DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019579/S-037
NDA 019641/S-030
NDA 019964/S-032

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 #	Supple-ment	Drug Name & Dosage Form	Letter Date	Receipt Date
19579	S-037	Terazol 7 (terconazole) Vaginal Cream, 0.4%	January 23, 2014	January 23, 2014
19641	S-030	Terazol 3 (terconazole) Vaginal Suppositories, 80 mg	January 23, 2014	January 23, 2014
19964	S-032	Terazol 3 (terconazole) Vaginal Cream, 0.8%	January 23, 2014	January 23, 2014

We acknowledge receipt of your amendments dated February 12 and July 22, 2014.

The January 23, 2014, submission constituted a complete response to our September 20, 2013, action letter.

These "Prior Approval" supplemental new drug applications provide for revised product labeling that pertain to CLINICAL PHARMACOLOGY, PRECAUTIONS (Drug Interactions and Pregnancy subsections), ADVERSE REACTIONS, and OVERDOSAGE sections of the TERAZOL USPI dated September 2012.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is 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 this NDA, 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 these supplemental applications, 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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
Director
Office of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
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
07/23/2014