DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-308/S-010

Personal Products Company
Attention: Elizabeth Turek
Senior Director, Regulatory Affairs
199 Grandview Road, Room SF101
Skillman, NJ 08558

Dear Ms. Turek:

Please refer to your supplemental new drug application dated October 4, 2004, received October 5, 2004, 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 submission dated January 7, 2005.

This supplemental new drug application provides for an alternate soft flexible disposable applicator for the non-prefilled applicator package and provides associate revised labeling.

We have 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 approved draft labeling (carton label and Drug Facts labeling submitted October 4, 2004 and text for the consumer information leaflet submitted January 7, 2005) and must be formatted in accordance with the requirements of 21 CFR 201.66.

In addition, make the following minor label change at the time of next printing and provide labeling that reflects this change in the next annual report:

> In accordance with 21 CFR 201.66(c)(9), only bold the telephone number listed under the ***"Questions?"*** heading in the **Drug Facts** label.

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

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

Sincerely yours,

{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

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

/s/

Charles Ganley
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