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February 12, 2009

Russell Katz, MD  
Food and Drug Administration  
Center for Drug Evaluation and Research  
5901 -B Ammendale Rd  
Beltsville, MD 20705-1 266

**RE: BG00012 (Dimethyl Fumarate): Multiple Sclerosis -- IND 73,061  
Information Amendment: Final Nonclinical Study Report  
Serial No. 0081**

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Dear Dr. Katz:

This submission contains the final report from a 2-year carcinogenicity study in mice administered BG00012 (Report No. P00012-05-03), entitled:

"A Two Year Oral (Gavage) Carcinogenicity Study in Mice with BG00012"

Please note that a summary of this study was provided in February 2008 (Serial No. 0043). [REDACTED]

Should you require any additional information, please contact Tammy Sarnelli, 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]  
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