DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

TRANSMITTED VIA FACSIMILE

JUN 25 1998

Michael Marsman, Pharm.D.
Associate Director, Regulatory Affairs
COR Therapeutics, Inc.
256 E. Grand Avenue
South San Francisco, CA 94080

RE: NDA#20-718
Integrilin (eptifibatide) Injection
MACMIS ID #6774

Dear Dr. Marsman:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials for Integrilin (eptifibatide) injection disseminated by COR Therapeutics, Inc.'s (COR) that violate the Federal Food, Drug and Cosmetic Act and its implementing regulations. Reference is made to the following promotional letters submitted under cover of Form FDA 2253: M.D. letter (IT0048B/21776203), Pharmacist letter (IT0047B/21776009), and M.D. with COR relationship letter (IT0046B/21776106). DDMAC has reviewed these materials and has determined that they promote Integrilin in a manner that is false or misleading because they are lacking in fair balance.

In the promotional letters referenced above, COR presents Integrilin's indications for use for the treatment of patients with acute coronary syndrome (unstable angina and non-Q-wave myocardial infarction) and for the treatment of patients undergoing percutaneous coronary intervention. However, COR fails to present **any** risk information associated with Integrilin's use. Promotional materials must present information relating to side effects and contraindications of the drug with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug. The approved product labeling for Integrilin lists contraindications, warnings, precautions, and adverse reactions associated with the use of Integrilin. Since Integrilin has significant risks associated with its use, these promotional letters are lacking in fair balance because they fail to identify these risks.

COR should immediately cease distribution of these and other similar promotional materials for Integrilin that contain the same or similar claims without balancing risk information. COR should submit a written response to DDMAC on or before July 10, 1998, describing its intent and plans to comply with the above.

COR should direct its response to the undersigned by facsimile at (301) 594-6771, or 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 COR that only written communications are considered official.

In all correspondence regarding this particular submission, please refer to MACMIS ID #6774 in addition to the NDA number.

Sincerely,

/S/

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