DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-450/S-052

Personal Products Company
Attention: Ms. Terry Glass, Esq.
Director, Regulatory Affairs
199 Grandview Road
Skillman, N.J 08558

Dear Ms. Glass:

Please refer to your supplemental new drug application dated January 18, 2002, received January 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Monistat 7 Cream Combination Pack.

We also refer to your submission dated June 13, 2002.

Your submission of June 13, 2002, constituted a complete response to our May 22, 2002 action letter.

This supplemental new drug application provides for a revised labeling for a co-packaged product that includes seven prefilled applicators (each containing 100 mg of 2% miconazole nitrate cream) and a 9 g tube of 2% miconazole nitrate cream for external use.

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 (consumer information leaflet and carton labels submitted June 13, 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 17-450/S-052." Approval of this submission by FDA is not required before the labeling is used.

In addition, please note the following recommendations:

1. Delete "New!" in the phrase on the hanging flap which reads "New! With Cream for External Use"after 6 months of OTC marketing.

2. In your Consumer Information Leaflet, insert a period after the second direction, first sentence, in the "Directions for using the Prefilled Applicators," under the heading "How Should I Use MONISTAT 7 Vaginal Cream Combination Pack?". This change can be submitted in the next annual report.

We request that you submit one copy of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print to the Division of Over-the-Counter Drug Products.

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 Tia Frazier, Regulatory Project Manager, at (301) 827-2271.

Sincerely,

{See appended electronic signature page}

Linda M. Katz, M.D., M.P.H.
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/

Linda Katz

8/7/02 11:10:17 AM