DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-795/S-024

SUPPLEMENT APPROVAL

Mayne Pharma, Inc.
Attention: Susan Canady
Senior Regulatory Affairs Specialist
1240 Sugg Parkway
Greenville, NC 27834

Dear Ms. Canady:

Please refer to your Supplemental New Drug Application (sNDA) dated August 2, 2016, received August 3, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Doryx MPC (doxycycline hyclate delayed-release tablets) 60 mg and 120 mg.

This Prior Approval supplemental new drug application provides for changes to the **Important Dosage and Administration Instructions (2.1)** subsection, **Pharmacokinetics** (**12.3)** subsection and **PATIENT COUNSELING** (**17)** Section of the prescribing information to add that the absorption of Doryx MPC tablets is not significantly affected by the simultaneous ingestion of food or milk. In addition, pancreatitis was added to the **ADVERSE REACTIONS** (**6**) Section, *Gastrointestinal* subsection, editorial revisions were made to **the Microbiology (12.4)** subsection and updates were made to the **REFERENCES (15)** Section.

APPROVAL & LABELING

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 agreed-upon labeling text.

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, 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).

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 Eva Zuffova, Regulatory Project Manager, at (301) 796-0697.

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:
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
05/31/2017