



NDA 20083/S-053  
NDA 20657/S-032

**SUPPLEMENT APPROVAL**

Janssen Pharmaceuticals, Inc.  
c/o Janssen Research & Development, LLC  
Attention: Andrea F. Kollath, DVM  
Director, Global Regulatory Affairs  
920 U.S. Highway 202 P.O. Box 300  
Raritan, NJ 08869-0602

Dear Dr. Kollath:

Please refer to your Supplemental New Drug Applications (sNDAs) dated April 25, 2013, received April 25, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

| Name of Drug Product                  | NDA Number | Supplement Number |
|---------------------------------------|------------|-------------------|
| Sporanox (itraconazole) Capsules      | 20083      | S-053             |
| Sporanox (itraconazole) Oral Solution | 20657      | S-032             |

We acknowledge receipt of your amendments dated January 14, and February 25, 2014.

These “Prior Approval” supplemental applications provide for changes to the **BOXED WARNING, Drug Interactions**; and the **DESCRIPTION, CLINICAL PHARMACOLOGY, MICROBIOLOGY, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE, DOSAGE AND ADMINISTRATION**, and **HOW SUPPLIED** sections of the labeling. Additionally, the **PATIENT INFORMATION** labeling text has also been revised.

**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, text for the patient 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 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).

### **PROMOTIONAL MATERIALS**

All promotional materials that include representations about your drug products must be promptly revised to be consistent with the labeling changes approved in these supplements, 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  
Director  
Division of Anti-Infective Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE:  
Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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SUMATHI NAMBIAR  
06/09/2014