DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-006/S-079
NDA 50-007/S-020
NDA 50-480/S-042
NDA 50-533/S-036

Pfizer Inc.
Attention: Beatrice Curran
Associate Director, WorldWide Regulatory Strategy
235 East 42nd Street 605/5/15
New York, NY 10017

Dear Ms. Curran:

Please refer to your supplemental new drug applications dated May 16, 2007, received May 18, 2007, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA 50-006 Vibramycin (doxycycline monohydrate) Oral Suspension
NDA 50-007 Vibramycin (doxycycline hyclate) Capsules
NDA 50-480 Vibramycin Calcium (doxycycline hyclate) Syrup
NDA 50-533 Vibramycin (doxycycline hyclate) Film-Coated Tablets

These applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These supplemental new drug applications have been submitted in response to an Agency letter requesting an update to the **WARNINGS and PRECAUTIONS/Information for Patients** sections of the labeling concerning *Clostridium difficile* associated diarrhea.

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text in the content of labeling [21CFR 31.50(1)] in structured product labeling FPL format submitted on May 16, 2007.

We note that your May 16, 2007 submission includes final printed labelings (FPLs) for your package inserts. You are responsible for assuring that the wording in these printed labelings are identical to that of the approved content of labeling in the structured labeling (SPL) format.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to each of these NDAs and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
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/

Wiley Chambers

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