DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-718/S-017

Millennium Pharmaceuticals, Inc.
Attention: Michael Marsman, Pharm.D.
256 East Grand Avenue
South San Francisco, CA 94080

Dear Dr. Marsman:

Please refer to your supplemental new drug application dated August 19, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Integrilin (eptifibatide) 20mg/10mL and 75mg/100mL Injection.

We acknowledge receipt of your submissions dated September 13 (three) and 20, and October 10 and 11, 2002, and June 5, 2003.

This supplemental new drug application provides for the use of Integrilin (eptifibatide) Injection for acute coronary symptoms and percutaneous coronary intervention.

We have completed the 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, and include the minor editorial revisions indicated, to the enclosed labeling (package insert submitted June 5, 2003). These revisions are terms of the approval of this application.

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 ten 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-017." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

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

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

MEDWATCH, HF-2
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, Regulatory Project Manager, at (301) 594 – 5312.

Sincerely,

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

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

/s/

Doug Throckmorton

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