

Food and Drug Administration  
Center for Drug Evaluation and Research

GASTROINTESTINAL DRUGS ADVISORY COMMITTEE (GIDAC)

January 23, 2008

Hilton Washington DC, Silver Spring, MD

AGENDA

Wednesday, January 23, 2008

8:00 a.m.	Call to Order	Alan L. Buchman, M.D. Acting Chair, GIDAC
	Conflict of Interest Statement	Mimi Phan, Pharm.D. Designated Federal Official, GIDAC
8:15 a.m.	Introduction/Background	Joyce A. Korvick, M.D., M.P.H. Deputy Director Division Gastroenterology Products, CDER/FDA
<b><u>SPONSOR PRESENTATIONS:</u></b>		
8:20 a.m.	Entereg (Alvimopan) Capsules Introduction	Linda Young, R.Ph., J.D. Vice President of Regulatory Affairs Adolor Corporation
8:25 a.m.	Postoperative Ileus (POI) A Surgical Perspective	Anthony Senagore, M.D., M.S., M.B.A. Vice President, Research and Education Spectrum Health, Grand Rapids, MI
8:35 a.m.	POI Clinical Development and Efficacy	Lee Techner, D.P.M. Senior Medical Director Adolor Corporation
9:00 a.m.	Study 014: Safety Findings	Eric Mortensen, M.D., Ph.D. GlaxoSmithKline
9:25 a.m.	POI Safety Risk Management	David Jackson, M.D. Senior Vice President & Chief Medical Officer Adolor Corporation
9:35 a.m.	Questions to the Sponsor	
10:10 a.m.	Break	

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**FDA PRESENTATIONS:**

10:25 a.m.	Efficacy Data	Ruyi He, M.D. Medical Team Leader Division of Gastroenterology Products, CDER/FDA
10:50 a.m.	Safety Data	Marjorie Dannis, M.D. Medical Reviewer Division of Gastroenterology Products, CDER/FDA
11:20 a.m.	Non-Clinical Findings	Tamal Chakraborti, Ph.D. Pharmacologist Division of Gastroenterology Products, CDER/FDA
11:30 a.m.	Post-Marketing Safety and Risk Minimization Action Plan	Joyce Weaver, Pharm.D., BCPS Senior Drug Risk Management Analyst Office of Surveillance and Epidemiology, CDER/FDA
11:45 a.m.	Questions to the FDA	
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Questions to the Committee and Recommendations	
3:00 p.m.	Break	
3:15 p.m.	Questions to the Committee and Recommendations	
5:00 p.m.	Adjourn	