

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number **20-718**

APPROVAL LETTER



NDA 20-718

MAY 18 1998

COR Therapeutics, Inc.
Attention: Ellen Martin
256 East Grand Avenue
South San Francisco, CA 94080

Dear Ms. Martin:

Please refer to your April 1, 1996 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Integrilin (eptifibatide) 20 mg/10 ml and 75 mg/100 ml, Injection.

We acknowledge receipt of your submissions dated March 31, April 10 and 24, and May 12, 13, and 15, 1998.

The user fee goal date is July 15, 1998.

This new drug application provides for the use of Integrilin for the following indications:

1. The treatment of patients with acute coronary syndrome (UA/NQMI), including patients who are to be managed medically and those undergoing percutaneous coronary intervention (PCI). In this setting, INTEGRILIN has been shown to decrease the rate of a combined endpoint of death or new myocardial infarction.
2. The treatment of patients undergoing PCI. In this setting, INTEGRILIN has been shown to decrease the rate of a combined endpoint of death, new myocardial infarction, or need for urgent intervention.

We have completed the review of this application, including the submitted draft labeling, 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 enclosed marked-up draft. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 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, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-718. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Cardio-Renal Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising
and Communications, HFD-40
5600 Fishers Lane
—Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

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 contact:

Ms. Colleen LoCicero
Regulatory Health Project Manager
(301) 594-5312

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number **20-718**

APPROVABLE LETTER



Food and Drug Administration
Rockville MD 20857

NDA 20-718

COR Therapeutics, Inc.
Attention: Ms. Ellen L. Martin
256 East Grand Avenue
South San Francisco, CA 94080

APR 1 1998

Dear Ms. Martin:

Please refer to your April 1, 1996 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Integrilin (eptifibatide), 20 mg/10 ml and 75 mg/100 ml, Injection.

We acknowledge receipt of your submissions dated March 5, 19, and 25, May 21, July 7, August 28, September 9, 26, and 30, October 13, 23, 24, and 28, November 10, 12 (two), 17, and 25, December 5, 9, 12, 15, and 18, 1997; January 6, 8, and 13 (two), February 12, and 27, and March 16 and 19, 1998.

The user fee goal date is April 1, 1998.

We have completed the review of this application as submitted with draft labeling, and it is approvable. Before this application may be approved, however, it will be necessary for you to submit final printed labeling in accordance with the enclosed marked-up draft.

Please provide the location in the NDA of the raw data for all studies that evaluated the occurrence of anti-Integrilin antibodies. If upon review of this data, it is determined that additional studies with the 180 $\mu\text{g}/\text{kg}$ and 2 $\mu\text{g}/\text{kg}\text{-min.}$ infusion dose are required to better characterize the occurrence of anti-Integrilin antibodies in humans, a phase IV commitment to perform additional studies may be requested.

During the meeting on March 25, 1998 between FDA, COR Pharmaceuticals and Duke Clinical Research Institute (DCRI), several issues were discussed that require further clarification.

Please submit 20 copies of the printed labels and other labeling, ten of which are individually mounted on heavy weight paper or similar material.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Cardio-Renal Drug Products and two copies of both the promotional material and the package insert directly to:

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Rockville, Maryland 20857

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action FDA may take action to withdraw this application.

The drug may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, please contact:

Ms. Colleen LoCicero
Consumer Safety Officer
Telephone: (301) 594-5312

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure