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

Bone, Reproductive, and Urologic Drugs Advisory Committee (BRUDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
December 7, 2017

DRAFT AGENDA

The committee will discuss appropriate patient selection criteria and clinical trial design features, including acceptable endpoints, for demonstrating clinical benefit for drugs intended to treat interstitial cystitis and bladder pain syndrome (IC/BPS). The committee will also discuss whether bladder pain syndrome and interstitial cystitis reflect overlapping or different populations, and whether it is appropriate to assess efficacy in the same way for both conditions.

8:00 a.m.	Call to Order and Introduction of Committee	**Vivian Lewis, MD** Chairperson, BRUDAC
8:10 a.m.	Conflict of Interest Statement	**Kalyani Bhatt, BS, MS** Designated Federal Officer, BRUDAC
8:15 a.m.	FDA Opening Remarks	**Audrey Gassman, MD** Deputy Director, Division of Bone, Reproductive and Urologic Products (DBRUP) Office of Drug Evaluation III (ODE III) Office of New Drugs (OND), CDER, FDA
8:30 a.m.	**INDUSTRY PRESENTATION #1**	**Aquinox Pharmaceuticals**
	Introduction	**Barbara Troupin, MD, MBA** Chief Medical Officer Vice President, Clinical Development & Regulatory Affairs Aquinox Pharmaceuticals, Inc.
	Defining an IC/BPS Population for Clinical Study	**Robert Moldwin, MD** Professor of Urology - The Smith Institute for Urology Zucker School of Medicine at Hofstra/Northwell Lake Success, New York
	Endpoint Selection for Clinical Trials in IC/BPS	**John Curtis Nickel, MD** Professor of Urology, Queen's University CIHR Canada Research Chair in Urologic Pain and Inflammation, Kingston General Hospital
	Conclusion	**Barbara Troupin, MD, MBA**

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DRAFT AGENDA (cont.)

9:00 a.m.	**INDUSTRY PRESENTATION #2**	**Urigen Pharmaceuticals, Inc.**
	Introduction	**Dan Vickery, PhD** President, Urigen Pharmaceuticals, Inc.
	IC/BPS Disease, Pathophysiology and Diagnosis	**Joel Teichman, MD, FRCSC** Professor, Department of Urologic Sciences University of British Columbia Vancouver, Canada
	Clinical Trial Patient Enrollment and Assessment Criteria	**C Lowell Parsons, MD** Chairman, Urigen Pharmaceuticals, Inc. Professor Emeritus of Urology School of Medicine University of California, San Diego
	Conclusion	**Dan Vickery, PhD**
9:30 a.m.	Clarifying Questions for both Industry Presentations	
10:15 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATIONS**	
	Clinical Perspective: Clinical Trials for Interstitial Cystitis/Bladder Pain Syndrome	**Debuene Chang, MD** Medical Officer DBRUP, ODE III, OND, CDER, FDA
	Regulatory Approach to Clinical Outcome Assessment Review for Drug Development	**Selena Daniels, PharmD, MS** Team Leader, Clinical Outcome Assessments Staff OND, CDER, FDA
11:30 a.m.	Clarifying Questions to FDA	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Clarifying Questions to Industry or FDA	
2:30 p.m.	**BREAK**	
2:45 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	