DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-308

Personal Products Company
Attention: Barbara Popek
Manager, Regulatory Affairs
199 Grandview Road, Room SF108
Skillman, NJ 08558

Dear Ms. Popek:

Please refer to your new drug application (NDA) dated August 31, 2000, received September 1, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MONISTAT® 1 COMBINATION PACK (miconazole nitrate 1200 mg soft gel vaginal insert and miconazole nitrate cream, 2%).

We acknowledge receipt of your submissions dated:

October 11, 2000	January 3, 2001	May 25, 2001
October 24, 2000	March 19, 2001	June 8, 2001
October 26, 2000	March 23, 2001	June 21, 2001
October 30, 2000	March 30, 2001	June 22, 2001
November 22, 2000	April 12, 2001	June 26, 2001
December 1, 2000	April 20, 2001	June 27, 2001
December 20, 2000	May 4, 2001	

as well as your facsimile transmissions dated May 30, June 15, June 18, June 26, and June 27, 2001.

This new drug application provides for the use of MONISTAT® 1 COMBINATION PACK for the treatment of vulvovaginal candidiasis.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (carton label, blister pack label, 9 gram tube label, and consumer information leaflet) and must be formatted in accordance with the requirements of 21 CFR 201.66. Marketing the product with FPL that is not identical to the approved labeling text and "Drug Facts" format may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (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 but no 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 NDA 21-308." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated June 27, 2001. This commitment is listed below.

1. Description of Commitment: To conduct a study to evaluate conditions of use of OTC 1200 mg miconazole nitrate soft gel vaginal insert combination pack in the treatment of vaginal yeast infection.

Protocol Submission:	Within 1 month of the date of this letter
Study Start:	Within 6 months of the date of this letter
Final Report Submission:	Within 24 months of the date of this letter

We further remind you of your commitment to use the approved labeling for the Vaginal Insert Blister Packs after exhausting the current inventory. During the June 15, 2001 teleconference between Personal Products Company and the Agency, you estimated that the Vaginal Insert Blister Packs would be exhausted during the initial launch. We agreed that you may use the current inventory until the current inventory is exhausted.

We also remind you of your commitment to use the approved labeling for the 9 gram tubes within six months of approval of this NDA. We agreed that you may use the current inventory for a period not to exceed six months from the date of approval of this NDA.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of this commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to this postmarketing study commitment must be prominently labeled "**Postmarketing Study Protocol," "Postmarketing Study Final Report," or "Postmarketing Study Correspondence."**

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). The submitted over-the-counter product labeling provides directions for use by children 12 years or older. We are waiving the pediatric study requirement for children under 12 years old on the basis that vaginal yeast infection in the pre-pubertal child does not lend itself to self-diagnosis and over-the-counter treatment.

In addition, please submit one copy of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final

print. For administrative purposes, this submission should be sent to the NDA and should be identified as new correspondence to the approved NDA 21-308.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

In line with Center for Drug Evaluation and Research policy, oversight of this application is being transferred to the Division of Over-the Counter Drug Products.

If you have any questions, call Daniel Keravich, Regulatory Project Manager, at (301) 827-2248.

Sincerely yours,

{See appended electronic signature page}

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosures