DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-718/S-025

Millennium Pharmaceuticals, Inc.
Attention: Ms. Melody Brown
40 Landsdowne Street
Cambridge, MA 02139

Dear Ms. Brown:

Please refer to your supplemental new drug application dated June 14, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Integrilin (eptifibatide) 0.75 and 2 mg/mL Injection.

We acknowledge receipt of your submission dated June 14, 2005.

This "Changes Being Effected in 30 days" supplemental new drug application provides for changes to the **WARNINGS** and **DOSAGE AND ADMINISTRATION** sections of the package insert as a results of post hoc analyses of the PROTECT-TIMI 30, ESPRIT and CRUSADE trials.

We have completed our review of this electronically submitted supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 16, 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:

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

Sincerely,

{See appended electronic signature page}

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

Attached:
Approved 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

10/12/2005 07:17:56 AM