



NDA 50-582/S-021

F. H. Faulding and Co.
c/o Warner Chilcott Inc.
Attention: Deborah Panei
Manager, Regulatory Affairs
Rockaway 80 Corporate Center
100 Enterprise Dr. Ste. 280
Rockaway, NJ 07866

Dear Ms. Panei:

Please refer to your supplemental new drug application dated December 20, 2002, received December 23, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Doryx[®] Capsules (coated doxycycline hyclate pellets), 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.

This supplemental new drug application provides for the addition of new dosing information.

We have completed the review of this application, 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 package insert submitted on December 20, 2002, and contain the following additional paragraph in the Dosage and Administration section, as agreed on May 27, 2003.

Sprinkling the Capsule Contents on Applesauce

Doryx[®] Capsules may also be administered by carefully opening the capsules and sprinkling the capsule contents on a spoonful of applesauce. However, any loss of pellets in the transfer would prevent using the dose. The applesauce should be swallowed immediately without chewing and followed with a cool 8-ounce glass of water to ensure complete swallowing of the capsule contents. The applesauce should not be hot, and it should be soft enough to be swallowed without chewing. In the event that a prepared dose of applesauce / Doryx[®] pellets can not be taken immediately, the mixture should be discarded and not stored for later use.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-582/S-021." 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., a "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) 827-2207.

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

**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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