DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-795

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 new drug application (NDA) dated April 5, 2004, received April 7, 2004, submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act for Doryx® (doxycycline hyclate) Delayed-Release Tablets, 75 mg and 100 mg.

This application is subject to the exemption provisions in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated:

June 10, 2004	October 26, 2004	November 23, 2004
December 10, 2004	December 14, 2004	December 20, 2004
January 11, 2005	February 18, 2005	March 10, 2005
March 18, 2005	April 13, 2005	April 27, 2005
April 29, 2005		

This new drug application provides for the use of Doryx® (doxycycline hyclate) Delayed-Release Tablets, 75 mg and 100 mg for the treatment of a variety of infections as described in the product labeling.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, and immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 submission "**FPL for approved NDA 50-795**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
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, please call Judit Milstein, Regulatory Project Manager at (301) 827-2207.

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 Research

Enclosure: Labeling for package insert, carton, and container label

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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 11:55:23 AM