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
October 30, 2019

AGENDA

The committee will discuss new drug application (NDA) 204017 (levonorgestrel and ethinyl estradiol) transdermal system, submitted by Agile Therapeutics, Inc., for the prevention of pregnancy in women of reproductive potential.

8:15 a.m.	Call to Order and Introduction of Committee	**Vivian Lewis, MD** Chairperson, BRUDAC
8:25 a.m.	Conflict of Interest Statement	**Kalyani Bhatt, BS, MS** Designated Federal Officer, BRUDAC
8:30 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
8:45 a.m.	**APPLICANT PRESENTATIONS**	**Agile Therapeutics, Inc.**
	Introduction	**Geoffrey Gilmore** Senior Vice President Agile Therapeutics, Inc.
	Need for More Contraceptive Options and Evolving Clinical Trial Environment	**David Portman, MD** CEO and Chief Medical Officer Sermonix Pharmaceuticals Founder, Director Emeritus, and Principal Investigator The Columbus Center for Women's Health Research Adjunct Instructor Department of Obstetrics and Gynecology Wexner Medical Center at The Ohio State University
	Study Design, Efficacy and Safety	**Elizabeth Garner, MD, MPH** Chief Medical Officer ObsEva SA Consultant, Former Chief Medical Officer Agile Therapeutics, Inc.
	Clinical Perspective	**David Portman, MD**
9:45 a.m.	Clarifying Questions to Applicant	
10:15 a.m.	**BREAK**	

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AGENDA (cont.)

10:30 a.m.	**FDA PRESENTATIONS**	
	Background	**Jerry Willett, MD** Clinical Team Leader DBRUP, ODE III, OND, CDER, FDA
	Effectiveness Considerations	**Yun Tang, PhD** Statistical Reviewer Division of Biometrics III Office of Biostatistics Office of Translational Sciences, CDER, FDA
	Safety Profile and Benefit-Risk Considerations	**Nneka McNeal-Jackson, MD** Clinical Reviewer DBRUP, ODE III, 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 Applicant or FDA	
2:30 p.m.	**BREAK**	
2:45 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	