

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration Rockville, MD 20857

IND 73,061

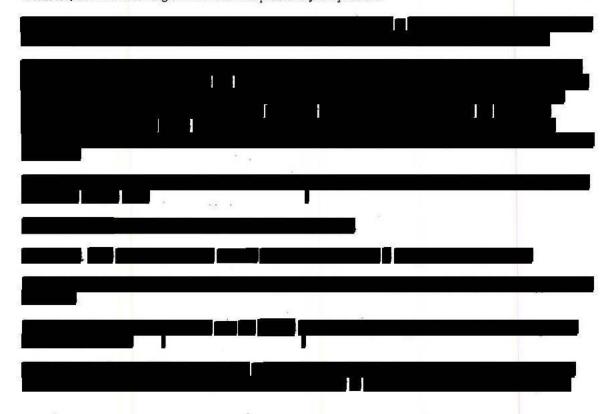
Biogen Idec, Inc.
Attention:
Senior Vice President, Regulatory Affairs
14 Cambridge Center
Cambridge, MA 02142

Dear

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

We also refer to your October 27, 2006, request, serial number 013, for a special clinical protocol assessment, received October 31, 2006. The protocol is entitled Study 109-MS-302: "A Randomized, Multicenter, Placebo-Controlled and Active Reference (Glatiramer Acetate) Comparison Study to Evaluate the Efficacy and Safety of BGOOOL2 in Subjects With Relapsing-Remitting Multiple Sclerosis". We acknowledge your December 8, 2006, request to withdraw protocol 109-MS-302.

We have completed our review of your special protocol assessment submission and, based on the information submitted, have the following comments and responses to your questions.





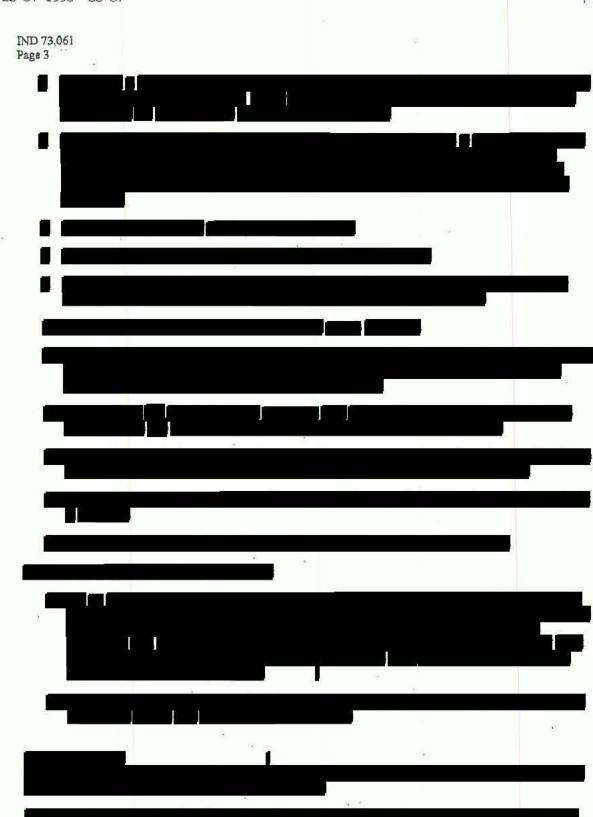
IND 73,061 Page 2

.

In addition, we have the following comments.

Nonclinical Comment 1. Chronic toxicity studies in two species (6 months in rodent and 9-12 months in non-rodent) are required to support the clinical trial you have proposed. You have not submitted a non-rodent chronic toxicity study of dimethyl furnarate. 11 1







IND 73,061 Page 4

If you wish to discuss our responses, you may request a meeting. Such a meeting will be categorized as a Type A meeting (refer to our "Guldance for Industry; Formal Meetings With Sponsors and Applicants for PDUFA Products"). Copies of the guidance are available through the Center for Drug Evaluation and Research from the Drug Information Branch, Division of Communications Management (HFD-210), 5600 Fishers Lane, Rockville, MD 20857, (301) 827-4573, or from the internet at http://www.fda.gov/cder/guidance/index.htm. This meeting would be limited to discussion of this protocol. If a revised protocol for special protocol assessment is submitted, it will constitute a new request under this program.

If you have any questions, call James H. Reese, PhD, Regulatory Project Manager, at 301-796-1136.

Sincerely,

(See appended electronic signature page)

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



This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

15/

Russell Katz 12/11/2006 04:43:01 PM



DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

