DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Rockville MD 20855

ANDA 063009/S-034

Teva Pharmaceuticals USA
Attention: Patricia Jaworski
Vice President, Regulatory Affairs
Commercial Generic Products
400 Chestnut Ridge Road
Woodcliff Lake, NJ 07677

Dear Madam:

Please refer to your supplemental new drug application dated June 26, 2008, received June 27, 2008, submitted pursuant to 21 CFR 314.70(b) [Prior Approval Supplement] regarding your abbreviated new drug application for Minocycline Hydrochloride Capsules USP, 75 mg and 100 mg.

Reference is also made to our letters dated October 07, 2011 and May 31, 2012, and your amendments dated February 16, 2012 and November 14, 2012.

This supplemental new drug application provides for final print package insert in response to our request dated February 07, 2008 regarding interpretive criteria and quality control parameters for *in vitro* susceptibility testing. It also provides revised container labels to match current formatting conventions.

We have completed the review of your application and it is approved. (b) (4) Please note that this ANDA 063009 is for 75 mg and 100 mg strengths. (b) (4). Additionally, further revise your insert labeling as follows at the time of next printing:

PROFESSIONAL PACKAGE INSERT:

GENERAL

We recommend that you delete "USP" from the established name except in the TITLE, DESCRIPTION, INDICATIONS AND USAGE, and HOW SUPPLIED sections of the insert.

DESCRIPTION

We note that you changed the formulation of the printing ink. Please ensure that you include these changes in the next Annual Report.

CLINICAL PHARMACOLOGY - Microbiology

Before the disc diffusion quality control table, please put the header "Quality control".

Revised labeling may be submitted in an annual report provided all changes are described in full.

We 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.

CONTENT OF LABELING

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.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The materials submitted are being retained in our files.

Sincerely,

{See appended electronic signature page}

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

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

/s/

LILLIE D GOLSON
01/02/2013
for Wm. Peter Rickman