DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-863/S-021

Otsuka America Pharmaceuticals, Inc.
Attention: Mr. Edwin O. Billips
2440 Research Blvd.
Rockville, MD 20850

Dear Mr. Billips:

We refer to your supplemental new drug application submitted on June 15, 2007, received June 18, 2007, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pletal (cilostazol) 50 mg and 100 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for revisions to the Post-Marketing Experience section of the package insert.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the submitted electronic labeling text.

If you issue a letter communicating important information about this drug product (*i.e.*, a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call:

Ms. Meg Pease-Fye, M.S.
Regulatory Health Project Manager
(301) 796-1130

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure : approved labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

11/13/2007 12:12:57 PM