DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-445/S-011, S-013, S-015, S-017

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 August 16, 1989, received August 17, 1989 (S-011); August 16, 1989, received August 17, 1989 (S-013); October 30, 1992, received November 3, 1992 (S-015), and March 27, 1995, received March 30, 1995 (S-017), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Minocin® (minocycline hydrochloride oral suspension) Oral Suspension. 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 April 20, 2000 and April 11, 2001. Your submission of April 20, 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 April 20, 2000 (CI 6016-2). 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

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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