DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STNs: BL 125084/46; BL 125084/76; (b)(4)

MAY 10 2006

ImClone Systems, Incorporated
Attention: Cheryl Anderson
Vice President, Regulatory Affairs
33 ImClone Drive
Branchburg, NJ 08876

Dear Ms. Anderson:

Please refer to your biologics license application (BLA) for Cetuximab submitted under section 351 of the Public Health Service Act.

Please also refer to your supplement, STN BL 125084/46 that included new indications, for use in combination with radiation therapy, for the treatment of locally or regionally advanced squamous cell carcinoma of the head and neck (SCCHN), and for use as a single agent for the treatment of patients with recurrent or metastatic SCCHN for whom prior platinum-based therapy has failed, approved March 1, 2006.

Upon review of the supplement, in conjunction with the FDA Center for Drug Evaluation and Research, Office of Regulatory Policy, it has been determined that STN 125084/46 was inappropriately bundled[1]. As noted in the May 8, 2006, teleconference between you and representatives of this office, the supplement has been split into three separate supplements (STN BL 125084/46, STN BL 125084/76, (b)(4)

1. 125084/46-Preserved. Cetuximab for use in combination with radiation therapy, for the treatment of locally or regionally advanced squamous cell carcinoma of the head and neck (SCCHN), approved March 1, 2006;

2. 125084/76-Preserved. Cetuximab for use as a single agent for the treatment of patients with recurrent or metastatic SCCHN for whom prior platinum-based therapy has failed, approved March 1, 2006; and,

(b)(4)

[1] Per agency policy as expressed in the FDA Guidance for Industry, "Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees." Available on the Internet at www.fda.gov/cder/guidance/index.htm.

All postmarketing commitments remain associated with STN 125084/46 as stated in the March 1, 2006, approval letter.

If you have any questions, please contact the regulatory project manager, Ms. Sharon Sickafuse, at 301-796-2320

Sincerely,

Patricia Keegan

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

CONCURRENCE PAGE

Letter Type: Other (OT)
Unbundling of Supplement

STN 125084/76 (Approved 3/1/06 – Review Completion Required by: RIS)

(b)(4)
(b)(4)

cc: Karen Jones, OODP/DBOP
Patricia Keegan, OODP/DBOP
Kaushikkumar Shastri, OODP/DBOP
Sharon Sickafuse, OODP/DBOP
Mark Rothmann, OPSS/OB
Connie O'Leary, OND/IO
Karen Weiss, OODP/IO
Richard Pazdur, OODP/IO
Michael D. Jones, CDER/ORP
DBOP BLA file (hard copy)

History: Jonesk:4-13-06:Jonesk:4-25-06:Sickafuse:5-8-06

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Office	Name/Signature	Date
DBOP	Sickafuse	5-9-06
OODP/DBOP	Karen D. Jones	5-10-06
OODP/DBOP	P. Keegan	5-10-2006
OODP/DBOP	Kelly Laudmann	5-12-06