# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**20-966/S-001, S-003, S-004**

**20-657/S-004, S-005**

## CORRESPONDENCE

DIV F. 20-966

NDA 20-657/S-005
NDA 20-966/S-004

MAY 15 2000

PRIOR APPROVAL SUPPLEMENT

Janssen Research Foundation
Attention: Edward G. Brann
1125 Trenton-Harbourton Road
P.O. Box 200
Titusville, N.J. 08560-0200

Dear Mr. Brann:

We have received your supplemental drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Products: SPORANOX® (itraconazole) oral solution 10 mg/ml and injection 10 mg/ml

NDA Numbers/Supplement Numbers: 20-657/S-005 and 20-966/S-004

Review Priority Classification: Standard (S)

Date of Supplements: April 28, 2000

Date of Receipt: May 1, 2000

These supplemental applications propose the following change:

> An additional indication for empirical therapy in febrile neutropenic patients with suspected fungal infections.

Unless we notify you within 60 days of the receipt date that the applications are not sufficiently complete to permit a substantive review, these applications will be filed under section 505(b) of the Act on June 30, 2000 in accordance with 21 CFR 314.101(a). If these applications are filed, the primary user fee goal date will be March 1, 2001 and the secondary user fee goal date will be May 1, 2001.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). If you have not already fulfilled the requirements of 21 CFR 314.55 (or 601.27), please submit your plans for pediatric drug development within 120 days from the date of this letter unless you believe a waiver is appropriate. Within approximately 120 days of receipt of your pediatric drug development plan, we will review your plan and notify you of its adequacy.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will make a determination whether to grant or deny a request for waiver of pediatric studies during the review of the application. In no case, however, will the determination be made later than the date action is taken on the application. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the Guidance for Industry on Qualifying for Pediatric Exclusivity (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" in addition to your plans for pediatric drug development described above. We recommend that you submit a Proposed Pediatric Study Request within 120 days from the date of this letter. If you are unable to meet this time frame but are interested in pediatric exclusivity, please notify the division in writing. FDA generally will not accept studies submitted to an NDA before issuance of a Written Request as responsive to a Written Request. Sponsors should obtain a Written Request before submitting pediatric studies to an NDA. If you do not submit a PPSR or indicate that you are interested in pediatric exclusivity, we will review your pediatric drug development plan and notify you of its adequacy. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity. FDA does not necessarily ask a sponsor to complete the same scope of studies to qualify for pediatric exclusivity as it does to fulfill the requirements of the pediatric rule.

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Special Pathogen and
Immunologic Drug Products
HFD-590
Attention: Document Room
5600 Fishers Lane
Rockville, MD 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Special Pathogen and
Immunologic Drug Products
HFD-590
Attention: Document Room
9201 Corporate Boulevard
Rockville, MD 20850

If you have any questions, call Rene Kimzey, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

/S/

5-15-00

Ellen C. Frank, R.Ph.
Chief, Project Management Staff
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research