DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019579/S-035
NDA 019641/S-028
NDA 019964/S-030

SUPPLEMENT APPROVAL

Janssen Pharmaceuticals, Inc.
Attention: Andrea Kollath, DVM
Director, Regulatory Affairs
1000 U.S. Highway 202 South
P.O. Box 300
Raritan, NJ 08869-0602

Dear Ms. Kollath:

Please refer to your Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) as listed below:

NDA #	Supplement	Drug Name & Dosage Form	Letter Date	Receipt Date
19579	S-035	Terazol 7 (terconazole) Vaginal Cream, 0.4%	October 3, 2012	October 3, 2012
19641	S-028	Terazol 3 (terconazole) Vaginal Suppositories, 80 mg	October 3, 2012	October 3, 2012
19964	S-030	Terazol 3 (terconazole) Vaginal Cream, 0.8%	October 3, 2012	October 3, 2012

We acknowledge receipt of your amendments dated July 26, and September 18, 2013.

These "Changes Being Effected" supplemental new drug applications provide for the following revisions to the package insert:

- Addition of a new **WARNINGS** section and text regarding reported anaphylaxis and toxic epidermal necrolysis
- Addition of a **Post-marketing Experience** subsection to the **ADVERSE REACTIONS** section.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at (301) 796-1202.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Acting Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
09/26/2013