May 14, 1998

NDA 20-912
20-913

Merck Research Laboratories
Attention: Larry P. Bell, M.D.
Sumneytown Pike, P.O. Box 4
BLA-20
West Point, PA 19486

Dear Dr. Bell:

Please refer to your October 31, 1997 new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aggrastat (tirofiban hydrochloride) Injection, 12.5 mg per 50 ml vial (NDA 20-912) and Aggrastat (tirofiban hydrochloride) Injection Premixed, 25 mg per 500 mL single dose container (NDA 20-913).

We acknowledge receipt of your submissions dated May 4, 5, 8 and 11, 1998.

The user fee goal date is July 5, 1998.

These new drug applications provide for the use of Aggrastat, in combination with heparin, for the treatment of acute coronary syndrome, including patients who are to be managed medically and those undergoing PTCA or atherectomy.

We have completed the review of these applications and have concluded that adequate information has been presented to demonstrate that the drugs are safe and effective for use as recommended in the final printed labeling included with your May 8 (package insert) and May 11 (carton and container labels), 1998 submissions. Accordingly, the applications are approved effective on the date of this letter.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of these drug products when they are available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

At the time of your next printing, please revise the Aggrastat (tirofiban hydrochloride) Injection Premixed container label so that the concentration reads, •50 μg/mL" instead of •0.05 mg/mL."

If you have any questions, please contact:

Mr. David Roeder
Regulatory Health Project Manager
(301) 594-5313

Sincerely yours,

Robert Temple, M.D.

Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research