DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-261/S-007

Johnson & Johnson Consumer & Personal Products Worldwide
Division of Johnson & Johnson Consumer Companies, Inc.
Attention: Nader Fotouhi
Manager, Regulatory Affairs
Agent for Johnson & Johnson Healthcare Products
199 Grandview Road
Skillman, New Jersey 08558-9418

Dear Mr. Fotouhi:

Please refer to your supplemental new drug application dated July 2, 2008, received July 3, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Monistat 3 Vaginal Cream (4% miconazole nitrate vaginal cream and 2% miconazole nitrate external vulvar cream).

We also acknowledge receipt of your submissions dated August 11 and 18, 2008 and October 14, 2008.

This supplemental new drug application provides for an alternate manufacturing site ((b) (4)) and associated labeling changes. (This supplement also provides for a new testing facility for (b) (4) Testing.)

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 (25g vaginal cream tube label, 9g external vulvar cream tube label and consumer information leaflet submitted July 2, 2008, enclosed; and carton label with Drug Facts for the package configuration with 3 disposable applicators submitted October 14, 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 21-261/S-007**." 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

Enclosure:

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

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