DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-308/S-004

Personal Products Comapny
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 February 14, 2002, received February 15, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Monistat 1 (miconazole nitrate) Combination Pack.

We also refer to your submissions dated May 9, July 16, and August 22, 2002.

Your submission on July 16, 2002, constituted a complete response to our June 14, 2002, action letter.

This supplemental new drug application provides for a revised carton to comply with the content and format requirements of 21 CFR 201.66.

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 Consumer Information Leaflet submitted July 16, 2002, and for the carton label submitted on August 22, 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/S-004." Approval of this submission by FDA is not required before the labeling is used.

In addition, you are reminded to remove the word “New!” in the phrase “New! Prefilled Applicator” on the hanging flap after 6 months of OTC marketing.

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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