

biogen idec

September 25, 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
2-Year mouse carcinogenicity study update
Serial No.: 0009**

Dear Dr. Katz:

Biogen Idec Inc. is submitting an update on the ongoing 2-year carcinogenicity study (Study P00012-05-03) in mice with BG00012:

The study is currently in Week 65 of the 104 Week study and the number of mice in Group 5 males (400 mg/kg) has reached 28. Consistent with our previous agreement with the Agency for the rat carcinogenicity study (see Serial 003 dated May 19, 2006, for details), we plan to suspend dosing of this group once the *n* value reaches 20, and to terminate the group should the *n* value reach 10 prior to the predetermined terminal necropsy.

Details on number of surviving animals in various groups as of Week 65 in Study P00012-05-03 are provided in Attachment 1.

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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