DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 9-175/S-039

SUPPLEMENT APPROVAL

Shionogi Pharma, Inc.
Attention: Dia P. Hill
Manager, Regulatory Affairs
Five Concourse Parkway
Suite 1800
Atlanta, GA 30328

Dear Ms. Hill:

Please refer to your Supplemental New Drug Application (sNDA) dated April 14, 2010, received April 15, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Furadantin® (nitrofurantoin) Oral Suspension, 25mg/5mL.

This "Changes Being Effected" supplemental new drug application provides for the following changes:

- An update to the company logo
- New revision date
- New component number
- Add the statement "(four times daily)" to the abbreviation QID

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text *and with the minor editorial revisions listed below*:

- Delete the abbreviation (b) (4) from the 230 mL carton and bottle labels, as it is redundant and confusing. The statement should be revised to read: "USUAL ADULT DOSE: 50 to 100 mg four times daily with food."

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that includes the revision above and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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 via publicly available labeling repositories.

Also within 14 days from the date of this letter, amend all pending supplemental applications for this NDA, including pending CBE supplements, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes with the revisions indicated above approved in this supplemental application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, MD
Deputy Division Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
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/

KATHERINE A LAESSIG
10/14/2010