ANDA 76-143

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 Inc. TEL: 954-349-4217

ATTN: Kalpesh Shroff 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 27, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Bupropion Hydrochloride Tablets 75 mg and 100 mg.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-143

Food and Drug Administration
Rockville MD 20857

JAN 17 2006

Apotex Corp.
Attention: Kalpesh Shroff
Project Leader, Regulatory Affairs
U.S. Agent for: Apotex Inc.
2400 N. Commerce Parkway, Suite 400
Weston, FL 33326

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 26, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Bupropion Hydrochloride Tablets USP, 75 mg and 100 mg.

Reference is also made to your amendments dated July 22, July 30, and December 3, 2004; and May 27, July 13, September 1, September 2, and September 23, 2005.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Bupropion Hydrochloride Tablets USP, 75 mg and 100 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Wellbutrin® Tablets, 75 mg and 100 mg, respectively, of GlaxoSmithKline. 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 abbreviated application require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this abbreviated application 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.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research