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

Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
January 16, 2020

DRAFT AGENDA

The committee will discuss new drug application (NDA) 204803, bupivacaine extended-release solution for instillation, submitted by DURECT Corp., for the proposed indication of post-surgical analgesia. The committee will discuss whether the Applicant adequately demonstrated the safety and efficacy of bupivacaine extended-release solution for post-surgical analgesia and the appropriateness of the proposed patient populations. The committee will also be asked to discuss the approvability of this product.

8:00 a.m.	Call to Order and Introduction of Committee	**Ronald S. Litman, DO, ML** Chairperson, AADPAC
8:05 a.m.	Conflict of Interest Statement	**Moon Hee V. Choi, PharmD** Designated Federal Officer, AADPAC
8:10 a.m.	FDA Introductory Remarks	**Rigoberto Roca, MD** Acting Division Director Division of Anesthesiology, Addiction Medicine and Pain Medicine (DAAP) Office of Neuroscience (ON) Office of New Drugs (OND) Clinical CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**DURECT Corporation**
	Clinical Context	**Tong J. Gan, MD, MHS, FRCA, MBA** Professor and Chairman Department of Anesthesiology Stony Brook School of Medicine
	Introduction to Clinical Program	**Neil Verity, PhD** Executive Director, Pharmacology Project Leader and Principal Scientist DURECT Corporation
	Efficacy and Safety	**Jon Meisner, MD** Sr. Medical Director, Medical Affairs DURECT Corporation
	General Surgeon's Perspective	**Asok Doraiswamy, MD, FACS** General Surgeon Methodist Hospital of Southern California Huntington Memorial Hospital

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Anesthesiologist's perspective	**Harold Minkowitz, MD** Anesthesiologist Memorial Hermann Katy Hospital Memorial Hermann Memorial City Medical Center
9:45 a.m.	Clarifying Questions	
10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATIONS**	
	Current Postsurgical Analgesic Treatment Options & Summary of Clinical Development Program	**Renee Petit-Scott, MD** Medical Officer DAAP, ON, OND Clinical, CDER, FDA
	Statistical Review of Efficacy Data	**Katherine Meaker, MS** Statistics Reviewer Division of Biometrics I, Office of Biostatistics Office of Translational Sciences, CDER, FDA
	Clinical Implications of Efficacy Data	**Renee Petit-Scott, MD**
	Assessment of Safety Data from Studies Submitted in Support of NDA	**Renee Petit-Scott, MD**
11:45 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Charge to the Committee	**Rigoberto Roca, MD**
2:05 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	**BREAK**	
3:15 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	