



OCT 29 2004

Our STN: BL 125019/70

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 IMAGE ACQUISITION AND INTERPRETATION section of the package insert to add prominent bone marrow uptake as a specific criterion for altered biodistribution 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 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: Final Draft Labeling