ANDA 77-030

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 Corporation,
U.S. Agent for: Apotex, Inc.

TEL: 847-279-7740

FAX: 847-353-2982

ATTN: Michael Lisjak (2 pages+cover)

PROJECT MANAGER: (301) 827-5798

FROM: Stanley Shepperson

cc: Bernice
Teva. Apotex, Inc.
(416) 401-3807

Dear Sir:

This facsimile is in reference to your abbreviated new drug application dated December 19, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Cilostazol Tablets, 50 mg and 100 mg.

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

12/10/04

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 77-030

DEC 10 2004

Apotex Corp.
U.S. Agent for: Apotex, Inc.
Attention: Marcy Macdonald
616 Heathrow Drive
Lincolnshire, IL 60069

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated January 15, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Cilostazol Tablets, 50 mg and 100 mg.

Reference is also made to your amendments dated September 9, September 15, October 26, November 3 (two amendments), November 8, and November 24, 2004.

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 Cilostazol Tablets, 50 mg and 100 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Pletal® Tablets, 50 mg and 100 mg, respectively, of Otsuka Pharmaceutical Company, Ltd.). 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.

Post-marketing 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
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

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 (HFD-42) 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