Dear Dr. Yuhas:


This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submission dated November 20, 2007.

This “Changes Being Effected” supplemental new drug application provides for revisions to the WARNINGS and PRECAUTIONS/Information for Patients sections to include information on Clostridium difficile associated disease (CDAD).

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on November 20, 2007.

We note that your November 20, 2007 submission includes final printed labeling (FPL) for your package insert. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:
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 Susmita Samanta, MD, Regulatory Project Manager, at (301) 796-0803.

Sincerely,

[See appended electronic signature page]

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

Enclosure: Labeling submitted on November 20, 2007
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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Kathrine Laessig
4/17/2008 02:46:06 PM