DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Our STN: BL 125104/106

COMPLETED AUG 25 2008

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

Dear Dr. Cohen:

Your request to supplement your biologics license application for Tysabri® to revise the label to include postmarketing cases of Progressive Multifocal Leukoencephalopathy (PML) in patients receiving Tysabri as monotherapy has been approved. Changes to the labeling occurred in the following sections:

1. Warnings and Precautions in the Highlights of Prescribing Information
2. Boxed Warning
3. Section 5 Warnings and Precautions, subsection 5.1 Progressive Multifocal Leukoencephalopathy (PML)
4. Section 6 Adverse Reactions, subsection 6.1 Clinical Trials Experience under Infections and 6.3 Postmarketing Experience
5. Section 17 Patient Counseling Information, subsection 17.2 Progressive Multifocal Leukoencephalopathy
6. Medication Guide

No other labeling change requests submitted to date are addressed in this letter.

FDA previously approved a Medication Guide required for distribution with this product in accordance with 21 CFR Part 208. FDA hereby approves the revised draft Medication Guide you submitted on August 14, 2008.

Please note that:

- this Medication Guide must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling [21 CFR 201.57(c)(18)] or 21 CFR 201.80(f)(2)];

- you are responsible for ensuring that this Medication Guide is available for distribution to every patient who is dispensed a prescription for this product [21 CFR 208.24];

- the final printed Medication Guide distributed to patients must conform to all conditions described in 21 CFR 208.20, including a minimum of 10 point text; and

- you are responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided [21 CFR 208.24(d)].

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

In accordance with section 909(b)(1) of FDAAA, Tysabri was identified as a product deemed to have in effect an approved Risk Evaluation and Mitigation Strategy (REMS) because the product had elements to assure safe use in effect on the effective date of Subtitle A. You are required to submit a proposed REMS by September 21, 2008. The Medication Guide approved with this supplement will be considered part of the REMS in accordance with 505-1. Under 21 CFR 208 and 505-1(e)(2) you are responsible for ensuring that the Medication Guide is available for distribution to patients who are dispensed Tysabri.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved STN BL 125104/106." In addition, 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.

LETTERS TO HEALTH CARE PROFESSIONALS

We note that you intend to issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter) upon approval of the final labeling. When that letter is mailed, we request that you submit an electronic copy of the final letter to both this BLA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

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

If you have any questions, please call Tamy Kim, PharmD, Safety Regulatory Project Manager at (301) 796-1125.

Sincerely,

8/25/08

Russell Katz, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research