DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-444/S-045
NDA 50-445/S-027

Triax Pharmaceuticals, LLC
Attention: Kathryn Bishburg, Pharm.D.
20 Commercial Drive, Suite 232
Cranford, NJ 07016

Dear Ms Bishburg:

Please refer to your supplemental new drug applications dated April 4, 2006, received April 11, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for

NDA 50-444 Minocin (sterile minocycline hydrochloride) Intravenous, 100 mg/vial
NDA 50-445 Minocin (minocycline hydrochloride) Oral Suspension

These applications are subject to the exemption provisions in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submission dated October 9, 2006.

Your submission of October 9, 2006 constituted a complete response to our September 25, 2006 action letter.

These supplemental new drug applications provide for updated wording for the **WARNINGS** section of the labeling with regard to *Clostridium difficile* associated disease (CDAD).

We completed our review of these applications, as amended. These applications are 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 format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical to the submitted labeling text dated October 9, 2006 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 October 9, 2006.

The final printed labeling (FPL) must be identical to the enclosed labeling dated October 9, 2006.

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 these submissions "**FPL for approved supplements NDA 50-444/S-045 and NDA 50-445/S-027**." Approval of these submissions 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, M.D.
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/

Janice Soreth
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