DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 077742

Par Pharmaceutical, Inc.
Attention: Julie Szozda
Submissions Manager, Regulatory Affairs
One Ram Road
Spring Valley, NY 10977

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated June 7, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Olanzapine and Fluoxetine Hydrochloride Capsules USP, 3 mg/25 mg (base), 6 mg/25 mg (base), 6 mg/50 mg (base), 12 mg/25 mg (base), and 12 mg/50 mg (base).

Reference is also made to your amendments dated October 5, 2005; June 15, June 30, September 22, September 26, and October 12, 2006; January 18, June 27, July 17, August 22, and December 18, 2007; January 2, February 19, May 13, and September 5, 2008; February 20, March 9, and October 2, 2009; August 16, September 29, and December 3, 2010; March 8, April 14, April 29, May 17, June 20, July 8, July 14, August 3, August 24, November 4, November 7, and December 22 2011; and January 20, February 9, and October 16, 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 (base), 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, 3 mg/25 mg (base), 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 application.

The RLD upon which your ANDA is based, Lilly's Symbyax, 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 '416 patent (except for the 3 mg/25 mg strength for which this patent is not listed), 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, 3 mg/25 mg (base), 6 mg/25 mg (base), 6 mg/50 mg (base), 12 mg/25 mg (base), and 12 mg/50 mg (base), under this ANDA. You have notified the agency that Par Pharmaceutical, Inc. (Par) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Par within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

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.

As of October 1, 2012, Par Pharmaceutical, Inc. (Par) 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 Oct. 1, 2012, your ANDA is now subject to a backlog fee. However, 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 supplements from Par or its affiliates, and Par 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 Federal Register notice announcing the facility fee amount. If the facility fee 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 appropriate 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 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.

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

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

11/02/2012

Deputy Director, Office of Generic Drugs, for
Gregory P. Geba, M.D., M.P.H.