DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-450/S-055

Johnson & Johnson Healthcare Products
Attention: Renee L. Alliegro
Manager, Regulatory Affairs
199 Grandview Road
Skillman, New Jersey 08558-9418

Dear Ms. Alliegro:

Please refer to your supplemental new drug application dated April 21, 2008, received April 22, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Monistat 7 (2% miconazole nitrate) vaginal cream.

We also acknowledge receipt of your submissions dated August 11, 15 and 18, 2008.

This supplemental new drug application provides for a new manufacturing site and associated labeling changes.

We have completed our review of this application. 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 (reusable applicator carton label, reusable applicator consumer information leaflet, reusable applicator cream tube label, and disposable applicator cream tube label submitted April 21, 2008, disposable applicator consumer information leaflet submitted August 15, 2008, and disposable applicator carton label submitted August 18, 2008), and must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 17-450/S-055**." Approval of this submission by FDA is not required before the labeling is used.

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 Mary Lewis, Regulatory Project Manager, at (301)796-0941.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Joel Schiffenbauer

8/21/2008 02:57:00 PM