DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

IND 73,061

Biogen Idec, Inc.
Attention: [redacted]
Senior Vice President, Regulatory Affairs
14 Cambridge Center
Cambridge, MA 02142

Dear [redacted]:

We refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for BG00012 (Dimethyl Fumarate).

We also refer to your October 27, 2006, request, serial number 013, for a special clinical protocol assessment, received October 31, 2006. The protocol is entitled Study 109-MS-302: "A Randomized, Multicenter, Placebo-Controlled and Active Reference (Glatiramer Acetate) Comparison Study to Evaluate the Efficacy and Safety of BG00012 in Subjects With Relapsing-Remitting Multiple Sclerosis". We acknowledge your December 8, 2006, request to withdraw protocol 109-MS-302.

We have completed our review of your special protocol assessment submission and, based on the information submitted, have the following comments and responses to your questions.

[redacted]

[redacted]

In addition, we have the following comments.

Nonclinical Comment

1. Chronic toxicity studies in two species (6 months in rodent and 9-12 months in non-rodent) are required to support the clinical trial you have proposed. You have not submitted a non-rodent chronic toxicity study of dimethyl fumarate. [redacted]

[redacted]

[redacted]

If you wish to discuss our responses, you may request a meeting. Such a meeting will be categorized as a Type A meeting (refer to our "*Guidance for Industry; Formal Meetings With Sponsors and Applicants for PDUFA Products*"). Copies of the guidance are available through the Center for Drug Evaluation and Research from the Drug Information Branch, Division of Communications Management (HFD-210), 5600 Fishers Lane, Rockville, MD 20857, (301) 827-4573, or from the internet at http://www.fda.gov/cder/guidance/index.htm. This meeting would be limited to discussion of this protocol. If a revised protocol for special protocol assessment is submitted, it will constitute a new request under this program.

If you have any questions, call James H. Reese, PhD, Regulatory Project Manager, at 301-796-1136.

Sincerely,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/
Russell Katz
12/11/2006 04:43:01 PM

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