

FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Gastrointestinal Drugs Advisory Committee (GIDAC)
Hilton Washington DC/Silver Spring, the Ballrooms
Silver Spring, MD

July 21, 2011

DRAFT AGENDA

The Committee will discuss the results from a clinical trial of supplemental Biologics License Application (sBLA) 103772/5301 Infliximab, REMICADE, by Centocor Ortho Biotech, Inc., in the treatment of pediatric patients with moderately to severely active ulcerative colitis.

8:00 a.m.	Call to Order Introduction of Committee	William Hasler, M.D. Acting Chair, GIDAC
8:15 a.m.	Conflict of Interest Statement	Kristine Khuc, Pharm.D. Designated Federal Officer, GIDAC
8:30 a.m.	Opening Remarks	Robert Fiorentino, M.D. Clinical Team Leader Division of Gastroenterology and Inborn Errors Products CDER, FDA
8:45a.m.	Sponsor Presentation	Centocor Ortho Biotech Inc.
	Introduction	Stella Jones, Ph.D. Vice President, Global Regulatory Affairs, Centocor
	Disease Overview & Clinical Efficacy	Jeffrey Hyams, M.D. Professor of Pediatrics, University of Connecticut
	Overview of Clinical Pharmacology	Joseph Adedokun, M.S., R.Ph. Sr. Research Scientist, Pharmacometrics, Centocor
	Safety & Conclusions	Robert Diamond, M.D. Lead Medical Director, Medical Affairs, Centocor
10:15 a.m.	Questions from the Committee to the Sponsor	
10:30 a.m.	BREAK	
10:45 a.m.	FDA Presentation	
	Clinical	Jessica Lee, M.D. Medical Officer Division of Gastroenterology and Inborn Errors Products CDER, FDA

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11:15 a.m.	Clinical Pharmacology	Nitin Mehrotra, Ph.D. Clinical Pharmacology Reviewer Office of Clinical Pharmacology CDER, FDA
11:20 a.m.	Infliximab: Hepatosplenic T-cell Lymphoma in Children and Young Adults with Inflammatory Bowel Disease	Ann Mackey, R.Ph., M.P.H. Safety Evaluator Team Leader Office of Safety and Epidemiology CDER, FDA
11:45 a.m.	Questions from the Committee to the FDA	
12:00 p.m.	LUNCH	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Committee Discussion and Questions to the Committee	
3:00 p.m.	BREAK	
3:15 p.m.	Continue Committee Discussion and Questions to the Committee	
4:00 p.m.	ADJOURN	