DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-649/S-021

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

Dear Dr. Bishburg

Please refer to your supplemental new drug application dated November 28, 2006, received November 30, 2006 submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for 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.

This supplemental new drug application provides for addition of Patheon Pharmaceuticals as an alternate drug product manufacturing, testing and packaging site.

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 and with the minor editorial revisions listed below:

> When submitting final printed labeling, include labeling containing the approved *C. difficile* warning.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling dated November 28, 2006. These revisions are terms of the approval of this application.

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-021**." Approval of this submission by FDA is not required before the labeling is used.

Submit content of labeling [21CFR 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 November 28, 2006 containing the revision mentioned above. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting in the DailyMed website.

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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