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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.

Following the meeting, Biogen Idec submitted two Phase 3 clinical trial protocols under the guidance of Special Protocol Assessment (Serial Nos. 012 and 013, dated 27 October 2006) to IND 73, 061. At the Agency's request, both Phase 3 protocols were withdrawn from the IND (Serial No. 014, dated 08 December 2006) pending submission of the 11-month dog toxicology study.

Although the protocols were withdrawn, the Agency provided written comments on both protocols (dated 11 and 12 December 2006).

At this time, we are resubmitting the two Phase 3 protocols, revised to reflect Agency comments, and all supporting data. Specifically, the following documents are included in this submission:

- Study P00012-05-05: "BG00012: An 11 Month Toxicity Study of BG00012 Administered by the Oral (Capsule) Route to Dogs with a 1-Month Recovery Period"
- Protocol 109-MS-301: "A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Comparison Study to Determine the Efficacy and Safety of BG00012 in Subjects with Relapsing-Remitting Multiple Sclerosis"
- Protocol 109-MS-302: "A Randomized, Multicenter, Placebo-Controlled and Active (Glatiramer Acetate) Comparison Study to Evaluate the Efficacy and Safety of BG00012 in Subjects with Relapsing-Remitting Multiple Sclerosis"

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- 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"
- [redacted]

[redacted]

Biogen Idec plans to initiate clinical trials sites in the United States in approximately 30 days of this submission. We would greatly appreciate any feedback the Agency may have on our two Phase 3 clinical trial protocols prior to initiation.

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
Phone (617) 679-3783

Fax (617) 679-3170