DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-863/S-011

Otsuka America Pharmaceutical, Inc.
Attention: Anutosh Saha, Ph.D.
2440 Research Blvd.
Rockville, MD 20850

Dear Dr. Saha:

Please refer to your supplemental new drug application dated July 29, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pletal (cilostazol) 50 and 100 mg Tablets.

We acknowledge receipt of your electronic submission dated August 15, 2005. This submission constituted a complete response to our January 27, 2005 action letter.

This supplemental new drug application provides for requested revisions to the **PRECAUTIONS** and **ADVERSE REACTIONS** sections of the package insert.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 15, 2005.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 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.
Acting Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Attached:
label

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

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