DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-308/S-008

Personal Products Company
Attention: Terry A. 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 August 1, 2003, received August 4, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Monistat 1 Combination Pack (miconazole nitrate vaginal insert and miconazole nitrate cream) 1200 mg insert and 2 % cream.

We acknowledge receipt of your submissions dated September 18, November 13, November 14, and November 21, 2003.

This supplemental new drug application proposes the following packaging changes and coinciding labeling revisions:

- a change in the(b)(4)-of the pre-filled applicator,
- a change in the-------iner/closure system such that the current secondary packaging (over pouch) becomes the primary container/closure system, and
- the addition of an alternative one-piece applicator plunger.

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 submitted labeling (carton and Drug Facts labeling, pouch labeling and consumer information leaflet submitted November 21, 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* (January 1999). 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 21-308/S-008." 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, HF-2
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}

Curtis Rosebraugh, M.D.
Deputy 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/

Curtis Rosebraugh
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