



NDA 50-444/S-042 and S-043

Wyeth Pharmaceuticals
Attention: Mary Ellen Menz, RN, MBA, JD
Manager, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Menz:

Please refer to your supplemental new drug applications dated September 10, and October 30, 2003, received September 11, and October 31, 2003, for supplements S-042 and S-043 respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MINOCIN[®] (minocycline for injection), Intravenous.

We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We also acknowledge receipt of your submission dated November 21, 2003, containing final printed labeling for both supplements.

These supplemental new drug applications provide for revisions to the label to comply with the Final Rule entitled "Labeling Requirements for Systemic Antimicrobial Drug Products Intended for Human Use" (68FR 6062, February 6, 2003) (S-042), and revisions to incorporate safety information under the ADVERSE REACTIONS section of the package insert (S-043).

We completed our review of these applications, and they are approved effective on the date of this letter for use as recommended in the final printed labeling submitted on November 21, 2003.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
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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