DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 065055/S-013

SUPPLEMENT APPROVAL

Par Pharmaceutical Inc.
One Ram Ridge Road
Spring Valley, New York 10977

Attention: Robin Heit
Associate, Regulatory Affairs

Dear Ms Heit:

Please refer to your Supplemental Abbreviated New Drug Application (sANDA) dated March 05, 2014 submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Doxycycline Capsules USP, 50 mg, 75 mg, 100 mg, and 150 mg.

This "Changes Being Effected" supplemental abbreviated new drug application provides for revised insert labeling in accordance with the NDA labeling, Monodox® Doxycycline Monohydrate Capsules, NDA 050641/S-027 approved October 11, 2013. The new NDA supplement is to provide for updates to the CLINICAL PHARMACOLOGY - Microbiology, INDICATIONS AND USAGE, PRECAUTIONS, and ADVERSE REACTIONS sections of the package insert.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter. However, please make the following post approval revisions to the insert labeling and submit them in a CBE supplement.

(b) (4)

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Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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 via publicly available labeling repositories.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory

requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

The material submitted is being retained in our files. If you have any questions, call or email Yen Anh Bui, Regulatory Project Manager, at (240) 402-8900 or yenanh.bui@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Wm. Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Attachment: 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/

THUYANH VU
07/10/2014
for Wm. Peter Rickman