DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020310/S-019

SUPPLEMENT APPROVAL

McNeil Consumer Healthcare
Attention: Lynn Kruger, MBA
Associate Director, Global Regulatory Affairs – CMC
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Ms. Kruger:

Please refer to your Supplemental New Drug Application (sNDA) dated May 19, 2010, received May 20, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nizoral® (ketoconazole) shampoo, 1%.

We acknowledge receipt of your submissions dated July 2, , and August 6, 2010.

This "Prior Approval" supplemental new drug application proposes the following changes:

- Change in the drug product manufacturing site from Janssen Cilag S.p.A Latina, Italy to the Janseen Pharmaceutica N.V. Beerse, Belgium site
- Increase in batch size
- Optimized manufacturing process
- Updated in-process specifications
- Updated suppliers of non-compendial excipients
- Updated non-compendial excipient specifications and analytical methods
- Revised drug product specifications and analytical methods
- Updated container closure specifications
- Revised post-approval stability protocol
- 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 enclosed labeling (4-, and 7-fl. oz. immediate container (bottle) labels, and carton labels submitted May 19, 2010), and 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 (June 2008)." 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 for approved NDA 020310/S-019**." Approval of this submission by FDA is not required before the labeling is used.

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: Carton and Immediate Container Labeling

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
09/17/2010