DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-444/S-036
NDA 50-445/S-019
NDA 50-649/S-011

Wyeth Pharmaceuticals
Attention: Roberta R. Acchione
Associate Director, U.S. Regulatory Affairs
P. O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Acchione:

Please refer to your supplemental new drug applications dated August 11, 1999, received August 13, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

1. NDA 50-444/S-036, Minocin® Intravenous (minocycline hydrochloride)

2. NDA 50-445/S-019, Minocin® Oral Suspension (minocycline hydrochloride)

3. NDA 50-649/S-011, Minocin® Pellet-Filled Capsules (minocycline hydrochloride)

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 acknowledge receipt of your submissions dated October 31, 2000, April 11, 2001, March 26, and May 29, 2002.

These supplemental new drug applications provide for the addition of a "**Geriatric Use**" subsection in the **PRECAUTIONS** section of the labeling.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must include the enclosed revised labeling, as agreed in the fax dated May 29, 2002.

1. For NDA 50-445/SLR-019:
   In the **PRECAUTIONS** section, add the following sentence at the end of the **Geriatric Use** subsection

   "Minocin® Oral suspension contains 4.3 mg (0.18 mEq) of sodium per 5 mL."

2. For NDA 50-649/SLR-011:
   In the **PRECAUTIONS** section, add the following sentence at the end of the **Geriatric Use** subsection

   "Minocin® Pellet-Filled Capsules (50 mg, 75 mg and 100 mg) do not contain sodium."

3. For NDA 50-444/SLR-036:
   In the **PRECAUTIONS** section, add the following sentence at the end of the **Geriatric Use** subsection

   "Minocin® IV (sterile Minocycline Hydrochloride, USP) does not contain sodium."

Please submit the copies of final printed labeling (FPL) electronically, according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submissions should be designated "FPL for approved supplements NDA 50-444/S-036, NDA 50-445/S-019, and NDA 50-649/S-011." Approval of these submissions by FDA are not required before the labeling are used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
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, M.D.
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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