



**NDA 50-649/S-005, S-007**

WYETH-AYERST RESEARCH  
Attention: Jean E. Raymond, P.A.  
Associate Director, Worldwide Regulatory Affairs  
P.O. Box 8299  
Philadelphia, PA 19101-8299

Dear Ms. Raymond:

Please refer to your supplemental new drug applications dated November 4, 1992, received November 9, 1992 (S-005); and March 27, 1995, received March 30, 1995 (S-007), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Minocin<sup>®</sup> (minocycline hydrochloride) Pellet-Filled Capsules. We note that this application is 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 July 11, 2000 and April 11, 2001. Your submission of July 11, 2000 constituted a complete response to our September 4, 1998 action letter.

These supplemental new drug applications provide for revisions to the **DESCRIPTION, CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE, PRECAUTIONS, ADVERSE REACTIONS, DOSAGE AND ADMINISTRATION, HOW SUPPLIED**, and **REFERENCES** sections of the package insert.

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 final printed labeling (FPL) submitted July 11, 2000 (CI 6156-1). Accordingly, these supplemental applications are approved effective on the date of this letter.

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 CDR. Jose R. Cintron, R. Ph., M.A., USPHS, Senior Regulatory Management Officer, at (301) 827-2125.

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

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/s/

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Janice Soreth  
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