DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103705/5247

February 21, 2007

Genentech, Incorporated
Attention: Todd W. Rich, M.D.
Vice President Clinical and Commercial
Regulatory Affairs
1 DNA Way, MS# 242
South San Francisco, CA 94080-4990

Dear Dr. Rich:

Your request to supplement your biologics license application for Rituximab to revise the Boxed Warnings, Warnings, and Adverse Reactions sections of the Package Insert and to revise the Patient Package Insert to include information on post-marketing reports of progressive multifocal leukoencephalopathy (PML) in patients treated with Rituximab therapy has been approved.

Pursuant to 21 CFR 201.57(f)(2), patient labeling must be reprinted at the end of the package insert.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

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

We acknowledge receipt of 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. Upon 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

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

Enclosure: Package Insert