

biogen idec

September 13, 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  
Information Amendment: Study C-1903 - Clinical Study Report  
Serial No.: 0008**

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Dear Dr. Katz:

Biogen Idec, Inc. is submitting to the IND the final clinical study report for Phase 1 study (C-1903), entitled:

"A Single-Center, Randomized, Crossover Study to Investigate Possible Food Effects on BG00012, When Administered as Single Oral Doses in Healthy Volunteers".

[REDACTED]

Biogen Idec Inc. is also submitting new investigator information for the following study:

109-HV-101: "A Single-Center, Randomized, Blinded, Placebo- and Active-Controlled Study to Evaluate the QTc Interval Prolongation Potential of BG00012 When Administered to Healthy Volunteers."

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], Senior Director, Regulatory Affairs Operations at 617-679-2416.

Sincerely yours,

[REDACTED]

Senior Vice President, Regulatory Affairs  
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