DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-385/S-003

Johnson & Johnson Consumer & Personal Products Worldwide
Attn.: Stephanie J. Davis
Associate Director, Regulatory Affairs
199 Grandview Road
Skillman, NJ 08558-9418

Dear Ms. Davis:

Please refer to your supplemental new drug application dated July 21, 2005, received July 22, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ertaczo™ (sertaconazole nitrate) Cream, 2%.

This "Prior Approval" supplemental new drug application provides for new 60 gram and 90g package sizes for the drug product.

We acknowledge your communication on November 22, 2005, withdrawing the 90 gram package size from the supplement, and acknowledge your commitment to revise the product package insert at the next printing to remove reference to the 90 gram package size.

We have completed our review of this supplemental application and it is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call CDR Frank H. Cross, Jr., Regulatory Project Manager, at (301) 796-0876.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief,
Branch 8,Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment,
Center for Drug Evaluation and Research,
U. S. Food and Drug Administration

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/s/

Hasmukh Patel

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