DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-795/S-010

SUPPLEMENT APPROVAL

Mayne Pharma International, Pty, Ltd.
c/o Warner Chilcott US, LLC
Attention: Maria Ferrara, MBA
Senior Regulatory Manager, Regulatory Affairs
100 Enterprise Drive
Rockaway, NJ 07866

Dear Ms Ferrara:

Please refer to your Supplemental New Drug Application (sNDA) dated May 28, 2009, received May 29, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Doryx (doxycycline hyclate delayed-release tablets, 80 mg, 100 mg, 150 mg and 200 mg).

We acknowledge receipt of your amendments, dated October 12, 2012 and February 21 and April 3, 8, and 11, 2013.

The October 11, 2012, submission constituted a complete response to our July 1, 2011, action letter.

This "Prior Approval" supplemental new drug application provides for the addition of a new 200-mg strength tablet and an alternative dosage regimen for treatment of uncomplicated urethral or endocervical infections caused by *Chlamydia trachomatis*.

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 note that your April 11, 2013, submission includes final printed labeling (FPL) for your package insert and patient package insert. We have not reviewed this FPL. 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.

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 and for the patient 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 that include labeling changes 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).

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your April 8, 2013, submission containing final printed carton and container labels.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for children 0-8 years of age for this application because there is evidence strongly suggesting that the drug product would be unsafe in this pediatric age group. As a tetracycline class antibacterial, DORYX should not be used in pediatric patients to the age of 8 years because of the effects of tetracyclines on tooth development and growth.

We note that you have fulfilled the pediatric study requirement for ages 8 to 16 years for this application. Dosing recommendations for pediatric patients are included in product labeling, based on prior studies. In adolescents diagnosed with uncomplicated urogenital *Chlamydia trachomatis* infection and treated with the adult dose of doxycycline, no significant variability as compared to adults is expected in terms of response to doxycycline 200 mg tablet taken once a day versus doxycycline 100 mg tablet taken twice a day. Thus, the Division has determined that no additional studies in the pediatric population are needed.

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

Sincerely,

{See appended electronic signature page}

John J. Farley, MD, MPH
Acting Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Carton and Container Labeling

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

/s/

JOHN J FARLEY
04/11/2013