DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-261/S-004

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

Dear Ms. Glass:

Please refer to your supplemental new drug application dated January 23, 2003, received January 24, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Monistat®3 (miconazole nitrate) Cream Combination Pack.

We acknowledge receipt of your submissions dated March 31, and May 29, 2003.

This supplemental new drug application provides for unfilled applicators with internal vaginal cream in combination with the external vulvar cream.

We completed our review of this application as amended, and it 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 submitted labeling (outer carton labeling, consumer information leaflet, immediate container (tube), and inner carton (applicator box) labeling) submitted on May 29, 2003, 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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-261/S-004." Approval of this submission by FDA is not required before the labeling is used.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Laura E. Shay, Regulatory Project Manager, at (301) 827-2274.

Sincerely,

{See appended electronic signature page}

Charles Ganley, MD
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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