DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STN: BL 125084/30

SEP 01 2005

ImClone Systems, Incorporated
Attention: Nikhil Mehta, Ph.D.
Vice President, Regulatory Affairs and Quality Assurance
33 ImClone Drive
Branchburg, NJ 08876

Dear Dr. Mehta:

Your request to supplement your biologics license application for Cetuximab to revise the WARNINGS and DOSAGE AND ADMINISTRATION sections of the package insert to include information on infusion observation periods and to revise the PRECAUTIONS and ADVERSE REACTIONS sections of the package insert to provide information on hypomagnesemia 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-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

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

Patricia Keegan, M.D.
Director
Division of Biologic Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Attachment: Revised Labeling