



**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Joint Meeting of the Gastrointestinal Drugs Advisory Committee (GIDAC) and the
Drug Safety and Risk Management Advisory Committee (DSaRM)
Gaithersburg Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, Maryland
FINAL 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/DSaRM
8:15 a.m.	Introduction/Background	Joyce A. Korvick, M.D., M.P.H. Director, Division Gastroenterology Products, CDER/FDA
<u>SPONSOR PRESENTATIONS:</u>		
8:20 a.m.	Introduction	David Feigal, M.D., MPH Senior Vice President, Regulatory Affairs, Biometrics and Global Pharmacovigilance & Risk Management Elan Pharmaceuticals, Inc.
8:25 a.m.	Crohn's Disease	William Sandborn, M.D. Professor of Medicine Gastroenterology Mayo Clinic
8:35 a.m.	Efficacy Data	Stephen Jones, MBBS Director, Clinical Development Elan Pharmaceuticals, Inc.
8:55 a.m.	Safety Data	Gordon Francis, M.D. Senior Vice President, Clinical Development Elan Pharmaceuticals, Inc.
9:20 a.m.	Risk-Management Plan	William Maier, MPH, PhD Senior Director, Epidemiology Elan Pharmaceuticals, Inc.
9:40 a.m.	Clinical Perspective	William Sandborn, M.D. Professor of Medicine Gastroenterology Mayo Clinic
9:50 a.m.	<i>Questions to the Sponsor</i>	
10:10 a.m.	Break	

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FDA PRESENTATIONS:

10:25 a.m.	Progressive Multifocal Leukoencephalopathy	Margo Smith, M.D. Associate Program Director, Department of Medicine Washington Hospital Center
10:40 am	Clinical Review	Anil Rajpal, M.D. Medical Reviewer Division of Gastroenterology Products, CDER/FDA
11:15 a.m.	Postmarketing Safety and RiskMAP	Claudia Karwoski, Pharm.D. Risk Management Team Leader OSE, CDER/FDA
11:35 a.m.	<i>Questions to the FDA</i>	
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:30 p.m.	<i>Questions to the Committee and Recommendations</i>	
3:00 p.m.	Break	
3:15 p.m.	<i>Questions to the Committee and Recommendations</i>	
5:00 p.m.	Adjourn	