DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 125019/132

NOV 02 2007

Biogen Idec
Attention: Nadine D. Cohen, Ph.D.
Senior Vice President, Regulatory Affairs
14 Cambridge Center
Cambridge, MA 02142

Dear Dr. Cohen:

Your request to supplement your biologics license application for Ibritumomab tiuxetan to include a new subsection entitled "Extravasation" in the Precautions section, to include a new Post-marketing Experience subsection in the Adverse Reactions section describing new reported adverse reactions of extravasation and radiation injury to adjacent organs/tissues, and to include a revision in the Dosage and Administration section of the package insert has been approved.

We note your October 19, 2007, submission included final content of labeling [CFR 601.14(b)] in structured product labeling (SPL) format; we will transmit it to the National Library of Medicine for public dissemination. Within 21 days of the date of this letter, amend any pending supplement(s) for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

Within 21 days of the date of this letter, amend any pending supplement(s) for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please refer to http://www.fda.gov/cder/biologics/default.htm for information regarding therapeutic biological products, including the addresses for submissions.

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