

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Joint Meeting of the Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk
Management Advisory Committee
Gaithersburg Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, Maryland
DRAFT AGENDA
July 31, 2007**

The Committees will discuss the efficacy and safety of TYSABRI (natalizumab) biological license application (BLA) 125104/33, Biogen Idec, Inc., for patients with moderately to severely active Crohn's disease.

8:00 a.m.	Call to Order and Introductions	David Sachar, M.D. (Chair) Gastrointestinal Drugs Advisory Committee (GIDAC)
8:10 a.m.	Conflict of Interest Statement	Victoria Ferretti-Aceto, Pharm.D. Designated Federal Official, GIDAC
10:05 a.m.	Break	
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
3:00 p.m.	Break	
5:00 p.m.	Adjourn	