



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

Our STN: 103705/5256

January 25, 2008

Genentech, Inc.  
1 DNA Way  
South San Francisco, CA 94080-4990

Attention: Todd W. Rich, M.D., M.B.A.  
Vice President, Regulatory

Dear Dr. Rich:

Please refer to your supplemental biologics license application dated March 28, 2007, received March 29, 2007, for Rituxan® (rituximab).

We acknowledge receipt of your submissions dated July 17, 23 and 31, August 22, September 6, and October 18, 2007, and January 24, 2008.

This supplemental biologics license application provides for expanding the indication for Rituxan® (rituximab) to include a claim to slow the progression of structural damage.

We have completed our review of this application, as amended, and it is approved effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We acknowledge your request to waive the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. As previously discussed with you, we are denying your request.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert and Medication Guide). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved sBLA 103705/5256."

**PEDIATRIC RESEARCH EQUITY ACT (PREA)**

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and

effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for ages 0 to 17 years until April 3, 2013.

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
HFD-001, Suite 5100  
5515 Security Lane  
Rockville, MD 20852

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.

If you have any questions, call Lauren Tornetta, Regulatory Project Manager, at (301) 796-2246.

Sincerely,



Rigoberto Roca, M.D.  
Deputy Director  
Division of Anesthesia, Analgesia  
and Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research