DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-308/S-005

Personal Products Company
Attention: Terry Glass
Director, Regulatory Affairs
199 Grandview Road, Room SF101
Skillman, NJ 08558

Dear Ms. Glass:

Please refer to your supplemental new drug application dated September 12, 2002, received September 12, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Monistat® 1 (miconazole cream) Combination Pack.

This "Changes Being Effected" supplemental new drug application provides for changes in the carton label, Drug Facts, and the Consumer Information Leaflet, to reflect the addition of secondary packaging consisting of a foil pouch over-wrap with a silica desiccant packet.

We have 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 September 12, 2002, and desiccant labeling submitted October 3, 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 21-308/S005." Approval of this submission by FDA is not required before the labeling is used.

In addition, please note the following recommendations for incorporation in your next printing:

1. Under ***Other information,*** in the Drug Facts section of the carton, add the following bullet to inform the consumer about the silica desiccant packet and to be consistent with the **Other Information** section of the Consumer Information Leaflet.

- do not eat or insert into the vagina the moisture adsorbent pouch

2. Use the word "adsorbent" rather than(b)------- ----to describe the silica desiccant packet, everywhere it occurs in the labeling.

3. In the section **How Should I Use MONISTAT® 1 Combination Pack with Prefilled Applicator?** on the back side back side of the consumer information leaflet, change the word -------- to "eat" in step 1.

4. Under **Other Information** on the back side of the consumer information leaflet, change the word (b)----------to "eat" in the second bulleted statement.

5. Remove the word "New!" in the phrase "New! Prefilled Applicator" on the hanging flap after 6 (b)---------OTC marketing.

The silica desiccant ("moisture adsorbent pouch") pouch labeling is acceptable. We note that this may be the first time a silica desiccant pouch has been used in an OTC product package. Although we do not believe that the labeling of this pouch poses a safety concern to the consumer, if future reports through MEDWATCH indicate that consumers are confusing the "moisture adsorbent pouch" with the drug product ovule, we will reevaluate the labeling of this product.

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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