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April 20, 2007

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

Submission of Clinical Trial Protocols

Serial No.: 0017

Dear Dr. Katz:

Reference is made to the End of Phase 2 meeting for Biogen Idec's product, BG00012 (dimethyl fumarate) held on August 30, 2006. At this meeting, the Agency requested that Biogen Idec submit the final study report for an ongoing 11-month chronic toxicology study in beagle dogs prior to the initiation of Phase 3 clinical trials.





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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

