biogen idec

October 27, 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.: 0012
REQUEST FOR SPECIAL PROTOCOL ASSESSMENT – Clinical Protocol

Dear Dr. Katz:

Biogen Idec, Inc. is submitting the following new Phase 3 clinical study protocol for Special Protocol Assessment:

1) Study 109-MS-301: "A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Comparison Study to Determine the Safety and Efficacy of BG00012 in Subjects with Relapsing-Remitting Multiple Sclerosis"

A draft version of the Study 109-MS-301 protocol was discussed with FDA at the End-of-Phase 2 meeting that was held on August 30, 2006. We believe that the attached final version of the protocol adequately addresses the issues raised by the Agency during the meeting.

This study will be initiated in the United States following the submission of 9-month dog toxicity study report to the IND. Please note that the non-US sites would not be included under the IND.

A request for a Special Protocol Assessment has been submitted for the second Phase 3 study 109-MS-302 on October 27, 2006.

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]