DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 5 1999

**TRANSMITTED VIA FACSIMILE**

J. Kris Piper
Senior Director Regulatory Affairs
Diatide, Inc.
9 Delta Drive
Londonderry, New Hampshire 03053

**RE: NDA 20-887**
AcuTect (Kit for the preparation of Technetium Tc-99m Apctide Injection)
MACMIS ID # 7439

Dear Mr. Piper:

This letter is in reference to Diatide, Inc.'s (Diatide) submissions, dated November 12, and 20, 1998, of promotional materials under cover of Form FDA 2253 for Acutect. The submissions included an Acutect Clinical Guide CD cover, a banner titled, "The First Imaging Modality To Target Acute DVT," and 4 convention panels (60TT1, 60TT2, 60TT3, and "New Acutect"). The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these promotional materials and has concluded that they are lacking in fair balance or are otherwise misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Fair Balance

The convention posters identified as 60TT1, 60TT2, 60TT3, and "New Acutect" fail to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to the effectiveness of the drug. Although safety and qualifying information is presented at the bottom of the posters in small print, the risk information is presented in a manner that minimizes its importance and readability.

The wall poster titled "Veins of the Lower Extremities" and the CD cover "Acutect Clinical Guide" fail to present any information relating to side effects and contraindications or other risk information. This risk-balancing information should be presented in a manner comparable in prominence and readability as the presentation of information relating to the effectiveness of the drug.

Diatide should immediately cease the dissemination of these violative promotional labeling pieces and all similar promotional materials that are lacking fair balance.

Diatide should respond in writing to DDMAC regarding this issue by January 20, 1999. Diatide's response should include Diatide's intent to comply with the above request should also include the date that it ceased disseminating these and any other violative promotional materials.

If you have any questions, please contact the undersigned by telephone at (301) 827-2831, facsimile (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds Diatide that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 7439 and NDA 20-887.

Sincerely,

Warren F. Rumble
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications