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March 11, 2008

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

Attn: Russell Katz, MD

**RE: IND 73,061: BG00012 (Dimethyl Fumarate): Multiple Sclerosis  
Response to Request for Information  
Serial No.: 0047**

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Dear Dr. Katz:

This submission contains the final report from a 2-year carcinogenicity study in rats administered BG00012 (Report No. P00012-04-11), entitled:

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

Please note that the audited draft report from this study was previously submitted on January 31, 2008 (Serial No. 0042). [REDACTED]

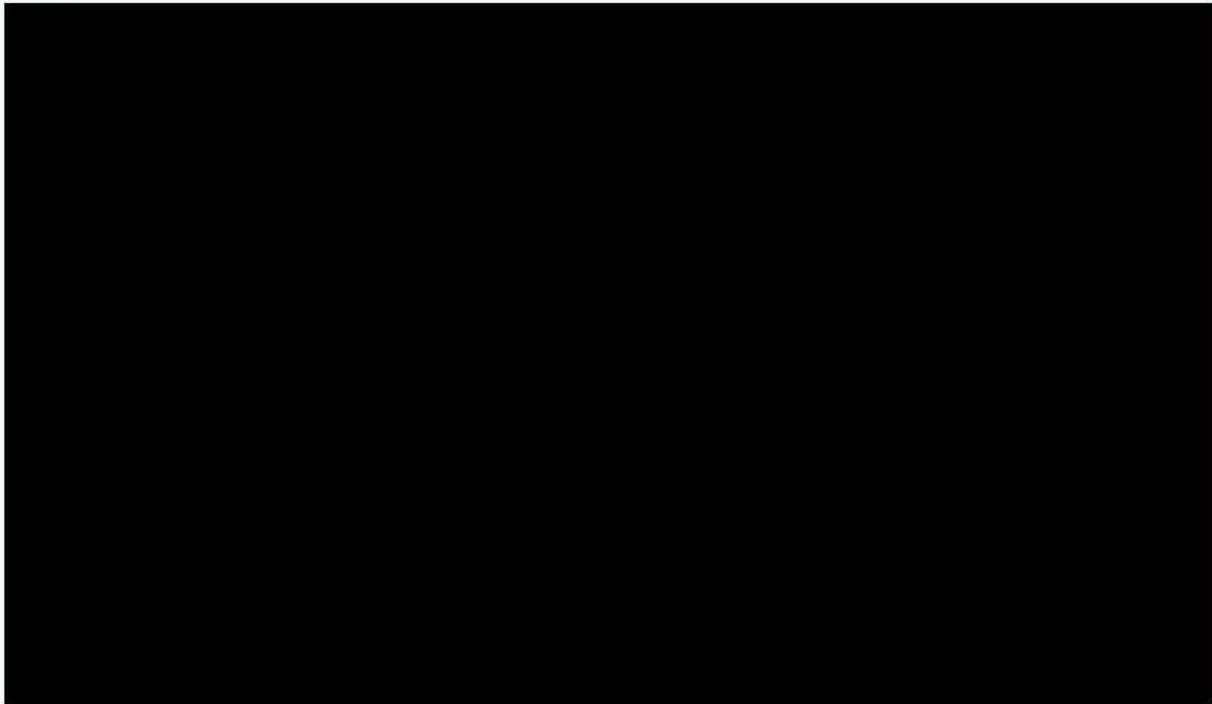
[REDACTED]

[REDACTED]

[REDACTED]

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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



Senior Vice President, Regulatory Affairs  
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