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

AGENDA

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).

8:30 a.m.	Call to Order and Introduction of Committee	**James Chodosh, MD** Chairperson, DODAC
8:35 a.m.	Conflict of Interest Statement	**LaToya Bonner, PharmD, NCPS** Designated Federal Officer, DODAC
8:40 a.m.	FDA Opening Remarks	**Wiley A. Chambers, MD** 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.	**APPLICANT PRESENTATIONS**	**Aerie Pharmaceuticals, Inc.**
	Introduction	**Marvin Garrett** Vice President Regulatory Affairs and Quality Assurance Aerie Pharmaceuticals, Inc.
	Unmet Medical Needs	**Richard A. Lewis, MD** Chief Medical Officer Aerie Pharmaceuticals, Inc. Past President, AGS
	Program Design and Efficacy	**Casey Kopczynski, PhD** Chief Scientific Officer Aerie Pharmaceuticals, Inc.
	Safety	**Theresa Heah, MD, MBA** Vice President, Clinical Research and Medical Affairs Aerie Pharmaceuticals, Inc.
	Benefits and Risks	**Janet Serle, MD** Professor of Ophthalmology Glaucoma Fellowship Director Icahn School of Medicine at Mount Sinai
9:45 a.m.	Clarifying Questions	

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AGENDA (cont.)

10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATIONS**	
	FDA Clinical Presentation	**Sonal D. Wadhwa, MD** Medical Officer DTOP, OAP, OND, CDER, FDA
	FDA Statistical Presentation	**Yunfan Deng, PhD** Statistical Reviewer Division of Biometrics 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**	