

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

***Dermatologic and Ophthalmologic Drugs Advisory Committee (DODAC) Meeting***  
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)  
10903 New Hampshire Avenue, Silver Spring, Maryland  
October 13, 2017

**DRAFT AGENDA**

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*The committee will discuss the safety and efficacy of new drug application (NDA) 208254, for netarsudil ophthalmic solution 0.02%, submitted by Aerie Pharmaceuticals Inc., for the proposed indication to reduce elevated intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT).*

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8:30 a.m.	Call to Order and Introduction of Committee	<b>James Chodosh, MD</b> Chairperson, DODAC
8:35 a.m.	Conflict of Interest Statement	<b>LaToya Bonner, PharmD, NCPS</b> Designated Federal Officer, DODAC
8:40 a.m.	FDA Opening Remarks	<b>Wiley A. Chambers, MD</b> Deputy Director Division of Transplant and Ophthalmology Products (DTOP), Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:45 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Aerie Pharmaceuticals, Inc.</b>
	Introduction	<b>Marvin Garrett</b> Vice President Regulatory Affairs and Quality Assurance Aerie Pharmaceuticals, Inc.
	Unmet Medical Needs	<b>Richard A. Lewis, MD</b> Chief Medical Officer Aerie Pharmaceuticals, Inc. Past President, AGS
	Program Design and Efficacy	<b>Casey Kopczynski, PhD</b> Chief Scientific Officer Aerie Pharmaceuticals, Inc.
	Safety	<b>Theresa Heah, MD, MBA</b> Vice President, Clinical Research and Medical Affairs Aerie Pharmaceuticals, Inc.
	Benefits and Risks	<b>Janet Serle, MD</b> Professor of Ophthalmology Glaucoma Fellowship Director Icahn School of Medicine at Mount Sinai

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**DRAFT AGENDA (cont.)**

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9:45 a.m. Clarifying Questions

10:00 a.m. **BREAK**

10:15 a.m. **FDA PRESENTATIONS**

FDA Clinical Presentation

**Sonal Wadhwa, MD**  
Medical Officer  
DTOP, OAP, OND, CDER, FDA

FDA Statistical Presentation

**Yunfan Deng, PhD**  
Statistical Reviewer  
Division of Biostatistics IV (DBIV)  
Office of Biostatistics (OB)  
Office of Translational Sciences (OTS), CDER, FDA

11:00 a.m. Clarifying Questions

11:30 a.m. **LUNCH**

12:30 p.m. **OPEN PUBLIC HEARING**

1:30 p.m. Questions to the Committee/Committee Discussion

2:30 p.m. **BREAK**

2:45 p.m. Questions to the Committee/Committee Discussion (cont.)

4:00 p.m. **ADJOURNMENT**