



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103948/5070

SEP 19 2007

Genzyme Corporation
Attention: Katherine O'Keefe, M.P.H.
Associate Director, Regulatory Affairs
4545 Horizon Hill Boulevard
San Antonio, TX 78229-2263

Dear Ms. O'Keefe:

Your request to supplement your biologics license application for Alemtuzumab (Campath) to expand the indication to include use as a single agent for treatment of B-cell chronic lymphocytic leukemia (B-CLL) has been approved.

We approved your biologics license application for treatment of B-cell chronic lymphocytic leukemia (B-CLL) in patients who have been treated with alkylating agents and who have failed fludarabine therapy, under the regulations at 21 CFR 601 Subpart E for accelerated approval of biological products for serious or life-threatening illnesses. Approval of this supplement fulfills your commitment made under 21 CFR 601.41 to verify the clinical benefit of Alemtuzumab by conducting protocol CAM 307.

The final printed labeling (FPL) must be identical to the enclosed labeling. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We acknowledge your written commitment to conduct a postmarketing study as described in your letter of September 19, 2007, as outlined below:

Postmarketing Study Commitment subject to reporting requirements of 21 CFR 601.70:

1. To conduct a QT study according to the principles of ICH E14: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (Section IID) in approximately 50 subjects receiving Alemtuzumab by the subcutaneous route of administration. A detailed protocol for this study will be submitted by September 30, 2008. The study will be initiated by December 31, 2008, and will be completed by September 30, 2010. A final study report will be submitted by June 30, 2011. A supplement with revised labeling, if applicable, will be submitted by September 30, 2011.

We request that you submit the clinical protocol to your IND, with a cross-reference letter to this biologics license application (BLA), STN BL 103948. Please use the following designators to

label prominently all submissions, including supplements, relating to the postmarketing study commitment as appropriate:

- Postmarketing Study Commitment Protocol
- Postmarketing Study Commitment - Final Study Report
- Postmarketing Study Correspondence
- Annual Status Report of Postmarketing Study Commitments

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. The status report for each study should include:

- information to identify and describe the postmarketing commitment,
- the original schedule for the commitment,
- the status of the commitment (i.e. pending, ongoing, delayed, terminated, or submitted),
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e. number enrolled to date and the total planned enrollment), and
- a revised schedule if the study schedule has changed and an explanation of the basis for the revision.

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our Web site (<http://www.fda.gov/cder/pmc/default.htm>). Please refer to the February 2006 Guidance for Industry: Reports on the Status of Postmarketing Study Commitments - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (see <http://www.fda.gov/cder/guidance/5569fnl.htm>) for further information.

Within 21 days of the date of this letter, submit 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. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved STN BL 103948/5070." In addition, within 21 days of the date of this letter, amend any pending supplement(s) for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

You may submit draft copies of the proposed introductory advertising and promotional labeling with a cover letter requesting advisory comments to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising and Communication, 5901-B Ammendale Road, Beltsville, MD 20705-1266. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by a FDA Form 2253.

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence to support that claim.

Please refer to <http://www.fda.gov/cder/biologics/default.htm> for 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 black ink that reads "Patricia Keegan". The signature is written in a cursive style with a large initial "P".

Patricia Keegan, M.D.

Director

Division of Biologic Oncology Products

Office of Oncology Drug Products

Center for Drug Evaluation and Research