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

COVER SHEET

NOTE: THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone at (301) 796-2250 or return it to us at the above address by mail, Attention [HFD-120]. Thank you in advance.

DATE: 8/10/06

TIME: _____

PLEASE DELIVER THE FOLLOWING PAGES TO:
Tammy Sarnelli / Biogen Idec

FAX NUMBER: 617-679-3170

FROM: J. Reese

Total number of pages, including cover page: 2

If you do not receive all pages or have any problems with receiving, call (301) 796-2250

MESSAGE:

IND 73,061

Tammy Sarnelli
Biogen Idec

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for BG00012 (Dimethyl Fumarate) capsules.

We also refer to your June 23, 2006, correspondence requesting an End of Phase 2 meeting to discuss the clinical development of BG00012.

Based on the statement of purpose, objectives, and proposed agenda, we consider the meeting a type B meeting as described in our guidance for industry titled Formal Meetings with Sponsors and Applicants for PDUFA Products (February 2000). The meeting is scheduled for:

Date: August 30, 2006
Time: 3:00 – 4:30 PM Eastern Time
Face to Face

CDER participants:
Russell Katz
Marc Walton
Eric Bastings
Janeth Rouzer Kammeyer
Paul Roney
Lois Freed
Martha Heimann
Ramana Uppoor
Kun Jin
James Reese

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

Jim Reese