



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 50-795/S-002

Warner Chilcott  
Attention: David Haenick, PhD  
Manager, Regulatory Affairs  
100 Enterprise Drive  
Rockaway, NJ 07866

Dear Dr. Haenick:

Please refer to your new drug application (NDA) dated February 17, 2006 received February 21, 2006, submitted 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 November 9, December 7, 14 and 19, 2006.

This new drug application provides instructions for administration of tablet contents with applesauce in the DOSAGE AND ADMINISTRATION section of the labeling.

We completed our review of these applications, as amended. 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 dated December 19, 2006. Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Submit content of labeling [21 CFR 314.50(1)] in structured product labeling format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical to the submitted labeling text dated December 19, 2006 receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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/S-002.**" 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  
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, RPh, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

*{See appended electronic signature page}*

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

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/s/

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Janice Soreth  
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