DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

MAY 1 1 1998

Ellen R. Westrick
Senior Director
Office of Medical/Legal
Merck & Co., Inc.
Sumneytown Pike
West Point, PA 19486

RE: NDA#20-912/20-913
Aggrastat (tirofiban hydrochloride) Injection
Aggrastat (tirofiban hydrochloride) Injection, Premixed
MACMIS ID #6643

Dear Ms. Westrick:

As part of its routine monitoring activities, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of a journal advertisement (982262-03-AGG) for Aggrastat, submitted by Merck & Co., Inc. (Merck) under cover of Form FDA 2253. DDMAC has determined that this advertisement is in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Specifically, this journal advertisement promotes an unapproved new drug.

The regulations promulgated pursuant to the Act at 21 CFR 312.7 state, among other things, that an investigational new drug may not be promoted as being safe and effective for the uses under investigation. Therefore, DDMAC usually considers pre-approval promotion of drug products to be violative. However, DDMAC has traditionally recognized two methods in which sponsors may discuss products under FDA review, without making promotional claims of safety or efficacy that are prohibited by the Act.

The first method of permissible pre-approval promotion is "institutional promotion." Institutional advertisements state that a particular drug company is conducting research in a certain therapeutic area. The advertisement may not suggest any particular drug by name (proprietary or established) or otherwise suggest that a particular drug will soon be approved for use in the therapeutic area under discussion.

The second method of permissible pre-approval promotion is "coming soon" advertisements. Coming soon advertisements announce the name of a new product that will be available soon, but do not make written, verbal, or graphic representations or suggestions concerning the safety, efficacy, or intended use of the product.

This advertisement is not considered an institutional advertisement because it makes representations about the product including its mechanism of action and its specific use in the therapeutic area of acute coronary syndromes. The ad implies that Aggrastat will be used in management of patients with selected acute coronary syndromes by targeting the major platelet surface receptor involved in platelet aggregation (GP IIb/IIIa). Although the ad does not mention Aggrastat by name, there is a clear association with Aggrastat by Merck's dissemination of the journal ad and Merck's description of the possible uses and mechanism of action for the product. Specifically, the journal ad makes the following statements:

- New Research Targets GP IIb/IIIa Receptor
- Developing a New Approach to the Management of Selected Acute Coronary Syndromes.

Merck should immediately discontinue use of this journal ad and other promotional materials that are similarly violative. Please respond in writing by May 26, 1998, with your intent to comply with the above. Address your response to the undersigned at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Merck that only written communications are considered official.

In all future correspondence regarding the issues raised in this letter, please refer to MACMIS ID *# 6643 in addition to the NDA numbers.*

Sincerely,

Janet Norden, MSN, RN
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications