DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50717/S-007

SUPPLEMENT APPROVAL

Zambon S.p.a. Italy
c/o Forest Laboratories, Inc.
Attention: Maricarmen Raposo, Senior Associate, Regulatory Affairs
Harborside Financial Center
Plaza Five, Suite 1900
Jersey City, New Jersey 07311

Dear Ms. Raposo:

Please refer to your Supplemental New Drug Application (sNDA) dated March 2, 2011, received March 3, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Monurol (fosfomycin tromethamine) Sachet.

This "Prior Approval" supplemental new drug application provides for minor editorial changes to the current package insert (Rev. 11/2007) recommended by the FDA Approval Supplement Request dated November 12, 2010.

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 enclosed labeling text and with the minor editorial revisions listed below.

- In the SUSCEPTIBILITY TESTING section, the Dilution Techniques subsection, the reference number 1 next to the word, "method" should be in superscript format, and it should changed from "method1" to "method[1]".

- In the SUSCEPTIBILITY TESTING section, the Dilution Techniques subsection, the first letter of the word, "Interpreted" should not be capitalized, and it should be changed from "Interpreted" to "interpreted".

- In the PRECAUTIONS section, the Information for Patients subsection, the phrase "Patients should be informed:" should be removed as a bullet point and re-aligned as a subtitle to this section.

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, except with the revisions listed, 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 via 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 with the revisions listed above 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).

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, contact Kyong Hyon, Regulatory Project Manager, at (301) 796-0734.

Sincerely,

{See appended electronic signature page}

Katherine Laessig, M.D.
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

KATHERINE A LAESSIG
04/11/2011