



ANDA 090911

Mylan Pharmaceuticals, Inc.  
U.S. Agent for: Matrix Laboratories Inc.  
Attention: Keith J. Giunta  
Director, Regulatory Affairs  
781 Chestnut Ridge Road  
P.O. Box 4310  
Morgantown, WV 26505

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 30, 2008, 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 March 20, June 1, October 13, October 21, and October 30, 2009; and January 6, January 7, January 15, January 18, and January 22, 2010.

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 (RLD), Solodyn Tablets, 45 mg (base), 90 mg (base), and 135 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 application. The “interim” dissolution specifications are as follows:

Volume: 900 mL  
Medium: 0.1 N Hydrochloric Acid  
Apparatus: Basket (I)  
Speed of Rotation: 100 RPM

Specifications:

For the 45 mg tablets:

<u>Time (hours)</u>	<u>Percent Dissolved</u>
1	40 - 60 (Q)
2	60 - 85 (Q)
4	NLT 85 (Q)

For the 90 mg and 135 mg tablets:

1	30 – 50 (Q)
2	60 - 80 (Q)
4	NLT 85 (Q)

These “interim” dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a “Special Supplement – Changes Being Effected” if there are no revisions to be made to the “interim” specifications, or if 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 Tablets, is subject to periods of patent protection. The following patents and their expiration dates are currently listed in the agency’s publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
5,908,838 (the ‘838 patent)	February 19, 2018
7,541,347 (the ‘347 patent)*	April 2, 2027
7,544,373 (the ‘373 patent)*	April 2, 2027

\*only listed for the 90 mg strength

These patents were not listed with the agency by the NDA holder when the Office of Generic Drugs (OGD) received your ANDA on October 1, 2008.

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, 45 mg (base), 90 mg (base), and 135 mg (base), under this ANDA. You have notified the agency that Matrix Laboratories Inc. (Matrix) complied with the requirements of section 505(j)(2)(B) of the Act. 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 [February 5, 2009], amends an application that is, on or before [October 8, 2008], 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).

With respect to 180-day generic drug exclusivity, we note that Matrix, by virtue of its timely submission to a substantially complete ANDA of an amendment containing a paragraph IV certification to the ‘838 patent, is a “first applicant” with respect to its ANDA for Minocycline Hydrochloride Extended-release Tablets, 45 mg (base), 90 mg (base), and 135 mg (base).<sup>1</sup> Therefore, with this approval, Matrix is eligible for 180 days of shared generic drug exclusivity for Minocycline Hydrochloride Extended-release Tablets, 45 mg (base), 90 mg (base), and 135 mg (base). This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, runs from the date of commercial marketing by a first applicant.

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 directly to:

---

<sup>1</sup>See part (b) of section 4 of the QI Supplemental Funding Act of 2008 (QI Act). These Transitional Rules provide that, with respect to patent information filed with the Secretary within the 60-day period after enactment of the QI Act–

“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 ... to contain a [paragraph IV certification] 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).”

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.

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 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.

Sincerely yours,

*{See appended electronic signature page}*

Keith Webber, Ph.D.  
Deputy Director  
Office of Pharmaceutical Science  
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
----- ANDA-90911	----- ORIG-1	----- MATRIX LABORATORIES LTD	----- MINOCYCLINE ER CAPSULES 135 mg

-----  
**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  
07/20/2010  
Deputy Director, Office of Generic Drugs  
for Keith Webber, Ph.D.