginal candidiasis.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the carton and Drug Facts labeling submitted September 7, 2004, and text for the consumer information leaflet submitted August 18, 2004), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-308/S-009." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

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

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Leah Cutter, Ph.D., Regulatory Project Manager, at (301) 827-2248.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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

/s/

Renata Albrecht
10/1/04 10:11:10 AM
NDA 21-308/S-009

Charles Ganley
10/1/04 11:35:30 AM