



**DEPARTMENT OF HEALTH & HUMAN
SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-913/S-008
20-912/S-009

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

Dear Dr. Elia:

Please refer to your supplemental new drug applications dated April 5, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aggrastat (tirofiban hydrochloride) Premixed Injection and Aggrastat Injection.

These supplemental new drug applications provide data to support the compatibility of Aggrastat Premixed Injection and Aggrastat Injection with eight intravenous therapeutics. Additionally, these applications provide draft labeling revised to reflect this intravenous compatibility information, as follows:

The last paragraph of the **DOSAGE AND ADMINISTRATION** /*Directions for Use* subsection was revised from the following:

(b)(4)

to the following:

AGGRASTAT may be administered in the same intravenous line as atropine sulfate, dobutamine, dopamine, epinephrine HCl, furosemide, lidocaine, midazolam, HCl, morphine sulfate, nitroglycerin, potassium chloride, propranolol HCl, and PEPCID* (famotidine) Injection. AGGRASTAT should not be administered in the same intravenous line as diazepam.

We completed our review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in your April 5, 2001 submitted draft package insert. Accordingly, these applications are approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the April 5, 2001 submitted package insert.

Please submit the FPL electronically to each application according to the guidance for industry titled 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, these submissions should be designated "FPL for approved supplement NDA 20-913/S-008 and NDA 20-912/S-009." Approval of these submissions 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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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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. Natalia Morgenstern
Chief, Project Management Staff
(301) 594-5328

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
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
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/s/

Doug Throckmorton
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