DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-718/S-022

Millennium Pharmaceuticals, Inc.
Attention: Ms. Melody Brown
75 Sidney Street
Cambridge, MA 02139

Dear Ms. Brown:

Please refer to your supplemental new drug application dated April 20, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Integrilin (eptifibatide) 0.75 and 2 mg/mL Injection.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of the adverse reaction, "acute profound thrombocytopenia" to the **Post-Marketing Experience** section of the approved package insert.

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

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert submitted to the Division on April 20, 2004.

Please submit the FPL electronically according to the guidance for industry entitled, "Providing Regulatory Submissions in Electronic Format – NDA." Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated, "FPL for approved supplement NDA 20-718/S-022." Approval of this submission by FDA is not required before the labeling is used.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Meg Pease-Fye, Regulatory Project Manager, at (301) 594-5312.

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

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

7/15/04 09:27:18 AM