DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-966/S-005

Johnson and Johnson Pharmaceutical Research and Development. L.L.C.
Attention: Hanna Benze
Director, Regulatory Affairs
1125 Trenton-Harbourton Rd.
P. O. Box 200
Titusville, NJ 08560-0200

Dear Ms. Benze:

Please refer to your supplemental new drug application dated January 30, 2002, received January 31, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sporanox® (itraconazole) Injection 10 mg/mL.

This supplemental new drug application provides for the following changes to the **DOSAGE AND ADMINISTRATION** section of the Sporanox® Injection label (added text is double underlined):

> Correct preparation and administration of SPORANOX® Injection are necessary to ensure maximal efficacy and safety. A precise mixing ratio is required in order to obtain a stable admixture. It is critical to maintain a 3.33 mg/mL itraconazole:diluent ratio. Failure to maintain this concentration will lead to the formation of a precipitate.
>
> Add the full contents (25 mL) of the SPORANOX® Injection ampule into the infusion bag provided, which contains 50 mL of 0.9% Sodium Chloride Injection, USP (normal saline). Mix gently after the solution is completely transferred. Withdraw and discard 15 mL of the solution before administering to the patient. Using a flow control device, infuse 60 mL of the dilute solution (3.33 mg/mL = 200 mg itraconazole, pH apx. 4.8) intravenously over 60 minutes, using an extension line and the infusion set provided. After administration, flush the infusion set with 15-20 mL of 0.9% Sodium Chloride Injection, USP, over 30 seconds-15 minutes, via the two-way stopcock. Do not use Bacteriostatic Sodium Chloride Injection, USP. The compatibility of SPORANOX® Injection with flush solutions other than 0.9% Sodium Chloride Injection, USP (normal saline) is not known. Discard the entire infusion line.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted January 30, 2001).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-966/S-005." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.
If you have any questions, call Robin Anderson, Labeling Reviewer, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Acting Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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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