



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 125085/82

SEP 21 2006

Genentech, Incorporated
Attention: Todd 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 Bevacizumab to revise the WARNINGS and DOSAGE AND ADMINISTRATION sections of the package insert to provide information on reversible posterior leukoencephalopathy syndrome and to revise the ADVERSE REACTIONS section regarding nasal septum perforation, has been approved.

We acknowledge your written agreement of September 15, 2006, to disseminate a Dear Health Care Professional (DHCP) letter and revised package insert label containing an Important Drug Warning to the hematology and oncology medical communities as follows:

Printing will be initiated within 72 hours from the date of this letter, by September 25, 2006. Distribution will begin by October 5, 2006. In addition, Genentech will post the revised package insert and DHCP letter on the company website by October 5, 2006.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. The final printed labeling (FPL) must be identical to the enclosed labeling text dated September 15, 2006. Marketing product with FPL that is not identical to the approved labeling may render the product misbranded and an unapproved new drug. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

Please submit within 30 days 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 September 15, 2006. Upon receipt and 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. Effective August 29, 2005, the new address for all submissions to this application is:

Food and Drug Administration
Center for Drug Evaluation and Research
Therapeutic Biological Products Document Room
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

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: Revised Labeling