DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-579/S-016, S-020
NDA 19-641/S-016, S-018
NDA 19-964/S-011, S-014

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Ms. Purve Patel
1125 Trenton-Harbourton Road
P.O.Box 200
Titusville, New Jersey 08560

Dear Ms. Patel:

Please refer to your supplemental new drug applications listed below, dated July 7, 1999, received July 8, 1999, 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-016
19-641	TERAZOL® 3 (terconazole) Vaginal Suppositories 80 mg	S-016
19-964	TERAZOL® 3 (terconazole) Vaginal Cream 0.8%	S-011

We acknowledge receipt of your submission dated February 7, 2003.

These supplements provide for the addition of a new **Geriatric Use** subsection at the end of the **PRECAUTIONS** section of the package insert, as follows:

Geriatric Use:

Clinical studies of TERAZOL® did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Please also refer to your supplemental new drug applications listed below, dated June 7, 2001, received June 8, 2001, 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-020
19-641	TERAZOL® 3 (terconazole) Vaginal Suppositories 80 mg	S-018
19-964	TERAZOL® 3 (terconazole) Vaginal Cream 0.8%	S-014

We acknowledge receipt of your submissions dated August 3, 2001, and February 7, 2003.

These "Changes Being Effected" supplemental new drug applications provide for the following changes to the labeling:

Carton

1. The following double underlined sentence was added to the Dosage section of the folding cartons of the sample put ups of the products.

   Dosage: One applicator intravaginally once daily. Do not reuse applicator.

Package Insert

2. The following double underlined sentence was added to **PATIENT INSTRUCTIONS, Cleaning the applicator** and to **HOW TO USE, Cleaning the applicator** in the patient instruction section of the package insert.

   Cleaning the applicator (Does not apply to sample applicators, which are for one time use only)
   .

We have completed our review of these applications as amended. These applications are 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 enclosed labeling (text for the folding carton and text for the patient instruction section of the package insertsubmitted on February 7, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDAs (January 1999) as soon as it is available, in no case more than 30 days after it is printed to each application. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-579/S-016 and S-020, NDA 19-641/S-016 and S-018, and NDA 19-964/S-011 and S-014." Alternatively, you may submit 20 paper copies of

the FPL. Please mount individually ten of the copies on heavyweight paper or similar material. Approval of these submissions by FDA is not required before the labeling is used.

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

Please submit one market package of each drug product when it is available.

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 Christine Lincoln, RN, MS, MBA, 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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