DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Suzanne M. Sensabaugh, M.S.
Associate Director, Regulatory Affairs
Genzyme Corporation
One Kendall Square
Cambridge, MA 02139

RE: NDA 20-367
Cerezyme (imiglucerase for injection)
MACMIS ID#: 10172

Dear Ms. Sensabaugh:

This letter concerns Genzyme Corporation's (Genzyme) dissemination of a direct-to-consumer (DTC) radio broadcast advertisement (ad) for Cerezyme (imiglucerase for injection). The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed this ad as part of its monitoring and surveillance program and concludes that it is misleading and fails to comply with regulatory requirements. Therefore, this ad violates the Federal Food, Drug, and Cosmetic Act and applicable regulations. Our specific objections follow.

Misleading Minimization of Material Fact and Risk Information

"Cerezyme (imiglucerase for injection) is generally well-tolerated, however, side effects related to therapy may occur. The most common side effects include nausea, rash, and hives. Anaphylactic reactions have been reported in less than 1% of the patient population. Periodic monitoring for antibody formation is recommended. Patients should notify their health care provider immediately if they experience any side effects with their treatment."

The ad is misleading because it minimizes a material fact in light of representations made about the drug. The ad misleadingly minimizes the material fact that this drug is injected into the bloodstream over the course of one to two hours, and does not adequately explain that the patient may experience a variety of local reactions at the site of the injection (e.g., discomfort, itching, burning, swelling, or sterile abscesses).

In addition, the ad lacks fair balance because the content and presentation of the ad misleadingly minimize risks associated with use of Cerezyme. Specifically, the "generally well tolerated" safety claim is neither stated in the approved product labeling nor supported by substantial evidence. Furthermore, by presenting that the safety claim at the beginning of the risk discussion, it minimizes the subsequent important information about warnings and side effects related to hypersensitivity reactions. Moreover, some of the listed side effects are not communicated in consumer-friendly

language or with the context needed to be understandable to listeners (terms such as "anaphylactic reactions," "antibody formation," and "hypersensitivity reactions"). Finally, the speed with which the risk information is spoken is not reasonably comparable to the speed of the presentation of benefits information.

Failure to Fulfill "Adequate Provision" Through Incomplete Presentation

The radio ad does not fulfill the regulatory requirement to either present a "brief summary" of all the risk concepts or to ensure "adequate provision" for disseminating the approved product labeling to a potentially diverse audience of consumers. The ad provides no source of labeling for consumers who might want to remain anonymous (e.g., a print ad), nor for those who prefer to obtain information rapidly (e.g., through the Internet). Also lacking is a clear disclosure that healthcare providers, such as doctors, are an additional source of drug product information (rather than "prescribing information" a phrase that is implies that the information is meant only for healthcare providers).

Failure to Disclose Prescription Drug Status

The ad is misleading because it fails to clearly identify that Cerezyme is only available by prescription.

We acknowledge Genzyme's July 12, 2001, letter to DDMAC stating that the radio ad was aired one time only and was immediately discontinued on June 29, 2001. Your letter responded to our June 29, 2001, telephone conversation during which DDMAC notified Genzyme that, based on the script alone, the ad appeared to be violative and we requested the audiotape for review. We request that Genzyme review all other promotional materials for Cerezyme to determine if there are other materials with the same or similar claims or presentations.

Please respond to Margaret M. Kober, R.Ph., by facsimile at (301) 594-6771, or in writing at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications HFD-42, Rm. 17-B-20, 5600 Fishers Lane, Rockville, Maryland 20857. Your written response should be received no later than July 27, 2001, and should include a list of any violative materials, a description of your method of discontinuation, and the discontinuation date for each item.

In all future correspondence on this matter, please refer to MACMIS ID# 10172 as well as the NDA number. DDMAC reminds you that only written communications are considered official.

Sincerely,

{See appended electronic signature page}

Joan Hankin, J.D.
Consumer Promotion Analyst
Division of Drug Marketing,
Advertising, and Communications

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joan Hankin
7/13/01 11:38:42 AM

Gaucher disease radio ad

Most people have never heard of a genetic condition called Gaucher disease. This disease affects about one out of every 450 Ashkenazi Jews and is more prevalent than Tay-Sachs. The signs and symptoms of Gaucher disease include delayed growth in children, bone pain and easily fractured bones, fatigue, easy bruising and bleeding, and enlarged liver and spleen. Fortunately, testing is easy and there is treatment for Type 1 Gaucher disease, called Cerezyme® that can reverse and/or halt some of these symptoms.

If you believe that you are experiencing the symptoms of Gaucher disease, you owe it to yourself to talk with your physician. If you would like more information on testing, treatment, or to obtain full prescribing information please call Genzyme at 800-745-4447.

(Please read this section more quickly than above to keep the ad under 1 minute.) Cerezyme® (imiglucerase for injection) is generally well tolerated, however, side effects related to therapy may occur. The most common side effects include nausea, rash, and hives. Anaphylactic reactions have been reported in less than 1% of the patient population. Periodic monitoring for antibody formation is recommended. Patients should notify their health care provider immediately if they experience any side effects with their treatment.