

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)
Meeting of the Gastrointestinal Drugs Advisory Committee
Holiday Inn Washington DC/College Park
10000 Baltimore Avenue, College Park, Maryland
November 17, 2011

FINAL AGENDA

The committee will provide recommendations to the Agency on the design and size of premarketing cardiovascular safety development programs necessary to support approval of products in the class of serotonin (5-hydroxytryptamine) receptor 4 agonists for the proposed indications of chronic idiopathic (of unknown cause) constipation, constipation predominant irritable bowel syndrome, gastroparesis, and gastroesophageal reflux disease that does not respond to a proton pump inhibitor.

8:00 a.m.	Call to Order and Introduction of Committee	Jean-Pierre Raufman, M.D. Committee Chairperson, Gastrointestinal Drugs Advisory Committee (GIDAC)
	Conflict of Interest Statement	Minh Doan, Pharm.D. Acting Designated Federal Officer
	<u>FDA Presentations</u>	
8:15 a.m.	Introductions/Opening Remarks	Joyce Korvick, M.D., M.P.H. Deputy Director for Safety, Division of Gastroenterology and Inborn Errors Products (DGIEP), Office of Drug Evaluation III (ODE III), Office of New Drugs (OND), CDER, FDA
8:35 a.m.	Background and Historical Overview	Aisha Peterson Johnson, M.D., M.P.H. Medical Officer, DGIEP, ODE III OND, CDER, FDA
	<u>Sponsor's Presentations</u>	<u>Johnson & Johnson Pharmaceutical Research & Development (J&JPRD), LLC</u>
8:45 a.m.	General Overview	Sheldon Sloan, M.D., M.Bioethics Internal Medicine Portfolio Leader Established Products, J&JPRD
	Non-clinical Cardiovascular Safety	Rob Towart, B.Sc., Ph.D., MRQA Director Licensing and Brand Support Center of Excellence for Cardiovascular Safety, J&JPRD

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FINAL AGENDA (cont.)

Sponsor's Presentations (cont.)

**Johnson & Johnson Pharmaceutical
Research & Development (J&JPRD),
LLC**

Clinical Pharmacology

Erik Mannaert, Ph.D.
Senior Director,
Clinical Pharmacology Therapeutic
Area Head, Established Products
J&JPRD

Clinical and Post Marketing Safety

Sheldon Sloan, M.D., M.Bioethics
Internal Medicine Portfolio Leader,
Established Products, J&JPRD

9:15 a.m.

Questions from the Committee

FDA Presentations (cont.)

9:25 a.m.

Tegaserod: Nonclinical

Ke Zhang, Ph.D.
Pharmacologist, DGIEP, ODE III
OND, CDER, FDA

Tegaserod: Clinical Pharmacology

Insook Kim, Ph.D.
Clinical Pharmacology Reviewer
Division of Clinical Pharmacology III
(DCP III), Office of Clinical
Pharmacology (OCP), Office of
Translational Sciences (OTS), CDER
FDA

Tegaserod: Clinical

**Aisha Peterson Johnson, M.D.,
M.P.H.**
Medical Officer, DGIEP, ODE III
OND, CDER, FDA

9:45 a.m.

Questions from the Committee

10:00 a.m.

BREAK

Sponsor's Presentations

Theravance, Inc.

10:15 a.m.

Preclinical Properties of Velusetrag (TD-5108)
and TD-8954, Selective 5-HT₄ Receptor
Agonists

David Beattie, Ph.D.
Senior Director, Pharmacology
Theravance, Inc.

10:45 a.m.

Questions from the Committee

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FINAL AGENDA (cont.)

FDA Presentations (cont.)

11:00 a.m.	ATI-7505 (Naronapride): Nonclinical	Sushanta Chakder, Ph.D. Pharmacologist, DGIEP, ODE III OND, CDER, FDA
	ATI-7505 (Naronapride): Clinical Pharmacology	Insook Kim, Ph.D. Clinical Pharmacology Reviewer DCP III, OCP, OTS, CDER, FDA
	ATI-7505 (Naronapride): Clinical	Aisha Peterson Johnson, M.D., M.P.H. Medical Officer, DGIEP, ODE III OND, CDER, FDA

11:30 a.m. Questions from the Committee

FDA Presentations (cont.)

11:45 a.m.	Summary	Robert Fiorentino, M.D., M.P.H. Medical Team Leader, DGIEP ODE III, OND, CDER, FDA
11:55 a.m.	Statistical Considerations	Eugenio Andraca-Carrera, Ph.D. Mathematical Statistician, Division of Biostatistics VII, Office of Biostatistics OTS, CDER, FDA
12:05 p.m.	Questions from the Committee	
12:15 p.m.	LUNCH	
1:15 p.m.	Open Public Hearing	
2:15 p.m.	Committee Discussion and Questions to the Committee	
3:15 p.m.	BREAK	
3:30 p.m.	Committee Discussion and Questions to the Committee (cont.)	
5:00 p.m.	ADJOURNMENT	