DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Our STN: BL 125104/67

OCT 0 3 2008

Biogen Idec, Inc.
Attention: Nadine D. Cohen, Ph.D.
Senior Vice President Regulatory Affairs
14 Cambridge Center
Cambridge, MA 02134

Dear Dr. Cohen:

This letter is in regard to your supplement to your biologics license application (BLA) dated December 6, 2007, received December 7, 2007, submitted under section 351 of the Public Health Service Act, for Tysabri (natalizumab). We also refer to your submission dated February 7, 2008.

Your request to supplement your biologics license application for Tysabri (natalizumab) to revise the label to include information regarding the use of plasma exchange to remove natalizumab has been approved.

The final printed labeling (FPL) must be identical to the enclosed labeling. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 125104/67."

You may submit draft copies of any proposed introductory advertising and promotional labeling with a cover letter requesting advisory comments to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising and Communication, 5901-B Ammendale Road, Beltsville, MD 20705-1266. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by a FDA Form 2253.

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.

If you have any questions, call James H. Reese, Ph.D., RAC, Regulatory Project Manager, at (301) 796-1136.

Sincerely,

10/3/08

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