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,

Patricia Keegan, M.D.
Director
Division of Biologic Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosures: Package Insert