biogen idec

June 23, 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.: 0005
Re: Request for End-of-Phase 2 Meeting (Type B)

Dear Dr. Katz:

Reference is made to Biogen Idec's Investigational New Drug Application for BG00012 (IND 73,061) submitted to the Agency on February 22, 2006. Biogen Idec is hereby requesting a face-to-face meeting to discuss the Phase 3 clinical development program for BG00012. [redacted]

The information for the requested meeting is as follows:

1) Product name: BG00012

2) Type of meeting being requested: Type B – End-of-Phase 2 meeting

3) Meeting objective: The objective of this meeting is to discuss and reach agreement on the Phase 3 clinical development plan intended to provide sufficient data on the safety and efficacy of BG00012 in subjects with relapsing forms of MS to support a marketing application.

4) Proposed agenda:

   - Brief Introduction by Biogen Idec (5 minutes)
   - Discussion of specific questions
   - Summary and conclusions

5) Listing of questions:
   A list of specific questions is provided in Attachment 1.

6) List of sponsor participants:
   [redacted]
   Tammy Sarnelli, Associate Director, Regulatory Affairs
   [redacted]
   Gilmore O'Neill, MD, Director, Clinical Development, Neurology

Minhua Yang, Lead Biostatistician

[redacted]

7) Proposed indication
"BG00012 is indicated for the treatment of patients with relapsing remitting multiple sclerosis to reduce the frequency of clinical exacerbations".

8) Supporting documentation: An information package will be submitted to the Agency four weeks in advance of the meeting.

9) Suggested dates and times for the meeting: We would like to suggest Aug 29 – 31 or September 5 – 7 as possible dates for your consideration.

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

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Attachment 1
List of proposed questions

Pharmacology/toxicology:

1) Is the present preclinical plan sufficient to support Phase 3 and registration?