DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

SEP 13 2005

Our STN: BL 125019/92

Biogen Idec Inc.
Attention: Nadine 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 Ibritumomab tiuxetan to revise the BOXED WARNINGS, WARNINGS and ADVERSE REACTIONS sections of the package insert to provide information on mucocutaneous and cutaneous reactions has been approved.

We acknowledge your commitment to disseminate a Dear Healthcare Professional Letter as described in your facsimile of September 13, 2005, as outlined below:

Postmarketing Commitment subject to reporting requirements of 21 CFR 601.70:

To submit a draft "Dear Health Care Professional (Important Prescribing Information)" letter, draft envelope, and distribution plan, including the list of intended recipients, by October 13, 2005.

We request that you submit this information to your biologics license application (BLA), STN BL 125019. Please use the following designators to label prominently all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- Postmarketing Study Protocol
- Postmarketing Study Final Report
- Postmarketing Study Correspondence
- Annual Report on Postmarketing Studies

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. The status report for each study should include:

- information to identify and describe the postmarketing commitment,
- the original schedule for the commitment,
- the status of the commitment (i.e. pending, ongoing, delayed, terminated, or submitted),

- an explanation of the status including, for clinical studies, the patient accrual rate (i.e. number enrolled to date and the total planned enrollment), and
- a revised schedule if the study schedule has changed and an explanation of the basis for the revision.

As described in 21 CFR 601.70(e), we may publically disclose information regarding this postmarketing commitment on our Web site (**http://www.fda.gov/cder/pmc/default.htm**). Please refer to the April 2001 Draft Guidance for Industry: Reports on the Status of Postmarketing Studies – Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (see **http://www.fda.gov/cber/gdlns/post040401.htm**) for further information.

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 August 29, 2005, the new address for all submissions to this application is:

Food and Drug Administration
Center for Drug Evaluation and Research
Therapeutic Biological Products Document Room
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

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

Enclosure: Revised Labeling