

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration Rockville, MD 20852

Our STN: BL 125085/67

APR 1 8 2008

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,

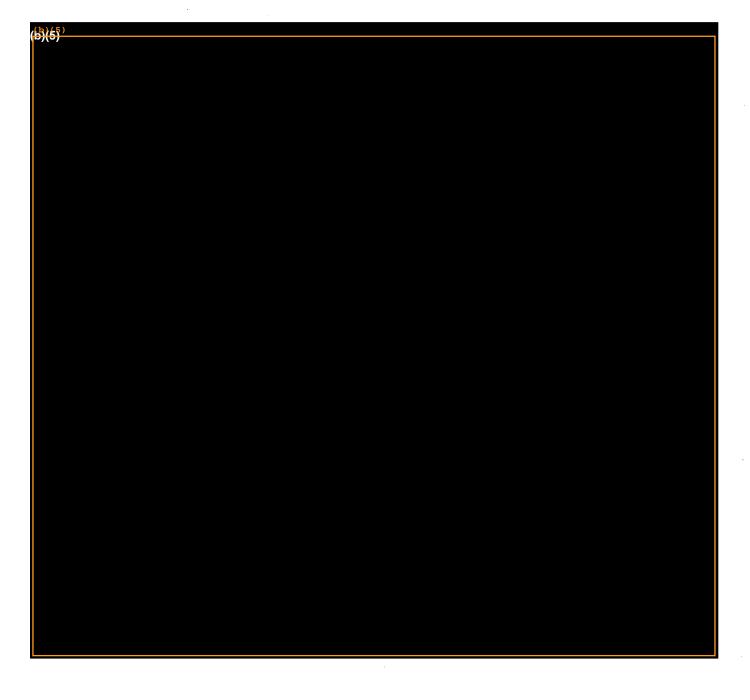
Patricia Keegan, M.D.

Director Division of Biologic Oncology Products Office of Oncology Drug Products Center for Drug Evaluation and Research

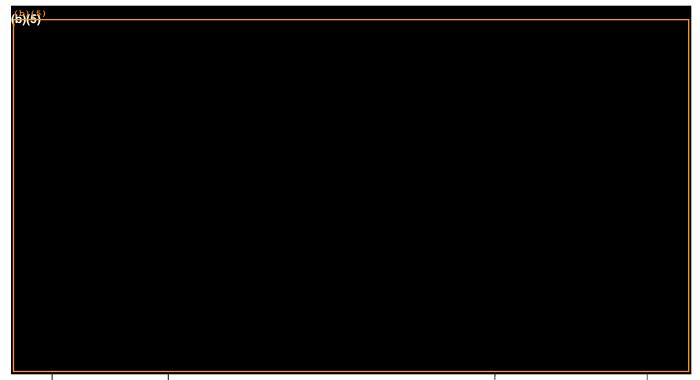
Enclosure: Final draft labeling

Page 2 - BL 125085/67

CONCURRENCE PAGE



Page 3 - BL 125085/67



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