DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 125084/167

ImClone Systems, Incorporated
Attention: Michael Langley, D.V.M.
Associate Director, U.S. Regulatory Affairs
Eli Lilly and Company
Lilly Corporate Center
D.C. 2543
Indianapolis, IN 46285

Dear Dr. Langley:

Your request to supplement your biologics license application for Erbitux (cetuximab) to revise the INDICATIONS AND USAGE (1), CLINICAL PHARMACOLOGY (12), and CLINICAL STUDIES (14) sections to provide information on lack of efficacy in patients with metastatic colorectal cancer whose tumors have KRAS mutations has been approved.

Within 21 days of the date of this letter, submit 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. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved STN BL 125084/167." In addition, 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