DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078940

Actavis Elizabeth LLC
Attention: Janak Jadeja
200 Elmora Avenue
Elizabeth, NJ 07207

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated May 25, 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 your amendments dated July 30, August 2, August 6, September 7, 2007; April 23, August 7, 2008; January 20, June 26, July 22, September 11, October 13, December 9, 2009; March 8, August 17, August 19, August 20, 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 Actavis Elizabeth LLC (Actavis) for infringement of the listed '590 patent. You notified the agency that Actavis complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of the '590 patent was brought against Actavis 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., Synthon 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.

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 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/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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-78940	ORIG-1	ACTAVIS ELIZABETH LLC	ATOMOXETINE HYDROCHLORIDE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KEITH O WEBBER
08/30/2010