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

Nonprescription Drugs Advisory Committee (NDAC) Meeting
September 11-12, 2023

AGENDA

The committee will discuss new data regarding the 'Generally Recognized as Safe and Effective' (GRASE) status of oral phenylephrine as a nasal decongestant that have become available since FDA last examined the issue.

DAY 1

9:00 a.m.	Call to Order	**Maria C. Coyle, PharmD, FCCP, BCPS, BCACP, CLS** Acting Chairperson, NDAC
9:05 a.m.	Introduction of Committee and Conflict of Interest Statement	**Jessica Seo, PharmD, MPH** Acting Designated Federal Officer, NDAC
9:20 a.m.	**INTRODUCTION AND REGULATORY HISTORY**	
	Welcome and Introduction	**Theresa Michele, MD** Director Office of Nonprescription Drugs (ONPD) Office of New Drugs (OND), CDER, FDA
	Background and Regulatory History of Oral Phenylephrine	**LCDR Ben Bishop, PharmD, MSc Reg Sci** Regulatory Review Officer Division of Nonprescription Drugs I (DNPD I) ONPD, OND, CDER, FDA
9:50 a.m.	**BREAK**	
10:00 a.m.	**FDA PRESENTATIONS**	
	Clinical Pharmacology of Oral Phenylephrine	**Yunzhao Ren, MD, PhD** Team Leader Division of Inflammation & Immune Pharmacology (DIIP) Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS) CDER, FDA
	Clinical Safety and Efficacy of Oral Phenylephrine as a Nasal Decongestant	**Peter Starke, MD, FAAP** Lead Clinical Reviewer DNPD I, ONPD, OND, CDER, FDA

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AGENDA (cont.)

FDA PRESENTATIONS (cont.)

	Sales of OTC Products Containing Phenylephrine or Pseudoephedrine in the United States	**Tracy Pham, PharmD** Drug Utilization Analyst Division of Epidemiology II (DEPI II) Office of Surveillance and Epidemiology (OSE) CDER, FDA
11:30 a.m.	Clarifying Questions	
11:55 a.m.	**LUNCH**	
12:55 p.m.	**INDUSTRY PRESENTATIONS**	
	Introduction	**Marcia D. Howard, PhD, CAE** Vice President, Regulatory & Scientific Affairs Consumer Healthcare Products Association (CHPA)
	Assessment of Nasal Congestion	**Howard M. Druce, MD** Clinical Professor of Medicine Division of Allergy, Immunology and Rheumatology Department of Medicine Rutgers New Jersey Medical School
	Clinical Pharmacology of Phenylephrine	**Cathy K. Gelotte, PhD** Clinical Pharmacology Consultant
	Efficacy	**Howard M. Druce, MD**
	Discussion and Comparison of Meta-Analyses	**Chris M. Mullin, MS** Director, Global Strategy Services North American Science Associates, LLC (NAMSA)
	Benefit-Risk Profile	**Marcia D. Howard, PhD, CAE**
2:25 p.m.	Clarifying questions	
2:50 p.m.	**BREAK**	
3:00 p.m.	**OPEN PUBLIC HEARING**	
5:00 p.m.	**ADJOURNMENT**	

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AGENDA (cont.)

DAY 2

9:00 a.m.	Call to Order	**Maria C. Coyle, PharmD, FCCP, BCPS, BCACP, CLS** Acting Chairperson, NDAC
9:05 a.m.	Introduction of Committee	**Jessica Seo, PharmD, MPH** Acting Designated Federal Officer, NDAC
9:20 a.m.	Summary and Introduction to Discussion	**Martha Lenhart, MD, PhD** Deputy Director DNPDI, ONPD, OND, CDER, FDA
9:30 a.m.	Charge to the Advisory Committee	**Martha Lenhart, MD, PhD**
9:40 a.m.	Questions to the Committee/Committee Discussion	
10:30 a.m.	**BREAK**	
10:45 a.m.	Questions to the Committee/Committee Discussion (cont.)	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Questions to the Committee/Committee Discussion (cont.)	
2:30 p.m.	**ADJOURNMENT**	