FOOD DRUG ADMINISTRATION
DIVISION OF NEUROLOGY DRUG PRODUCTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002
FAX: (301) 796-9842
COVER SHEET

DATE: 12/11/06

TIME: _____

PLEASE DELIVER THE FOLLOWING PAGES TO:
Tammy Sarnelli / Biogen Idec

FAX NUMBER: 617-679-3170

FROM: T. Reese

Total number of pages, including cover page: 6

If you do not receive all pages or have any problems with receiving, call (301) 796-~~2250~~ 1136

MESSAGE:
Tammy, 302 was checked in on 10/31. So the PDUFA date is 12/15. The letter will come sometime (?) this week.
Tim

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Rockville, MD 20857

IND 73,061

Biogen Idec, Inc.
Attention: Nadine D. Cohen, Ph.D.
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 012, for a special clinical protocol assessment, received October 27, 2006. The protocol is entitled Study 109-MS-301: "A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Comparison Study to Determine the Safety and Efficacy of BG00012 in Subjects with Relapsing-Remitting Multiple Sclerosis". We acknowledge your December 8, 2006, request to withdraw protocol 109-MS-301.

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]

[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

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