DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091424

Lupin Limited
U.S. Agent for: Lupin Pharmaceuticals Inc.
Attention: Leslie Sands
Director, Regulatory Affairs
Harborplace Tower, 111 South Calvert Street, 21st Floor
Baltimore, MD 21202

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated April 6, 2009, 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), 55 mg (base), 65 mg (base), 80 mg (base), 90 mg (base), 105 mg (base), 115 mg (base), and 135 mg (base).

Reference is also made to your amendments dated August 27, September 18, November 19, November 23, December 2, December 7, and December 23, 2009; January 4, January 6, February 3, February 5, March 9, August 12, September 16, September 21, September 28, October 28, November 27, December 2 and December 6, 2010; and January 11, January 21, January 25, February 3, March 14, April 18, April 27, May 16, June 13, July 20, August 19, August 25, October 21, October 25, October 31, November 7, November 17, and November 22, 2011.

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, your ANDA insofar as it provides for Minocycline Hydrochloride Extended-Release Tablets, 45 mg (base), 55 mg (base), 90 mg (base) and 135 mg (base), is approved, effective on the date of this letter. As explained below, your ANDA insofar as it provides for Minocycline Hydrochloride Extended-Release Tablets, 65 mg (base), 80 mg (base), 105 mg (base) and 115 mg (base), is tentatively approved.

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

U.S. Patent Number	Expiration Date
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
7,790,705 (the '705 patent)	November 20, 2025
7,919,483 (the '483 patent)	February 28, 2027

*listed only for the 90 mg strength

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), 55 mg (base), 65 mg (base), 80 mg (base), 90 mg (base), 105 mg (base), 115 mg (base), and 135 mg (base), under this ANDA.[1] You have notified the agency that Lupin Limited (Lupin) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '838 patent was initiated against Lupin within the 45-day statutory period in the U.S. District Court for the District of Maryland [Medicis Pharmaceutical Corp. v. Lupin Limited & Lupin Pharmaceuticals Inc., Civil Action No. 09-3062(JFM).] You have also notified the agency that the litigation ended on July 21, 2011, upon the courts signing a consent judgment pursuant to a settlement agreement in the case.

I. Approval of Minocycline Hydrochloride Extended-Release Tablets, 45 mg (base), 55 mg (base), 90 mg (base) and 135 mg (base).

The Division of Bioequivalence has determined your Minocycline Hydrochloride Extended-Release Tablets, 45 mg, 55 mg, 90 mg and 135 mg, to be bioequivalent and, therefore, therapeutically

[1] It is noted that, with respect to the 45 mg, 90 mg, and 135 mg strengths, which were the strengths contained in your ANDA when it was received, the '705, '347, '373, '483 patents were listed after submission of your ANDA, and your certifications to these patents were submitted in amendments to your ANDA. Therefore, any litigation with respect to these patents does not give rise to a 30-month stay of approval with respect to these three strengths.

equivalent to the RLD, Solodyn Extended-release Tablets 45 mg (base), 55 mg (base), 90 mg (base) and 135 mg (base), respectively, of Medicis Pharmaceutical Corporation.

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 900 mL of 0.1 N HCl at 37°C using USP Apparatus I (Basket) at 100 rpm. The test product should meet the following "interim" specifications:

Time (hours)	Percent Dissolved
0.5	NMT (b) (4)
1.5	(b) (4)
4.0	NLT (b) (4)

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.

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:

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 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 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.

II. Tentative Approval of Minocycline Hydrochloride Extended-Release Tablets, 65 mg (base), 80 mg (base), 105 mg (base) and 115 mg (base).

As noted above, your ANDA insofar as it pertains to Minocycline Hydrochloride Extended-Release Tablets, 65 mg (base), 80 mg (base), 105 mg (base) and 115 mg (base), is tentatively approved. This is because a substantially complete ANDA containing paragraph IV certifications to one or more of the listed patents was submitted for these five strengths prior to the submission of your ANDA. Your Minocycline Hydrochloride Extended-release Tablets 65 mg (base), 80 mg (base), 105 mg (base) and 115 mg (base) will be eligible for final approval upon the expiration of the other applicant's 180-day generic drug exclusivity or when that applicant's eligibility for 180-day generic drug exclusivity has been otherwise resolved.

Our decision to tentatively your ANDA insofar as it pertains to the 65 mg (base), 80 mg (base), 105 mg (base) and 115 mg (base) strengths, is based upon information currently available to the agency (i.e., data in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). This decision is subject to change on the basis of new information that may come to our attention.

To reactivate your ANDA prior to final approval of your Minocycline Hydrochloride Extended-release Tablets 65 mg (base), 80 mg (base), 105 mg (base) and 115 mg (base), please submit a "MINOR AMENDMENT TO ORIGINAL #2 – FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT TO ORIGINAL #2 – FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with cGMPs are subject to agency review before final approval of the supplemental application will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple supplements prior to final approval may also result in a delay in the issuance of the final approval letter.

Please note that under section 505 of the Act, your Minocycline Hydrochloride Extended-Release Tablets, 65 mg, 80 mg, 105 mg and 115 mg, may not be marketed without final agency approval. The introduction or delivery for introduction into interstate

commerce of these strengths before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, your 65 mg, 80 mg, 105 mg and 115 mg strengths will not be deemed approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book."

For further information on the status of this ANDA, or prior to submitting additional amendments, please contact Mark Gonitzke, Project Manager, at 240-276-8422.

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

11/30/2011

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