DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-718/S-010
S-013

COR Therapeutics, Inc.
Attention: Michael R. Marsman, Pharm.D.
256 East Grand Avenue
South San Francisco, CA 94080

Dear Dr. Marsman:

Please refer to your supplemental new drug applications dated June 29, 2000 (S-010) and February 12, 2001 (S-013), received June 30, 2000 and February 13, 2001, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Integrilin (eptifibatide) Injection.

We acknowledge receipt of your submission dated May 14, 2001 that constituted a complete response to our March 28, and April 30, 2001 action letters.

S-010 provides for labeling revised to reflect the findings of the ESPRIT ("Enhanced Suppression of the Platelet IIb/IIIa Receptor with Integrilin Therapy (the 'ESPRIT Study); A Phase III Study in Patients Undergoing Percutaneous Coronary Intervention with Stent Implantation") study. The revisions include a new dosing recommendation for patients undergoing Percutaneous Coronary Intervention (PCI) and a revised recommended target range for the activated clotting time (ACT) during PCI.

S-013 provides for the addition of information to the package insert on bleeding events from post-marketing adverse event reports.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted May 14, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). As stated in our August 28, 2000 response to your August 4, 2000 request for a waiver of the pediatric study requirement for this application, we have waived the pediatric study requirement for this application.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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

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

If you have any questions, please call:

Ms. Colleen LoCicero
Regulatory Health Project Manager
(301) 594-5332

Sincerely yours,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research