DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-887

SEP 14 1998

Diatide, Inc.
9 Delta Drive
Londonderry, NH 03053

Attention: J. Kris Piper
Senior Director Regulatory Affairs and Quality Assurance

Dear Mr. Piper:

Please refer to your new drug application (NDA) dated August 19, 1997, received August 20, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AcuTect™ (Kit for the Preparation of Technetium Tc 99m Apcitide) for injection, 100 ug peptide.

We acknowledge receipt of your submissions dated September 16, and 24, October 24, November 7, and 11, 1997; and January 6, 20, and 22, February 4, 11, 13, and 27, March 13, and 27, April 24, May 6, 22, and 28, June 17, and 26, July 2, and 21, August 10, 11, 14, and 28, 1998. Your submission of March 13, 1998 constituted a full response to our February 20, 1998 action letter. The user fee goal date for this application is September 16, 1998.

This new drug application provides for the use of AcuTect™ (Kit for the Preparation of Technetium Tc 99m Apcitide) for injection, 100 ug peptide, for scintigraphic imaging of acute venous thrombosis in the lower extremities of patients who have signs and symptoms of acute venous thrombosis.

We have completed the review of this application, 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 enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug. The following additions to the vial and carton labels and package insert proposed in your August 14, 1998, letter are acceptable.

1. Include "Manufactured for Diatide, Inc., Londonderry, NH 03053 by Dr. Rentschler Biotechnolgie GmbH, Laupheim, Germany."

2. Include "Distributed by Diatide, Inc. and Nycomed Amersham."

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 "FPL for approved NDA 20-887." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitments specified in your submissions dated March 13, and July 21, 1998. These commitments, along with any completion dates agreed upon, are listed below.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

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.

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, contact Catalina Ferre-Hockensmith, Consumer Safety Officer, at (301) 443-3500.

Sincerely,

Paula Botstein, M.D.
Acting Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure