DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-641/S-014

Watson Laboratories, Inc.
Attention: Wendy DeSpain, B.S., R.A.C.
Manager, Regulatory Liasion
Proprietary Regulatory Affairs
577 Chipeta Way
Salt Lake City, UT 84108

Dear Ms. DeSpain:

Please refer to your supplemental new drug application dated February 22, 2007, received February 23, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mondox (doxycycline monohydrate) Capsules, NDA 50-614.

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

We acknowledge your submission dated March 1, 2007.

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 *Clostidium difficile* associated diarrhea.

We have completed our review of this application, as amended. 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 1, 2007.

We note that your March 1, 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 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}

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure:

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Wiley Chambers

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