



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 50-582/S-027

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

Dear Ms. Desai:

Please refer to your supplemental new drug application dated March 30, 2007 received April 2, 2007, submitted under 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.

This supplemental new drug application was submitted in response to an Agency letter requesting an update to the **WARNINGS and PRECAUTIONS/Information for Patients** sections of the labeling concerning *Clostridium difficile* associated diarrhea.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text in the content of labeling [21CFR 31.50(1)] in structured product labeling FPL format submitted on March 30, 2007.

We note that your March 30, 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 labeling (SPL) format.

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, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

*{See appended electronic signature page}*

Katherine A. Laessig, M.D.  
Deputy 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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Kathrine Laessig  
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