DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 077528

Teva Pharmaceuticals USA
Attention: Jean Zwicker
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) received on January 10, 2005, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Olanzapine and Fluoxetine Capsules USP, 6 mg/25 mg (Base), 12 mg/25 mg (Base), 6 mg/50 mg (Base), and 12 mg/50 mg (Base).

Reference is also made to the tentative approval letter issued by this office on July 17, 2007, and to your amendments dated March 5, and April 9, 2008; February 23, and March 30, 2010; and January 21, September 15, October 7, October 10, November 23, December 5, and December 28, 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 the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Olanzapine and Fluoxetine Capsules USP, 6 mg/25 mg (Base), 12 mg/25 mg (Base), 6 mg/50 mg (Base), and 12 mg/50 mg (Base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Symbyax Capsules, 6 mg/25 mg (Base), 12 mg/25 mg (Base), 6 mg/50 mg (Base) and 12 mg/50 mg (Base), respectively, of Eli Lilly and Company (Lilly). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The reference listed drug (RLD) upon which your ANDA is based, Lilly's Symbyax Capsules, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 5,945,416 (the '416 patent) and 6,960,577 (the '577 patent) expire on March 24, 2017, and November 1, 2017, respectively.

With respect to the '577 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act that this is a method of use patent, and that it does not claim any indication for which you are seeking approval under your ANDA.

With respect to the '416 patent, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Olanzapine and Fluoxetine Hydrochloride Capsules, 6 mg/25 mg (Base), 12 mg/25 mg (Base), 6 mg/50 mg (Base), and 12 mg/50 mg (Base), under this ANDA. You notified the agency that Teva Pharmaceuticals USA (Teva) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Teva within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, we note that Teva was the first ANDA applicant to submit a substantially complete ANDA for Olanzapine and Fluoxetine Hydrochloride Capsules, 6 mg/25 mg (Base), 12 mg/25 mg (Base), 6 mg/50 mg (Base), and 12 mg/50 mg (Base), with a paragraph IV certification to the a patent listed for the RLD. As the first applicant, therefore, Teva was eligible for 180 days of generic drug exclusivity for Olanzapine and Fluoxetine Hydrochloride Capsules, 6 mg/25 mg (Base), 12 mg/25 mg (Base), 6 mg/50 mg (Base), and 12 mg/50 mg (Base). The Agency has determined, however, that Teva has forfeited its 180-day exclusivity period because it failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed.[1] See section 505(j)(5)(D)(I)(IV) of the Act.

[1] Teva's ANDA 077528 was received (filed) on January 10, 2005. 30 months from that date was July 10, 2007. ANDA 077528 was tentatively approved on July 17, 2007. The agency finds that this failure to obtain tentative approval by July 10, 2007, was not caused by a change in or a review of the requirements for approval, nor was a related citizen petition submitted that was subject to section 505(q) of the Act.

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/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

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
06/19/2012
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.