DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STN: BL 125019/58

OCT 2 2 2004

IDEC Pharmaceuticals Corporation
Attention: Leslie Shelly, Ph.D.
Director, Regulatory Affairs
5200 Research Place
San Diego, CA 92122

Dear Dr. Shelly:

Your request to supplement your biologics license application for Ibritumomab tiuxetan to revise the CLINICAL PHARMACOLOGY, CLINICAL STUDIES, WARNINGS, PRECAUTIONS, DOSAGE AND ADMINISTRATION, and IMAGE ACQUISITION AND INTERPRETATION sections of the package insert has been approved.

This fulfills your commitment to continue to assess patients enrolled in studies 106-04 and 106-06 for progression-free and overall survival as stated in commitment number 3 of the February 19, 2002, approval letter for BL 125019/0.

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). In addition, you may wish to submit draft copies of the proposed introductory advertising and promotional labeling with a cover letter requesting advisory comments to the Division of Drug Marketing, Advertising and Communication (HFD-42), Center for Drug Evaluation and Research, 5600 Fishers Lane/Room 8B45, Rockville, MD 20857. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by an FDA Form 2253.

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence to support that claim.

Please refer to http://www.fda.gov/cder/biologics/default.htm for important information regarding therapeutic biological products, including the addresses for submissions. Effective October 4, 2004, the new address for all submissions to this application is:

CDER Therapeutic Biological Products Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
12229 Wilkins Avenue
Rockville, Maryland 20852

This information will be included in your biologics license application file.

Sincerely,

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

Enclosure: Labeling