DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-444/S-038
NDA 50-445/S-022
NDA 50-649/S-015

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

Dear Dr. Menz:

Please refer to your supplemental new drug applications 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for

NDA number	Name	Document date	Receipt date
50-444/S-038	Minocin® (minocycline for Injection) Intravenous	March 22, 2002	March 25, 2002
50-445/S-022	Minocin® (minocycline hydrochloride) Oral Suspension	February 8, 2002	February 11, 2002
50-649/S-015	Minocin® (minocycline hydrochloride) Pellet-filled capsules	February 8, 2002	February 11, 2002

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 acknowledge receipt of your submissions dated February 20, 2004 (NDA 50-444/S-038 and NDA 50-649/S-015) and February 23, 2004 (NDA 50-445/S-022). These submissions constituted a complete response to our action letter dated November 19, 2003.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the **CONTRAINDICATONS, PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE** and **DOSAGE AND ADMINISTRATON** as well as minor editorial revisions and compendial changes to the **DESCRIPTION, CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE** and **HOW SUPPLIED** sections of the package insert.

We have completed our review of these applications, as amended and they are 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 package insert submitted on February 20, 2004 (NDA 50-444/S-038 and NDA 50-649/S-015) and February 23, 2004 (NDA 50-445/S-022), and include the following agreed upon text in the **PRECAUTIONS** section, Pregnancy subsection.

"*Teratogenic Effects: Pregnancy Category D. (*See **WARNINGS***)*
All pregnancies have a background risk of birth defects, loss, or other adverse outcome regardless of dug exposure. There are no adequate and well-controlled studies on the use of minocycline in pregnant women. Minocycline, like other tetracycline-class antibiotics, crosses the placenta and may cause fetal harm when administered to a pregnant woman. Rare spontaneous reports of congenital anomalies including limb reduction have been reported in post-marketing experience. Only limited information is available regarding these reports; therefore, no conclusion on causal association can be established. If minocycline is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential; hazard to the fetus."

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 supplement NDA 50-444/S-038, NDA 50-445/S-022 and NDA 50-649/S-015**." 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 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

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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