



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Amgen, Incorporated
Attention: Randy Fenrick, Ph.D., MBA
Senior Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320

NOV 06 2007

Dear Dr. Fenrick:

Your request to supplement your biologics license application for panitumumab (Vectibix) to revise the WARNINGS section of the package insert to include a new subsection entitled, "Increased Toxicity with Combination Chemotherapy", and to revise the INDICATIONS AND USAGE section to include the qualifier "as a single agent" to the Indications statement has been approved. The data supporting the new WARNINGS subsection are from study 20040249 entitled, "A Randomized, Open-label, Controlled, Clinical Trial of Chemotherapy and Bevacizumab With and Without Panitumumab in the First-line Treatment of Subjects with Metastatic Colorectal Cancer (PACCE Trial)."

We note your October 19, 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