DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 90-024

Impax Laboratories, Inc.
Attention: Michelle P. Wong, Ph.D.
Senior Director, Regulatory Affairs
30831 Huntwood Avenue
Hayward, CA 94544

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated October 5, 2007, 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 November 9, and December 19, 2007; and February 22, March 31, April 10, June 9, July 28, August 8, September 10, and September 12, 2008.

We have completed the review of this ANDA 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 ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Minocycline Hydrochloride Extended-release Tablets, 45 mg (base), 90 mg (base), and 135 mg (base) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Solodyn® Tablets, 45 mg (base), 90 mg (base), and 135 mg (base), respectively, of Medicis Pharmaceutical Corporation (Medicis).

The referenced listed drug product (RLD) upon which you have based your ANDA, Medicis' Solodyn® Tablets, 45 mg (base), 90 mg (base), and 135 mg (base), is subject to a period of patent protection. The following patent and expiration date are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), the 5,908,838 ('838) patent, expiring February 19, 2018.

The '838 patent was not listed with the agency by the NDA holder when the Office of Generic Drugs (OGD) received your ANDA on October 5, 2007.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '838 patent is invalid , unenforceable, or will not be infringed by your manufacture, use, or sale of Minocycline Hydrochloride Extended-release Tablets, 45 mg (base), 90 mg (base), and 135 mg (base), under this ANDA. You have notified the agency that Impax complied with the requirements of section 505(j)(2)(B) of the Act. In addition, we note that no action for infringement of '838 patent was brought against Impax within 45 days of the receipt of notice of your paragraph IV certification.
We note that the '838 patent was filed with the Secretary not later than 60 days after the enactment of the QI Supplemental Funding Act of 2008 (QI Act). The QI act provides that with respect to patent information filed with the Secretary within the 60-day period after enactment, "each applicant that, not later than 120 days after the date of the enactment of this Act, amends an application that is, on or before the enactment of this Act, a substantially complete application (as defined in paragraph (5)(B)(iv) of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j))) to contain a certification described in paragraph (2)(A)(vii)(IV) of such section 505(j) with respect to that patent shall be deemed to be a first applicant (as defined in paragraph (5)(B)(iv) of such section 505(j)." Because you amended your substantially complete application not later than 120 days after the date of enactment of the QI act, to contain a paragraph IV certification to the '838 patent, you are deemed to be a first applicant (as defined in 21 U.S.C. 505(j)(5)(B)(iv)).

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

Medium:	0.05M phosphate buffer, pH 6.8
Volume:	900 mL
Apparatus:	Paddle
Speed of Rotation:	50rpm
Temperature:	37°C

The test product should meet the following specifications:

1 hour: NLT (b)(4) and NMT (b)(4)

2 hour: NLT (b) (4) and NMT (b) (4)
5 hour: 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.

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.

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 505-1(i).

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
Division of Drug Marketing, Advertising, and Communications
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 Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at

http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "***Miscellaneous Correspondence – SPL for Approved ANDA 90-024***".

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
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/

Gary Buehler

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