DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-649/S-022

Triax Pharmaceutical, LLC
Attention: Kathryn Bishburg, PharmD
Executive Director, Regulatory Affairs
20 Commerce Drive, Suite 232
Cranford, NJ 07016

Dear Dr. Bishburg:

Please refer to your supplemental new drug application dated September 17, 2007, received September 21, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NDA 50-649 Minocin® (minocycline hydrochloride) 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.

We acknowledge receipt of your submission dated May 1, 2008.

This supplemental new drug application provides for a change in the **DOSAGE AND ADMINISTRATION** section of the labeling regarding Minocin administration with food.

We have completed the 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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for packaging insert).

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 copies of the FPL on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplements 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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

If you have any questions, call Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Kathrine Laessig
6/30/2008 10:43:25 AM