biogen idec

February 22, 2006

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

Attn: Russell Katz, MD

RE: IND 73,061 Initial Investigational New Drug Application
BG00012 (Dimethyl Fumarate): Multiple Sclerosis
Serial No.: 000

Dear Dr. Katz:

Biogen Idec is submitting the Investigational New Drug (IND) Application for its product, BG00012, which is being developed as treatment of relapsing forms of multiple sclerosis. A pre-IND meeting was held on September 1, 2005 between representatives of the FDA and Biogen Idec. The overall clinical development plan, pharmacology/ toxicology information, previous human experience and the proposed clinical study were discussed at that meeting. A copy of the pre-IND meeting minutes is included in Module 1.12.1.

The proposed clinical trial included in this application is a Phase 1 study entitled: "A Single-Center, Randomized, Blinded, Placebo- and Active-Controlled Study to Evaluate the QTc Interval Prolongation Potential of BG00012 When Administered to Healthy Volunteers". A copy of this protocol is provided in Module 5.3.3.4.

This IND is being submitted in e-CTD format with hard copies of the cover letter and FDA Form 1571 following agreement with the agency at the pre-IND meeting.

Should you require any additional information, please contact Tammy Sarnelli, Associate Director, Regulatory Affairs at 617-679-3513. The contact for technical aspects for this submission is Michael Sauter, Senior Director, Regulatory Affairs Operations at 617-679-2416.

Sincerely yours,

[redacted]

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