



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STN: BL 125085/67

APR 18 2006

Genentech, Incorporated
Attention. Robert L. Garnick, M.D.
Senior Vice President, Regulatory Affairs, Quality, and Compliance
1 DNA Way, MS# 242
South San Francisco, CA 94080-4990

Dear Dr. Garnick:

Your request to supplement your biologics license application for Bevacizumab to revise the WARNINGS section of the package insert to provide information on gastrointestinal perforation, has been approved.

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

This information will be included in your biologics license application file.

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia Keegan" followed by a flourish.

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

CONCURRENCE PAGE

(b) (5)



(b)(5)


