DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-827/S-014 **SUPPLEMENT APPROVAL**

Johnson & Johnson Healthcare Products
Consumer and Personal Products Worldwide
Attention: John Jacobs, Vice President
Global Regulatory Affairs
185 Tabor Road
Morris Plains, New Jersey 07950

Dear Mr. Jacobs:

Please refer to your supplemental new drug application dated April 7, 2009, received April 8, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Monistat® 3 (4% miconazole nitrate) vaginal cream.

We acknowledge receipt of your submission dated September 22, 2009.

This "Changes Being Effected" (CBE-30) supplemental new drug application provides for the addition of the Draxis facility as an alternate packaging site and the associated labeling changes.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the labeling (immediate container, carton and consumer information leaflet) submitted on April 7, 2009. These must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling (FPL) for approved NDA20-827/S-014**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
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 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

cc: Nader Fotouhi, Ph.D.
Manager, Regulatory Affairs
J&J Consumer & Personal Products Worldwide
199 Grandview Road
Skillman, New Jersey 08558-9418

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20827	SUPPL-14	JOHNSON AND JOHNSON HEALTHCARE PRODUCTS	MONISTAT 3

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
10/02/2009