



NDA 50-649/S-019

Triax Pharmaceutical, LLC  
Attention: Keith S. Rotenberg, PhD  
Sr. Vice President, Regulatory Affairs  
20 Commercial Drive, Suite 232  
Cranford, NJ 07016

Dear Dr. Rotenberg:

Please refer to your supplemental new drug application dated February 20, 2007 received February 26, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Minocin (minocycline) Pellet-Filled Capsules.

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

Your submission of February 20, 2007 constituted a complete response to our September 25 and November 1, 2006 action letters.

This supplemental new drug application provides for changes to the class labeling for *C. difficile*-associated diarrhea (CDAD).

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Submit content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical to the submitted labeling text dated February 20, 2007. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

The final printed labeling (FPL) must be identical to the enclosed labeling dated February 20, 2007.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 50-649/S-022**." Approval of this submission by FDA is not required before the labeling is used.

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:

MEDWATCH  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

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 Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

*{See appended electronic signature page}*

Janice M. Soreth, MD  
Director  
Division of Anti-Infective and Ophthalmology  
Products  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Janice Soreth

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