

**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

DRAFT 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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DRAFT 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 and Voting

5:00 p.m. **ADJOURNMENT**