Public Health Service

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 20-827/S-006

Personal Products
Attention: Barbara Popek
Manager Regulatory Affairs
199 Grandview Road
Skillman, New Jersey 08558

Dear Mrs. Popek:

Please refer to your new supplemental drug application (SNDA) dated August 31, 1999, received September 1, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Monistat® 3 (miconazole nitrate cream 4%) Vaginal Cream.

This supplemental new drug application provides revisions in the cream tube labeling by increasing the font size of the phrases "For vaginal use only. Do not use in eyes or take by mouth."

We have completed the review of this application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (immediate container labels submitted August 31, 1999) 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 20-827." Approval of this submission by FDA is not required before the labeling is used.

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.

If you have any questions, call Tia Frazier, R.N., Regulatory Health 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

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