DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50795/S-20

SUPPLEMENT APPROVAL

Mayne Pharma International Pty Ltd.
Attention: Susan R. Canady
Regulatory Affairs Specialist
1240 Sugg Parkway
Greenville, NC 27834

Dear Ms. Canady:

Please refer to your Supplemental New Drug Application (sNDA) dated December 30, 2014, received December 31, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DOXTERIC (doxycycline hyclate delayed-release tablets) 50 mg.

This "Prior Approval" supplemental new drug application provides for revised container and carton label for 50 mg strength.

APPROVAL & LABELING

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.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your December 30, 2014 submission containing final printed carton and container labels.

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 Naseya Minor, Regulatory Project Manager, at (301) 796-0756.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
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/

SUMATHI NAMBIAR
03/04/2015