DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20083/S048
NDA 20083/S049
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SUPPLEMENT APPROVAL

Janssen Pharmaceuticals, Inc.
c\o Janssen Research & Development, LLC
Attention: Melissa L. Gannon
Director, Global Regulatory Affairs
920 Route 202 South, P.O. Box 300
Raritan, NJ 08869-0602

Dear Ms. Gannon:

Please refer to your Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SPORANOX (itraconazole) Capsules:

Supplement Number	Supplement Date	Supplement Type
S048	June 22, 2011	Changes Being Effected
S049	September 19, 2011	Prior Approval
S050	December 2, 2011	Prior Approval

We acknowledge receipt of your amendment dated April 4, 2012, to supplements 49 and 50.

The "Changes Being Effected" supplemental new drug application (S048) proposes to add dyspnea and acute generalized exanthematous pustulosis (AGEP) to the ADVERSE REACTIONS (Postmarketing Experience) section of the United States Package Insert (USPI). In addition, editorial updates were made and the Patient Information was revised to be consistent with the revised USPI.

The "Prior Approval" supplemental new drug application (S049) proposes to remove references to Sporanox (itraconazole) Injection from sections of the USPI for Sporanox (itraconazole) Capsules. The Patient Information was also revised to be consistent with the revised USPI.

The "Prior Approval" supplemental new drug application (S050) provides for revisions to the BOXED WARNING, CLINICAL PHARMACOLOGY (Pharmacokinetics and Metabolism), CONTRAINDICATIONS (Congestive Heart Failure, Drug Interactions), WARNINGS (Cardiac

Dysrhythmias) and PRECAUTIONS (Drug Interactions, Calcium Channel Blockers and Other) sections of the product labeling as requested in the Agency letter of September 29, 2011.

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, text submitted April 4, 2012.

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 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 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).

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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 Alison Rodgers, Regulatory Project Manager, at (301) 796-0797.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Deputy Director for Safety
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
04/18/2012