DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

Ellen L. Martin
Director, Regulatory Affairs
COR Therapeutics, Inc.
256 East Grand Avenue
South San Francisco, CA 94080

SEP 25 1997

RE: **NDA#** 20-718
Integrilin (intrifiban)
MACMIS ID #5843

Dear Ms. Martin:

As part of its routine monitoring activities, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of a COR Pharmaceuticals, Inc.'s (COR) journal advertisement regarding Integrilin (intrifiban) and the PURSUIT Trial. DDMAC has determined that this advertisement is in violation of the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder. Specifically, this product 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 several representations about the product including its specific use in reducing morbidity and mortality associated with unstable angina. Specifically, the journal ad makes implied claims that the PURSUIT Trial will demonstrate that Integrilin will decrease mortality and morbidity in patients with unstable angina. Although the ad does not mention Integrilin by name, there is a clear association with Integrilin by COR's dissemination of the journal ad and COR's description of possible uses and mechanism of action for the product. For example, the journal ad states:

> Steadily increasing evidence implicates arterial thrombosis resulting from platelet aggregation as a pivotal contributor to the morbidity and mortality associated with unstable angina. This suggests that, by helping to prevent arterial thrombus formation, a therapy founded on broad-based inhibition of platelet aggregation should diminish morbidity and mortality in patients presenting with unstable angina.

COR should immediately discontinue use of this journal ad and other promotional materials that are similarly violative. Please respond in writing by October 9, 1997, 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 COR that only written communications are considered official.

In all future correspondence regarding the issues raised in this letter, please refer to MACMIS ID # 5843 in addition to the NDA number.

Sincerely,

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