DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-641/S-018

SUPPLEMENT APPROVAL

Watson Laboratories, Inc.
Attention: Lawrence J. Ventura, D.V.M., MBA
Associate Director, Regulatory Affairs
Brand Division
577 Chipeta Way
Salt Lake City, UT 84108

Dear Dr. Ventura:

Please refer to your Supplemental New Drug Application (sNDA) dated July 11, 2008, received July 14, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Monodox Capsules 50 mg, 75 mg and 100 mg.

We acknowledge receipt of your amendments dated October 19, and November 21, 2011.

The October 19, 2011, submission constituted a complete response to our June 18, 2011, action letter.

This "Prior Approval" labeling supplemental new drug application proposes to update the Microbiology subsection of the package insert, *in vitro* susceptibility test interpretive criteria (breakpoints) and quality control parameters for *in vitro* susceptibility testing sections. Additionally, it provides for updates to the References section to reflect the most recent dates of the cited publications.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text. We request, however, that you review the package insert for correct spelling, italicization of proper names, and reference numbers.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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

Sincerely,

{See appended electronic signature page}

Sumati Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

SUMATHI NAMBIAR
01/11/2012