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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

May 7, 2001

Our STN Number: BL 103948/0

Michael A. Recupero
Millennium and ILEX Partners, LP
75 Sidney Street
Cambridge, MA 02139

Dear Mr. Recupero:

This letter hereby issues Department of Health and Human Services U.S. License No. 1289 tc introduce or deliver for introduction into interstate commerce, those products for which your

Under this license you are authorized to manufacture the product Alemtuzumab. Alemtuzuma

Under this authorization, you are approved to manufacture Alemtuzumab at ----------
----------. In accordance with approved labeling, A

You are not currently required to submit samples of future lots of Alemtuzumab to the Center meet specifications.

The dating period for Alemtuzumab shall be 24 months from the date of manufacture when st studies should be submitted throughout the dating period, as they become available, including

Any changes in the manufacturing, testing, packaging or labeling of Alemtuzumab, or in the r approval of this product is granted under the accelerated approval of biological products regu threatening illnesses or conditions.

Approval under these regulations requires, among other things, that you conduct adequate anc

studies with due diligence. If postmarketing studies fail to verify that clinical benefit is confe

Granting of this approval is contingent upon completion of a clinical study, as outlined in you

1. We acknowledge your intention to address the commitment of verification of the clinic Lymphocytic Leukemia", submitted on March 16, 2001, and revised on April 20, 2001. labeling will be submitted in November 2006. It is understood that, to fulfill the require

We acknowledge that you have committed to do the following as part of protocol ------- (usin

2. Immunological assessment of the effect of Alemtuzumab therapy on responses to vacci
3. Assessment of the incidence of loss of CD52 expression at the time of relapse or diseas
4. A quantitative analysis of the incidence and magnitude of HAHA and anti-idiotypic ant

We also acknowledge the additional written commitments of March 5, March 16, April 27, ar

5. Submission of the final study report for protocol -------: "A Phase II Study, Including P
6. Submission of the validation plan for the human-anti-humanized antibodies (HAHA) as
7. Submission of the validation plan for the FACS based immune function assay in June 2
8. To evaluate data from the CMCL potency assay (QA 10379) and the monomer content supplement by June 2002.
9. To evaluate data from the residual Protein A assay (QA 10370) performed for lot releas

It is required that adverse experience reports be submitted in accordance with the adverse exp 600.80 and be submitted to the Center for Biologics Evaluation and Research, HFM-210, Foc

You are required to submit reports of biological product deviations in accordance with 21 CF may affect the safety, purity, or potency of the product, and meets the other criteria in the reg

Please submit all final printed labeling at the time of use and include implementation informa required to be submitted using FDA Form 2567 or Form 2253 to the Advertising and Promoti dissemination of any promotion labeling.

All promotional claims must be consistent with and not contrary to approved labeling. No cor

Sincerely yours,

--- *signature* ---

Steven A Masiello
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

--- *signature* ---

Jay P. Siegel, M.D., FACP
Director
Office of Therapeutics Research and Review

Center for Biologics Evaluation and Research

Last Updated: 5/9/2001

Date created: September 25, 2003