DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-670/S-011

Personal Products Company
Attention: Ms. Terry Glass
Director, Regulatory Affairs
199 Grandview Road, Room SF 101
Skillman, New Jersey 08558

Dear Ms. Glass:

Please refer to your supplemental new drug application dated October 29, 2002, received October 30, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Monistat®3(miconazole nitrate suppositories and external cream) Combination Pack.

This "Changes Being Effected" supplemental new drug application provides for labeling changes made to the Monistat®3 Combination Pack to include additional instructions for disposable vaginal suppository applicators.

We completed our review of this application 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 (consumer information leaflet) and carton labels submitted October 29, 2002), 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 20-670/S-011." Approval of this submission by FDA is not required before the labeling is used.

In addition, please note the following labeling recommendations for both package configurations (reusable applicator and disposable applicator), unless otherwise specified. Implement these changes at the next printing and provide an updated version in the following annual report.

1. Carton Labeling (Principal Display Panel: top, bottom, and side panels)

A. Revise the declaration of net quantity of contents to distinctly identify both products within the package.

B. Revise the product name on the top, bottom and side panels to reflect the USP name for miconazole nitrate vaginal suppositories as follows:
"MONISTAT® 3
COMBINATION PACK
Miconazole Nitrate Vaginal Suppositories (200 mg) and External Cream (2%)
Vaginal Antifungal"

2. Drug Facts

A. Under ***Warnings***, bold the entire warning "**Do not use if you have never had a vaginal yeast infection diagnosed by a doctor**".

B. Bold bullets one and two under the section "**Ask a doctor before use if you have**".

C. Under the section "**Ask a doctor before use if you have**", add the bolded sentence "**You may have a more serious condition.**" directly after the first sentence in the second bullet.

D. Under the section "**When using this product**", add a third bullet stating "mild increase in vaginal burning, itching or irritation may occur".

E. Bold the entire section under "**Stop use and ask a doctor if**".

F. Under "**Stop use and ask a doctor if**", revise the third bullet from "you get a rash, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge" to " you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge".

G. Under ***Directions***, revise the first bulleted statement to read "before using this product read the enclosed consumer information leaflet for complete instructions and information".

H. Under the "***Directions***" section of the reusable applicator label, revise the third bulleted statement to read "suppositories: insert 1 suppository into the vagina at bedtime for 3 nights in a row. Wash applicator after use."

I. Under "***Other information***", revise the word "opened" in the second bullet to "open". Consider reordering the bullets to be in accordance with recently approved labeling (NDA 21-308, Monistat 1 Combination Pack).

J. Under "***Other information***", identify/describe the tamper-evident feature of the suppository packaging in accordance with 21 CFR 211.132.

K. Provide the graphic specifications used for ***Drug Facts*** (e.g. the type sizes, fonts, bullet sizes, hairline sizes, barline sizes, etc.) in accordance with 21 CFR 201.66(d).

3. Consumer Information Leaflet

Revise the Consumer Information Leaflet to be consistent with changes made to the carton label and Drug Facts.

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

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 Laura 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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