Our STN: BL 103705/5262

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
Adverse Reactions, Post-Marketing Reports section of the package insert to include additional
information on infections and information on disease progression of Kaposi's sarcoma has been
approved.

Pursuant to 21 CFR 201.57(c)(18) and 201.80(f)(2), patient labeling must be reprinted
immediately following the last section of labeling or, alternatively, accompany the prescription
drug labeling.

We note your September 20, 2007, submission included final content of labeling
[CFR 601.14(b)] in structured product labeling (SPL) format; we will transmit it to the National
Library of Medicine for public dissemination. 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.

Marketing the product with labeling that is not identical to the approved labeling text may render
the product misbranded and an unapproved new drug.

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,

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

Enclosure: Final Draft Labeling