DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-913/S-010

Merck & Co., Inc.
Attention: Michael C. Elia, Ph.D.
Director, Regulatory Affairs
Sumneytown Pike
P.O.Box 4, BLA-20
West Point, PA 19486

Dear Dr. Elia:

Please refer to your supplemental new drug application dated January 23, 2002, received January 24, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aggrastat (Tirofiban Hydrochloride) Injection Premixed, 0.05 mg/mL.

This supplemental new drug application provides for a new 100 mL configuration of Aggrastat Injection Premixed, 0.05 mg/mL.

We have completed the review of this supplemental application, and have concluded that adequate information has been provided to demonstrate that the drug product is safe and effctive for use as recommended in the draft labeling in your January 23, 2002 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

Please submit final printed labeling (FPL), identical to your draft labeling (text for the package insert and container labels) in the next Annual Report.

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, call Colleen Locicero, RPh, Regulatory Health Project Manager, at (301) 594-5332.

Sincerely,

{See appended electronic signature page}

Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Cardio-Renal Drug Products, (HFD-110)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Kasturi Srinivasachar

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