DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-670/S-014

Personal Products Company
Attention: Renee L. Alliegro
Manager, Regulatory Affairs
199 Grandview Road
Skillman, NJ 08558-9418

Dear Ms Alliegro:

Please refer to your supplemental new drug application dated November 16, 2006, received November 17, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Monistat 3-Combination Pack (200 mg, miconazole nitrate vaginal suppositories and 2% miconazole nitrate cream).

We acknowledge receipt of your submissions dated November 8, and November 16, 2006, and March 16, 2007.

This supplemental new drug application provides for an alternate preparation of the vaginal suppository as a gelatin-encapsulated vaginal suppository, and associated labeling changes.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the revisions indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical to, and include the revisions indicated, to the enclosed labeling (carton and Drug Facts labeling and Consumer Information Leaflet submitted March 16, 2007) and must be in the "Drug Facts" format (21 CFR 201.66) where applicable. These revisions are terms of the approval of this application. 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.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement "NDA 20-670/S-014**." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the flag "New!" 6 months after introduction into the marketplace.

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, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

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

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