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

Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) Meeting
October 30, 2026

DRAFT AGENDA

The Committee will discuss new drug application (NDA) 219694, for atropine sulfate ophthalmic solution 0.01%, submitted by Sydnexis. Inc. The proposed indication (use) is for slowing of myopia progression in children 3 years of age or older.

8:30 a.m.	Call to Order and Introduction of Committee	**Michael X. Repka, MD, MBA** Acting Chairperson
8:35 a.m.	Conflict of Interest Statement	**LaToya Bonner, PharmD, MBA** Designated Federal Officer
8:40 a.m.	FDA Introductory Remarks	**William Boyd, MD** Director Division of Ophthalmology Office of Specialty Medicine
8:50 a.m.	**APPLICANT PRESENTATION**	**Sydnexis, Inc.**
	Introduction	**Patrick Johnson, PhD** Sydnexis, Inc. President
	Pediatric Myopia: Evidence, Practice and Unmet Need	**Rahul Bhola, MD** Medical Director of Ophthalmology, Rady Children's Hospital Orange County (CHOC) Division Chief, CHOC Specialists Ophthalmology
	Study 001 Results	**Tina Rutar, MD** Pediatric Ophthalmologist Cataract and Laser Institute of Southern Oregon
	Clinical Perspective	**Robert Clark, MD** Pediatric Ophthalmologist Associate Clinical Professor Stein Eye Institute, UCLA
	Sydnexis Responses to FDA Issues	**Janet Cheetham, PharmD** Sydnexis, Inc. **Jason, Connor, PhD** Confluence Stat **Robert Clark, MD**

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DRAFT AGENDA (cont.)

	Conclusion	**Patrick Johnson, PhD**
9:50 a.m.	Clarifying Questions	
10:20 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATION**	
	NDA 219694 Yovo (atropine sulfate ophthalmic solution) 0.01%	**Heather de Beaufort, MD** Clinical Reviewer Division of Ophthalmology Office of Specialty Medicine **Abel Eshete, PhD** Team Leader Division of Biometrics IV Office of Translational Sciences
11:30 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	**ADJOURNMENT**	

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