FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
April 7, 2016

DRAFT AGENDA

The committee will discuss new drug application (NDA) 207999, obeticholic acid (OCA) oral tablets, submitted by Intercept Pharmaceuticals, Inc., proposed for the treatment of primary biliary cirrhosis in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.

8:00 a.m.	Call to Order and Introduction of Committee	**Jean-Pierre Raufman, MD** Chairperson, GIDAC
8:05 a.m.	Conflict of Interest Statement	**Cindy Hong, PharmD** Designated Federal Officer, GIDAC
8:15 a.m.	FDA Opening Remarks	**Dragos Roman, MD** Associate Director Division of Gastroenterology and Inborn Errors Products (DGIEP) Office of Drug Evaluation III (ODE III) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	**APPLICANT PRESENTATIONS**	**Intercept Pharmaceuticals, Inc.**
	Primary Biliary Cirrhosis (PBC): Diagnosis, Natural History and Role of Current Therapy	**Kris Kowdley, MD, FACP, FAASLD** Director of the Liver Care Network and Research Director of the Organ Care Program Swedish Medical Center Seattle, Washington
	Introduction	**Linda Robertson, PhD** Vice President, Regulatory Affairs and Quality Assurance Intercept Pharmaceuticals, Inc.
	Unmet Medical Need in Patients with PBC	**Dave Jones, MD** Professor of Liver Immunology University of Newcastle Institute of Cellular Medicine Director, UK-PBC Study Group Consortium
	Program Rationale for OCA in Patients with PBC	**David Shapiro, MD, FRCP** Chief Medical Officer Intercept Pharmaceuticals, Inc.

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (cont.)

	Efficacy of OCA in Patients with PBC	**Leigh MacConell, PhD** Vice President, Clinical Development Intercept Pharmaceuticals, Inc.
	Safety of OCA in Patients with PBC	**Roya Hooshmand-Rad, MD, PhD** Executive Director, Medical Safety and Pharmacovigilance Intercept Pharmaceuticals, Inc.
	Benefit-Risk of OCA in Patients with PBC: A Transplant Hepatologist's Perspective	**John M. Vierling, MD, FACP, FAASLD** Professor of Medicine and Surgery Chief of Hepatology Director of Advanced Liver Therapies Baylor College of Medicine
10:05 a.m.	Clarifying Questions to the Presenters	
10:20 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATIONS**	
	Global PBC Study Group Data Analysis	**Min Min, PhD** Mathematical Statistician Division of Biostatistics III Office of Biostatistics Office of Translational Sciences (OTS) CDER, FDA
	OCA Safety and Efficacy	**Ruby Mehta, MD** Medical Reviewer DGIEP, ODE III, OND, CDER, FDA
	OCA Dosing Considerations	**Dhananjay Marathe, PhD** Senior Pharmacometrics Reviewer Division of Pharmacometrics Office of Clinical Pharmacology OTS, CDER, FDA
	Regulatory Perspective	**Lara Dimick, MD** Cross Discipline Team Leader DGIEP, ODE III, OND, CDER, FDA

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DRAFT AGENDA (cont.)

12:00 p.m.	Clarifying Questions to the Presenters
12:15 p.m.	**LUNCH**
1:15 p.m.	Open Public Hearing
2:15 p.m.	Questions to the Committee and Committee Discussion
3:00 p.m.	**BREAK**
3:10 p.m.	Questions to the Committee and Committee Discussion (cont.)
5:00 p.m.	**ADJOURNMENT**