

**Food and Drug Administration
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*

DRAFT AGENDA

The Peripheral and Central Nervous System (PCNS) Drugs Advisory Committee will discuss a supplement to biologics licensing application (BLA) 125104, natalizumab (Tysabri), Biogen Idec, Inc., indicated for the treatment of multiple sclerosis.

March 7, 2006

8:00	Call to Order and Opening Remarks	Chair
	Introduction of Committee	
	Conflict of Interest Statement	Sohail Mosaddegh, RPh., Pharm.D. Executive Secretary, CDER, FDA
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8:15	Opening Remarks and Overview of Issues	Russell Katz, M.D. Director, Division of Neurology Products (DNP), FDA
8:30	<u>Sponsor Presentations</u>	Biogen Idec
	<ul style="list-style-type: none">• Introduction and Overview• Efficacy• Safety• Proposed Risk-Management Plan• Summary and Risk/Benefit Assessment	
10:00	Questions from Committee to Sponsor	
10:15	Break	
10:30	<u>FDA Presentation</u>	FDA
	<ul style="list-style-type: none">• Efficacy• Safety• Risk Management issues	
11:45	Questions from Committee to FDA	

Peripheral and Central Nervous System Drugs Advisory Committee

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DRAFT AGENDA (cont.)

March 7, 2006 Cont.

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 Opening Remarks

Chair

Introduction of Committee

Conflict of Interest Statement

Sohail Mosaddegh, RPh., Pharm.D.
Executive Secretary, CDER, FDA

8:15 Committee Discussion and Response to FDA Questions

10:00 Break

10:15 Resume Discussion

Noon Lunch

1:00 Resume Discussion

3:00 Break

3:15 Resume Discussion

5:00 Adjourn