DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 065485/S-004

Barr Laboratories, Inc.
(An indirect, wholly-owned subsidiary of Teva Pharmaceuticals, USA)
Attention: Robert S. Vincent
Director, Regulatory Affairs
400 Chesnut Ridge Road
Woodcliff Lake, NJ 07677

Dear Sir:

This is in reference to your supplemental abbreviated new drug application received on November 19, 2009, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Minocycline Hydrochloride Extended-release Tablets, 45 mg (base), 90 mg (base) and 135 mg (base).

Reference is also made to your amendments dated January 15, March 30, May 7, June 10 and July 15, 2010; March 10 and 22, April 19, May 11, and July 25, 2011; February 28, May 2 and May 10, 2012.

This ANDA was approved on March 17, 2009, for the 45 mg (base), 90 mg (base) and 135 mg (base) strengths. This supplemental application submitted as a "Prior Approval Supplement", provides for two additional strengths, 65 mg (base) and 115 mg (base); and updated labeling to provide for these two additional strengths.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the supplemental ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Minocycline Hydrochloride Extended-release Tablets, 65 mg (base) and 115 mg (base) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Solodyn (Minocycline HCl) Extended-release Tablets, 65 mg (base)

and 115 mg (base), respectively, of Medicis Pharmaceutical Corporation (Medicis).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. The "interim" dissolution specifications are as follows:

Dissolution Testing should be conducted in

Medium:	0.1 N HCl
Volume:	900 mL
Apparatus:	USP Apparatus I (Basket)
Speed of Rotation:	100 rpm
Specifications:	1 hour: (b) (4) %
	2 hours: (b) (4) %
	4 hours: NLT (b) (4) %

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement – Changes Being Effected when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Medicis' Solodyn Extended-release Tablets, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this product:

U.S. Patent Number	Expiration Date
5,908,838 (the '838 patent)	February 19, 2018
7,790,705 (the '705 patent)	June 24, 2025
7,919,483 (the '483 patent)	March 7, 2027

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Minocycline Hydrochloride Extended-release Tablets, 65 mg (base) and 115 mg (base), under this ANDA. You have notified the agency that Barr Laboratories, Inc. (Barr) complied with the requirements of section 505(j)(2)(B) of the Act, and that

litigation was initiated against Barr for infringement of the '838 and '705 patents within the statutory 45-day period in the United States District Court for the District of Maryland [Civil Action No. 1:09-cv-03464-JFM]. You have also notified the agency that the litigation has been dismissed.

With respect to 180-day generic drug exclusivity, we note that Barr was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to one or more of the patents listed for Minocycline Hydrochloride Extended-release Tablets, 65 mg (base) and 115 mg (base). Therefore, with this approval, Barr is eligible for 180 days of generic drug exclusivity for Minocycline Hydrochloride Extended-release Tablets, 65 mg (base) and 115 mg (base). This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

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.

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.

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/U_CM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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/

ROBERT L WEST

05/18/2012

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.