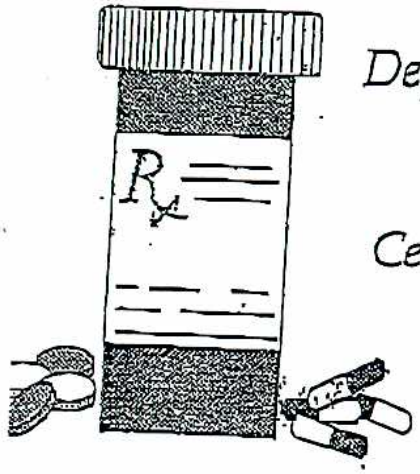
FAX COVER SHEET



Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Rockville, Maryland

Date: 9/12/06

To: Tammy / Bernice / Apotex

Phone: 954-345-4200 Fax: 9-1-416-401-3809

From: SIMON ENG 9-1-954-349-42

Phone: (301) 827-5848 FAX: (301) 594-0180

Number of pages: 4
(Including Cover Sheet)

Comments: Congrats ! 77746 is Ap'ed !

RECEIVED
SEP 12 2006
REGULATORY AFFAIRS
Apotex Corp.

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Thank you.

DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 77-746

Food and Drug Administration
Rockville MD 20857

SEP 12 2006

Apotex Corp.
Attention: Tammy McIntire
U.S. Agent for Apotex Inc.
2400 N. Commerce Parkway, Suite 400
Weston, FL 33326

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated June 30, 2005, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Midodrine Hydrochloride Tablets, 2.5 mg, 5 mg, and 10 mg.

Reference is also made to your amendments dated September 1, and December 8, 2005; and February 23, March 30, April 3, April 7, May 8, May 24, and August 28, 2006.

We have completed the review of this abbreviated application 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 application is approved, effective on the date of this letter.

The Division of Bioequivalence has determined your Midodrine Hydrochloride Tablets, 2.5 mg, 5 mg, and 10 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, ProAmatine® Tablets, 2.5 mg, 5 mg, and 10 mg, respectively, of Shire Development, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

FDA granted marketing approval for Shire's ProAmatine Tablets pursuant to 21 CFR 314.510 (Subpart H) on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint. This effect is reasonably likely, based upon epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit on the basis of an effect on a clinical endpoint other than

survival or irreversible morbidity. Approval under this section is subject to the requirement that the applicant agree to study the drug further to verify and describe its clinical benefit where there is uncertainty as to the relation of the surrogate endpoint to the benefit, or of the observed clinical benefit to the ultimate outcome. To date, Shire has not satisfied its post-marketing studies commitment for ProAmatine Tablets.

Under 21 CFR 314.530, for new drugs approved under Section 314.510 and 314.520, FDA may withdraw approval following a hearing if:

(1) The post-marketing clinical study fails to verify clinical benefit;

(2) The applicant fails to perform the required postmarketing study with due diligence;

(3) Use of the drug product after marketing demonstrates that the postmarketing restrictions are inadequate to assure the safe use of the drug product;

(4) The applicant fails to adhere to the postmarketing restrictions agreed upon;

(5) The promotional materials are false or misleading; or

(6) Other evidence demonstrates that the drug product is not shown to be safe or effective under its conditions of use.

Please note that if approval of the listed drug is withdrawn or suspended for any of the reasons specified in 21 CFR 314.530, the approval of your abbreviated new drug application (ANDA), which relies on the finding of safety and effectiveness for the listed drug, may also be withdrawn pursuant to 21 CFR 341.150 and 314.151, or suspended prior to withdrawal pursuant to 21 CFR 314.153.

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 that 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,

Robert Lee Test/for

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