ANDA 77-883

OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 240-276-9327

FAX TRANSMISSION COVER SHEET

APPLICANT: Apotex Corp.
U.S. Agent for Apotex Inc.

TEL: 954-384-3986

FAX: 954-349-4233

ATTN: Kiran Krishnan

PROJECT MANAGER: (240) 276-8555

FROM: Theresa Liu

Dear Sir:

This facsimile is in reference to your abbreviated new drug application dated June 15, 2006, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Balsalazide Disodium Capsules, 750 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 77-883

Apotex Inc.
US Agent: Apotex Corp.
Attention: Kiran Krishnan
Manager, Regulatory Affairs
2400 North Commerce Parkway, Suite 400
Weston, FL 33326

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated November 3, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Balsalazide Disodium Capsules, 750 mg.

Reference is also made to your amendment dated October 16, and November 8, 2006, August 22, September 21 and 24, October 31, and November 9, 2007.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Balsalazide Disodium Capsules, 750 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Colazal Capsules, 750 mg, of Salix Pharmaceuticals, 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(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,

(Signature)

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
12/28/2007 10:09:14 AM
for Gary Buehler