DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-579/S-026
NDA 19-641/S-022
NDA 19-964/S-021

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Kathleen F. Dusek, R.Ph.
Associate Director, Marketed Products-Regulatory Affairs
1125 Trenton-Harbourton Road
P.O. Box 200
Titusville, New Jersey 08560

Dear Ms. Dusek:

Please refer to your supplemental new drug applications listed below, dated January 6, 2004, received January 7, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act:

NDA #	Drug Product	Supplement number
19-579	TERAZOL® 7 (terconazole) Vaginal Cream 0.4%	S-026
19-641	TERAZOL® 3 (terconazole) Vaginal Suppositories 80 mg	S-022
19-964	TERAZOL® 3 (terconazole) Vaginal Cream 0.8%	S-021

We acknowledge receipt of your submissions dated June 24, 2004.

These supplements provide for the removal of all references to pre-filled applicators and replace information concerning the vaginal suppository in the TERAZOL® labeling.

We have completed the review of these supplemental new drug applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the final printed labeling dated January 6, 2004 (enclosed). Accordingly, these supplemental applications are approved effective on the date of this letter.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
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 Robin Anderson, R.N., M.B.A., Labeling Reviewer, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
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/

Renata Albrecht

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