DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-006/S-076
NDA 50-007/S-016
NDA 50-480/S-037
NDA 50-533/S-032

Pfizer, Inc.
Attention: Pritpal Nijjar
Regulatory Manager
235 East, 42nd Street
New York, NY 10017

Dear Ms. Nijjal:

Please refer to your supplemental new drug applications dated January 29, 2004, received January 30, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

Vibramycin® Monohydrate (doxycycline monohydrate Oral Suspension) (NDA 50-006),
Vibramycin® (doxycycline hyclate) Capsules (NDA 50-007),
Vibramycin® Calcium (doxycycline calcium oral suspension) Syrup (NDA 50-480), and
Vibra-Tabs® (doxycycline hyclate) Film Coated Tablets (NDA 50-533)

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 your submissions dated February 26, 2004, containing final printed labeling (FPL).

These supplemental new drug applications provide for revised labeling to comply with the Final Rule entitled "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use" (68FR 6062, February 6, 2003).

We completed the review of these supplemental applications and they are approved effective on the date of this letter for use as recommended in the final printed labeling (FPL) submitted on February 26, 2004.

If a letter communicating important information about these drug products (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 these NDA's 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

3/12/04 02:25:23 PM