DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-582/S-024

F. H. Faulding and Co.
c/o Warner Chilcott, Inc
Attention: David Haenick, PhD
Manager, Regulatory Affairs
Rockaway 80 Corporate Center
100 Enterprise Drive, Suite 280
Rockaway, NJ 07966

Dear Dr. Haenick:

Please refer to your supplemental new drug application dated October 27, 2004, received October 29, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Doryx® (doxycycline hyclate) Delayed-Release Capsules, 75 mg and 100 mg.

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 November 17, 2004, and April 29, 2005.

This supplemental new drug application provides for formatting revisions to the package insert (W0838G018) and bulk leaflet (443271), in response to the Division's request dated September 24, 2003.

We completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. Changes to the label can be implemented at the next printing.

The final printed labeling (FPL) must be identical to the package insert enclosed with this letter.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submissions "**FPL for approved supplement NDA 50-582/S-024**". Approval of this submission by FDA is not required before the labeling is used.

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

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Judit Milstein, Regulatory Project Manager, at (301) 827-2120.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and

Enclosure: Package insert (W0838G018) and bulk leaflet (443271)

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
5/6/05 11:58:05 AM