DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-579/S-025
NDA 19-964/S-020

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
ATTN: Purve Patel
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Dear Ms. Patel:

Please refer to your supplemental new drug applications dated March 21, 2003, received March 24, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product	NDA Number	Supplement Number
TERAZOL® 7 (terconazole) Vaginal Cream 0.4%	19-579	S-025
TERAZOL® 3 (terconazole) Vaginal Cream 0.8%	19-964	S-020

These supplemental new drug applications provide for the replacement of the reusable applicator with prefilled applicators for these two products and deletion of all labeling regarding TERAZOL® 3 (terconazole) Vaginal Suppositories 80 mg from the combined package insert as reflected below and in the attached marked-up package insert:

Package insert

1. PRODUCT TITLE
- The descriptor "(prefilled applicators)" was added to each product title.
- Reference to TERAZOL® 3 (terconazole) Vaginal Suppositories 80 mg has been deleted.

2. DESCRIPTION
- Reference to TERAZOL® 3 (terconazole) Vaginal Suppositories 80 mg has been deleted.

3. CLINICAL PHARMACOLOGY
- Reference to TERAZOL® 3 (terconazole) Vaginal Suppositories 80 mg has been deleted.

4. INDICATIONS AND USAGE
- Reference to TERAZOL® 3 (terconazole) Vaginal Suppositories 80 mg has been deleted.
- The descriptor "(prefilled applicators)" was added to each product title.

5. CONTRAINDICATIONS
- Reference to suppositories has been deleted.

6. PRECAUTIONS, General:
- The precaution regarding the suppositories has been deleted.

7. PRECAUTIONS, Drug Interactions:
- Reference to TERAZOL® 3 (terconazole) Vaginal Suppositories 80 mg has been deleted.

8. PRECAUTIONS, Pregnancy: Teratogenic Effects:
- Reference to TERAZOL® 3 (terconazole) Vaginal Suppositories 80 mg has been deleted.

9. ADVERSE REACTIONS
- The TERAZOL® 3 Vaginal Suppositories 80 mg susbsection has been deleted.

10. DOSAGE AND ADMINISTRATION
- The descriptor "(prefilled applicators)" was added to each product title.
- "Full" has been replaced with "prefilled."
- Reference to TERAZOL® 3 (terconazole) Vaginal Suppositories 80 mg has been deleted.

11. HOW SUPPLIED
- The descriptor "(prefilled applicators)" was added to each product title.
- "Tubes with an ORTHO® Measured Dose Applicator" was replaced with "prefilled applicator."
- Reference to TERAZOL® 3 (terconazole) Vaginal Suppositories 80 mg has been deleted.

12. PATIENT INSTRUCTIONS
- The descriptor "(prefilled applicators)" was added to each product title.
- Instructions for filling the applicator were deleted.
- Instructions for cleaning the applicator were deleted.
- Reference to TERAZOL® 3 (terconazole) Vaginal Suppositories 80 mg has been deleted.

Carton labels
- "Tube and Applicator" was replaced with "(prefilled applicators)."
- The net weight was revised.
- A warning was added to prevent use if the applicator wrapper is missing or damaged.

Immediate container label
- The tube label for each product has been eliminated.

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text (enclosed).

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (carton labels submitted March 21, 2003). Please note that all previous revisions as reflected in the most recently approved package insert (NDA 19-579/S-016 and NDA 19-964/S-011 approved March 11, 2003) must be included.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Please submit a Microsoft Word version of the FPL in the same submission with the PDF version. Alternatively, you may submit 20 paper copies of the FPL as

soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submission should be designated "FPL for approved supplement NDA 19-579/S-025, NDA 19-964/S-020." Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for the prefilled applicators for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of each drug product when 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 Christina H. Chi, Ph.D., Regulatory Project Manager, 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

Enclosure (package insert)

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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