



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

ANDA 078901

Sandoz Inc.  
Attention: Bernadette Attinger  
Director, Regulatory Affairs  
506 Carnegie Center, Suite 400  
Princeton, NJ 08540

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 28, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Olanzapine and Fluoxetine Capsules USP, 3 mg/25 mg, 6 mg/25 mg, 12 mg/25 mg, 6 mg/50 mg and 12 mg/50 mg.

Reference is also made to your amendments dated September 5, and October 11, 2007; January 23, and May 21, 2008; July 8, 2009; May 17, and May 28, 2010; January 21, March 1, March 3, September 12, September 15, September 27, October 13, and October 21, 2011; and February 21, March 2, March 12, March 22, and August 17, 2012.

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, 3 mg/25 mg, 6 mg/25 mg, 12 mg/25 mg, 6 mg/50 mg, and 12 mg/50 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Symbyax Capsules, 3 mg/25 mg, 6 mg/25 mg, 12 mg/25 mg, 6 mg/50 mg, and 12 mg/50 mg, respectively, 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, Symbyax Capsules, 3 mg/25 mg, 6 mg/25 mg, 12 mg/25 mg, 6 mg/50 mg, and 12 mg/50 mg, of Eli Lilly and Company (Eli Lilly), 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") for this drug product:

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
5,945,416 (the '416 patent)	March 24, 2017
6,960,577 (the '577 patent)	November 1, 2017

Your ANDA contains paragraph IV certification to the '416 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Olanzapine and Fluoxetine Capsules USP, 6 mg/25 mg, 12 mg/25 mg, 6 mg/50 mg, and 12 mg/50 mg, under this ANDA. You have notified the agency that Sandoz Inc. (Sandoz) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Sandoz 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 the '577 patent, your ANDA contains statements 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.

As of October 1, 2012, Sandoz Inc. (Sandoz) must pay fees in accordance with the Generic Drug User Fee Amendments of 2012 (Public Law 112-144, Title III). Because your ANDA was pending on October 1, 2012, your ANDA is now subject to a backlog fee. You will not be penalized until the backlog fee payment is overdue. As indicated in the Federal Register (FR) notice (77 FR 65199), published on October 25, 2012, the backlog fee is due no later than 30 days after publication of the notice. If you do not pay the fee by the due date, statutory penalties take effect. At that time, FDA cannot receive any further ANDAs or supplemental applications from Sandoz or its affiliates, and Sandoz will be placed on a publicly available arrears list until the fee is paid.

In addition, your ANDA is now subject to facility fee(s). As noted above, you must pay fees in accordance with the Generic Drug User Fee Amendments of 2012 (Public Law 112-144, Title III). You will not be penalized for nonpayment of the facility fee until the fee payment is overdue. The fee must be paid by

the date listed in the FR notice announcing the facility fee amount. If the facility fee(s) is not paid by the due date, statutory penalties take effect. At that time, FDA will deem misbranded this ANDA product and all products from facilities that have not paid the appropriate fee. In addition, facilities that have not paid the fee will be placed on a publicly available arrears list, until the fee is paid or the facilities are removed from the ANDA.

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 inserts 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 Office of Prescription Drug Promotion 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}*

Gregory P. Geba, M.D., M.P.H.  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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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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LEIGH A SEARS on behalf of SARAH K NGUYEN  
11/16/2012

ROBERT L WEST  
11/16/2012  
Deputy Director, Office of Generic Drugs, for  
Gregory P. Geba, M.D., M.P.H.