ANDA 77-666

OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 301-594-0180

FAX TRANSMISSION COVER SHEET

APPLICANT: Apotex Corp. TEL: 954-384-3986

ATTN: Kiran Krishnan FAX: 954-349-4233

FROM: Thomas Hinchliffe PROJECT MANAGER: (301) 827-5771

Dear Sir:

This facsimile is in reference to your abbreviated new drug application dated March 31, 2005, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Mirtazapine Tablets, 15 mg, 30 mg, and 45 mg.

We are pleased to inform you that this application is APPROVED!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-666

Apotex Corp.
U.S. Agent for: Apotex Inc.
Attention: Kiran Krishnan
Manager, Regulatory Affairs
2400 North Commerce Parkway, Suite 400
Weston, Florida 33326

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 31, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Mirtazapine Tablets USP, 15 mg, 30 mg, and 45 mg.

Reference is also made to your amendments dated July 29, September 1, September 2, and October 25, 2005; February 23, July 31, and November 13, 2006; and June 1, June 7, June 27, and July 26, 2007.

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 Mirtazapine Tablets USP, 15 mg, 30 mg, and 45 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Remeron Tablets, 15 mg, 30 mg, and 45 mg, respectively, of Organon USA, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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.

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
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.

Sincerely yours,

(See appended electronic signature page)

Gary Buehler
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
8/22/2007 01:53:07 PM
for Gary Buehler