



ANDA 079021

Mylan Pharmaceuticals, Inc.  
Attention: S. Wayne Talton  
781 Chestnut Ridge Road  
P.O. Box 4310  
Morgantown, WV 26504

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated May 26, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Atomoxetine Hydrochloride Capsules, 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg.

Reference is made to the tentative approval letter issued by this office on November 25, 2009, and to your amendments dated December 1, 2009 June 28, August 12, August 13, August 25, and August 26, 2010.

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded 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 Atomoxetine Hydrochloride Capsules, 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Strattera Capsules of Eli Lilly and Company. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Lilly's Strattera Capsules, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,658,590 (the '590 patent) is scheduled to expire (with pediatric exclusivity added) on May 26, 2017.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '590 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Atomoxetine Hydrochloride Capsules,

10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against Mylan Pharmaceuticals, Inc. (Mylan) for infringement of the listed '590 patent. You notified the agency that Mylan complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of the '590 patent was brought against Mylan within the statutory 45-day period in the United States District Court for the District of New Jersey [Eli Lilly and Company v. Actavis Elizabeth LLC, Glenmark Pharmaceuticals Inc. USA, Sun Pharmaceutical Industries Limited, Sandoz Inc., Mylan Pharmaceuticals Inc., Apotex Inc., Aurobindo Pharma Ltd., Teva Pharmaceuticals USA, Inc., Synthron Laboratories, Inc., Zydus Pharmaceuticals, USA, Inc., Civil Action No. 07-3770 (DMC)]. You have also notified the agency that the court decided that the '590 patent is invalid. Therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

Mylan is eligible for 180 days of generic drug exclusivity for Atomoxetine Hydrochloride Capsules, 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg. Mylan was a first applicant to submit a substantially complete ANDA with a paragraph IV certification for Atomoxetine Hydrochloride Capsules, 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg, and Mylan has lawfully maintained this certification. As provided in section 505(j)(5)(B)(iv)(I), the exclusivity will begin to run from the date of the first commercial marketing of Atomoxetine Hydrochloride Capsules, 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg (including the first commercial marketing of the listed drug) by any first applicant. Within 10 days of first commercial marketing, please submit correspondence to this ANDA informing the agency of the date you begin commercial marketing of Atomoxetine Hydrochloride Capsules, 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg. Please also be aware that, under section 505(j)(5)(D), the 180-day exclusivity shall be forfeited by Mylan if a forfeiture event, as described in section 505(j)(5)(D), occurs with respect to Mylan.

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 section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA application 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.

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.

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

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ANDA-79021

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ORIG-1

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MYLAN  
PHARMACEUTICA  
LS INC

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ATOMOXETINE  
HYDROCHLORIDE

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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KEITH O WEBBER

08/30/2010