DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STN: BL 103737/5055

NOV 0 2 2004

IDEC Pharmaceuticals, Incorporated
Attention: Nadine D. Cohen, Ph.D.
Senior Vice President, Regulatory Affairs
5200 Research Place
San Diego, CA 92122

Dear Dr. Cohen:

Your request to supplement your biologics license application for Rituximab to revise the ADVERSE REACTIONS, Infectious Events section of the package insert to include information on fatal infections in patients with HIV-associated lymphoma 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 address 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,

(b)(6)

(b)(6) Patricia Keegan, M.D.
Director
Division of Therapeutic Biologic Oncology Products
Office of Drug Evaluation VI
Center for Drug Evaluation and Research

Enclosure: Final Draft Labeling