



NDA 50-795/S-003

APPROVAL

Warner Chilcott, Inc.
Attention: Deepa B. Desai, MS
Senior Manager, Regulatory Affairs
100 Enterprise Drive
Rockaway, NJ 07866

Dear Ms. Desai:

Please refer to your supplemental new drug application (NDA) dated March 21, 2007, received March 22, 2007, 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.

This supplemental new drug application has been submitted in response to an Agency letter requesting an update to the **WARNINGS** and **PRECAUTIONS** section if the labeling concerning *Clostridium difficile* associated diarrhea.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on March 21, 2007.

We note that your March 21, 2007 submission includes final printed labeling (FPL) for your package insert. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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

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

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 Evaluation and Research

Enclosure:

**This is a representation of an electronic record that was signed electronically and
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/s/

Wiley Chambers
12/18/2007 03:50:33 PM