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October 6, 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
Request for correction: End-of-Phase 2 meeting minutes
Serial No.: 010

Dear Dr. Katz:

Reference is made to the Agency's letter dated September 29, 2006 regarding the official minutes of the End-of-Phase 2 meeting held on August 30, 2006 to discuss the clinical development of BG00012. Biogen Idec would like to request the following revisions to the minutes:

[redacted]

2) Page 2: In Meeting discussion under Pharmacology/Toxicology section, the meeting minutes read:

   - The Sponsor asked if they could begin their Phase 3 trial prior to submitting the 12 month repeat dose toxicity study in monkeys. The monkey study will be submitted within three months of initiation of the clinical trial. The Sponsor has already submitted a nine month repeat dose toxicity study in dogs. The Division stated that this approach is acceptable.

   The requested revision is underlined:

   - The Sponsor asked if they could begin their Phase 3 trial prior to submitting the 12 month repeat dose toxicity study in monkeys. The monkey study will be submitted within three months of initiation of the clinical trial <u>in the US</u>. The Sponsor has already submitted <u>a 6-month repeat dose toxicity study in rats and will submit the 9-month repeat dose toxicity study in dogs when the study is complete. The audited draft report from the 9-month repeat dose toxicity study in dogs will be submitted prior to the initiation of Phase 3 clinical trials in the US</u>. The Division stated that this approach is acceptable.

Biogen Idec 14 Cambridge Center Cambridge, MA 02142 Phone 617 679 2000 www.biogenidec.com

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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

Fax (617) 679-3170

FOOD DRUG ADMINISTRATION
DIVISION OF NEUROLOGY DRUG PRODUCTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002
FAX: (301) 796-9842
COVER SHEET

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DATE: 9/29/06

TIME: _____

PLEASE DELIVER THE FOLLOWING PAGES TO:
Tammy Sarnelli / N.D. Cohen / Biogen Idec

FAX NUMBER: 617-679-~~3783~~ 3170

FROM: J. Reese

Total number of pages, including cover page: 8

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville, MD 20857

Biogen Idec, Inc.
Attention: Nadine D. Cohen, Ph.D.
Senior Vice President, Regulatory Affairs
14 Cambridge Center
Cambridge, MA 02142

Dear Dr. Cohen:

Please refer to your Investigational New Drug Application (IND) file for BG00012.

We also refer to the End of Phase 2 meeting between representatives of your firm and the FDA on August 30, 2006. The purpose of the meeting was to discuss the continued development of BG00012.

The official minutes of that meeting are enclosed. You are responsible for notifying us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call James H. Reese, Ph.D., Regulatory Project Manager, at (301) 796-1136.

Sincerely,

{See appended electronic signature page}

Russell Katz, M. D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

MEMORANDUM OF MEETING MINUTES

MEETING DATE:	August 30, 2006
TIME:	3:00 – 4:30 PM
LOCATION:	White Oak, Building 22, Rm. 1309
APPLICATION:	PIND 73,061, BG00012
TYPE OF MEETING:	B: End of Phase 2
MEETING CHAIR:	Dr. Russell Katz

FDA Attendees
Russell Katz
Kun Jin
Eric Bastings
Janeth Rouzer-Kammeyer
Paul Roney
Ta-Chen Wu
James Reese

Biogen Idec Attendees
[redacted]
Tammy Sarnelli
Katherine Dawson
[redacted]
Carmen Bozic
[redacted]

The questions discussed below were submitted as part of the EoP2 package dated July 24, 2006. The Sponsor's questions are presented below in italics, followed by the preliminary FDA response (conveyed to the sponsor by e-mail just prior to the meeting), and then a summary of the discussion from the meeting.

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