



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103948/5065

Genzyme Corporation
Attention: Mark P. Hayes, Ph.D.
Vice President, Regulatory Affairs
4545 Horizon Hill Boulevard
San Antonio, TX 78229

DEC 19 2006

Dear Dr. Hayes:

Your request to supplement your biologics license application for Alemtuzumab to remove the freeze-watch indicators from Alemtuzumab packaging and to revise the How Supplied section of the package insert to provide instruction on thawing accidentally frozen Alemtuzumab at 2-8°C before administration has been approved.

Please submit the 36-month stability data for cycle B samples in the next Annual Report.

Please submit final printed labeling at the time of use and include implementation information on FDA Form 356h. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) submitted December 7, 2006. Marketing product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

Please submit within 30 days content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text dated December 7, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

Please refer to <http://www.fda.gov/cder/biologics/default.htm> for important information regarding therapeutic biological products, including the addresses for submissions.

This information will be included in your biologics license application file.

Sincerely,

A handwritten signature in cursive script that reads "Patricia Keegan".

Patricia Keegan, M.D.

Director

Division of Biologic Oncology Products

Office of Oncology Drug Products

Center for Drug Evaluation and Research

Enclosures: Package Insert