Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee

March 7 and 8, 2006

Holiday Inn Gaithersburg, The Ballrooms
Two Montgomery Village Avenue, Gaithersburg, Maryland

AGENDA

The committee will discuss Tysabri (Natalizumab) biologic license application 125104/15; Biogen Idec Inc. for an indication in patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. The committee will discuss the risks (including progressive multifocal leukoencephalopathy (PML)) associated with Tysabri administration, the efficacy of Tysabri in the treatment of multiple sclerosis relapses and/or disability, the possible return of Tysabri to the marketplace, and proposed risk management plan(s) for Tysabri.

March 7, 2006

8:00	Call to Order and Introductions	Karl Kieburtz, M.D., M.P.H. Chair, Peripheral and Central Nervous System Drugs Advisory Committee (PCNS)
	Conflict of Interest Statement	Lt. Sohail Mosaddegh, RPh., Pharm.D. Acting Executive Secretary, PCNS
8:15	Opening Remarks and Overview of Issues	Russell Katz, M.D. Director, Division of Neurology Products (DNP), FDA
8:30	**Sponsor Presentations**	Biogen Idec Inc.
	Introduction	Burt Adelman, M.D. Executive Vice President, Development Biogen Idec Inc.
	Efficacy Data	Alfred Sandrock, M.D., Ph.D. Vice President, Neurology Biogen Idec Inc.
	Safety Data	Michael Panzara, M.D., M.P.H Vice President, Neurology Biogen Idec Inc.
	Risk-Management Plan	Carmen Bozic, M.D. Vice President, Drug Safety and Risk Management Biogen Idec Inc.
	Clinical Perspective	Richard A. Rudick, M.D. Director, The Mellen Center Chairman, Division of Clinical Research Cleveland Clinic Foundation

10:00 Questions from Committee to Sponsor

AGENDA (continued)

10:15	Break	
10:30	**FDA Presentation**	FDA
	Background, Efficacy and PML	Susan McDermott, M.D. Clinical Reviewer, DNP, FDA
	Safety	Alice Hughes, M.D. Clinical Safety Reviewer, DNP, FDA
	Risk Minimization Action Plan	Diane Wysowski, Ph.D. Reviewer, Office of Drug Safety, FDA
11:45	Questions from Committee to FDA	
Noon	**Lunch**	
1:00	Open Public Hearing	
3:00	Break	
3:15	Resume Open Public Hearing	
5:00	**Adjourn**	

March 8, 2006

8:00	Call to Order and Introductions	Karl Kieburtz, M.D., M.P.H Chair, PCNS
	Conflict of Interest Statement	Sohail Mosaddegh, RPh., Pharm.D. Acting Executive Secretary, PCNS
8:15	Committee Discussion and Response to FDA Questions	
10:00	Break	
10:15	Resume Committee Discussions and Response to FDA Questions	
Noon	**Lunch**	
1:00	Resume Discussion	
3:00	Break	
3:15	Resume Discussion	
5:00	**Adjourn**	