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

Joint Meeting of the Gastrointestinal Drugs Advisory Committee (GIDAC) and the Pediatric Advisory Committee (PAC)

DoubleTree by Hilton Hotel Bethesda – Washington, DC, the Grand Ballroom
8120 Wisconsin Avenue, Bethesda, Maryland
May 3, 2018

AGENDA

The committees will discuss new drug application (NDA) 209904, for stannsoporfin injection, for intramuscular use, submitted by InfaCare Pharmaceutical Corporation, proposed for the treatment of neonates greater than or equal to 35 weeks of gestational age with indicators of hemolysis who are at risk of developing severe hyperbilirubinemia.

8:00 a.m.	Call to Order and Introduction of Committee	**F. Sessions Cole, MD** Acting Chairperson, PAC
8:10 a.m.	Conflict of Interest Statement	**Jay R. Fajiculay, PharmD** Designated Federal Officer, GIDAC
8:15 a.m.	FDA Introductory Remarks	**Stephanie O. Omokaro, MD** Lead Medical Officer Division of Gastroenterology and Inborn Errors Products (DGIEP) Office of Drug Evaluation (ODE) III Office of New Drugs (OND), CDER, FDA
8:35 a.m.	**APPLICANT PRESENTATIONS**	**InfaCare Pharmaceutical Corporation**
	Introduction	**Lawrence A. Hill, PharmD, MBA** Vice President, Clinical Development Mallinckrodt Pharmaceuticals
	Unmet Need	**Jeffrey Maisels, MD, DSc** Chair Emeritus and Professor Department of Pediatrics Oackland University William Beaumont School of Medicine
	Clinical Pharmacology, Efficacy and Safety	**Nancy Ruiz, MD** Senior Medical and Clinical Advisor InfaCare, A Mallinckrodt Pharmaceuticals Company
	Long-Term Neurodevelopmental Safety	**Dawn Phillips, PT, MS, PhD** Research Scientist, Outcomes Research Evidera
	Risk Management Considerations	**Lawrence A. Hill, PharmD, MBA**
	Benefit-Risk / Clinical Perspective	**Jeffrey Maisels, MD, DSc**
9:50 a.m.	Clarifying Questions	

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AGENDA (cont.)

10:05 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATIONS**	
	Clinical Pharmacology Findings of Stannsoporfin	**Shen (Steven) Li, PhD** Clinical Pharmacology Reviewer Division of Clinical Pharmacology III Office of Clinical Pharmacology Office of Translational Sciences (OTS), CDER, FDA
	Analyses of Efficacy Data	**Feiran Jiao, PhD** Mathematical Statistician Division of Biometrics III Office of Biostatistics, OTS, CDER, FDA
	Summary of Findings from Nonclinical Safety Studies in Neonatal Animals	**David Joseph, PhD** Lead Pharmacologist DGIEP, ODE III, OND, CDER, FDA
	Focused Safety Evaluation	**Y. Veronica Pei, MD, MEd, MPH** Medical Officer DGIEP, ODE III, OND, CDER, FDA
	Proposed Risk Evaluation and Mitigation Strategy (REMS) for NDA 209904 Stannsoporfin	**Charlotte Jones, MD, PhD, MSPH** Medical Officer Division of Risk Management Office of Medicaton Error Prevention and Risk Management Office of Surveillance and Epidemiology, CDER, FDA
11:30 a.m.	Clarifying Questions	
11:45 a.m.	**LUNCH**	
12:45 p.m.	**OPEN PUBLIC HEARING**	
1:45 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	**BREAK**	
3:10 p.m.	Questions to the Committee/Committee Discussion (cont.)	
4:30 p.m.	**ADJOURNMENT**	