biogen idec

September 11, 2006

Center for Drug Evaluation and Research
Food and Drug Administration
5901 -B Ammendale Rd
Beltsville, MD 20705-1 266

Attn: Russell Katz, MD

RE: IND 73,061: BG00012 (Dimethyl Fumarate): Multiple Sclerosis
Serial No.: 0007
Response to Non-Hold Issues

Dear Dr. Katz:

Reference is made to the IND clinical hold letter for BG00012 dated April 19, 2006, which listed both Clinical-hold and Non-hold deficiencies. Biogen Idec submitted a complete response to the clinical hold issues on May 12, 2006 and was informed on June 14, 2006 by the FDA that the clinical hold for IND 73,061 has been lifted.

In response to the non-hold deficiencies identified in the April 19, 2006 letter, the following information is included in this submission:

1. Responses to IND non-hold deficiencies
2. Copy of the revised Investigator's Brochure along with Summary of Changes

In addition, a copy of the final protocol for Study 109-HV-101 (a copy of the draft version was submitted in the initial IND) has been included.

This submission is provided electronically as an amendment to the electronic IND.

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 [redacted].

Sincerely yours

[redacted]

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