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

Pulmonary-Allergy Drugs Advisory Committee (PADAC) Meeting
May 11, 2023

DRAFT AGENDA

The committee will discuss new drug application (NDA) 214697, for epinephrine nasal spray, submitted by ARS Pharmaceuticals Inc., for the proposed indication of emergency treatment of allergic reactions (Type I) including anaphylaxis in adults and children ≥ 30 kilograms.

9:00 a.m.	Call to Order	**David Au, MD, MS** Chairperson, PADAC
9:10 a.m.	Introduction of Committee and Conflict of Interest Statement	**Takyiah Stevenson, PharmD** Designated Federal Officer, PADAC
9:15 a.m.	FDA Introductory Remarks	**Miya Paterniti, MD** Clinical Team Leader Division of Pulmonology, Allergy, and Critical Care (DPACC) Office of Immunology and Inflammation (OII) Office of New Drugs (OND), CDER, FDA
9:35 a.m.	**APPLICANT PRESENTATIONS**	**ARS Pharmaceuticals Inc.**
	Introduction	**Richard Lowenthal, MSc, MSEL** CEO, President and Co-Founder ARS Pharmaceuticals Inc.
	Unmet Need in Use of Epinephrine	**Thomas Casale, MD** Professor of Medicine and Pediatrics Director, Division of Allergy & Immunology University of South Florida
	neffy Development Rationale: Pharmacokinetic (PK), Pharmacodynamic (PD) and Safety Data	**Sarina Tanimoto, MD, PhD** ARS Pharmaceuticals Inc. Chief Medical Officer
	Clinical Perspective and Conclusion	**John Oppenheimer, MD** Clinical Professor of Medicine Director, Clinical Research Pulmonary & Allergy University of Medicine and Dentistry of New Jersey (UMDNJ) – Rutgers University
10:50 a.m.	Clarifying Questions to the Applicant	
11:10 a.m.	**BREAK**	

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

Pulmonary-Allergy Drugs Advisory Committee (PADAC) Meeting
May 11, 2023

DRAFT AGENDA (cont.)

11:20 a.m.	**FDA PRESENTATIONS**	
	Overview of the Clinical Program	**Jennifer Lan, MD** Medical Officer DPACC, OII, OND, CDER, FDA
	Overview of the Clinical Pharmacology Data	**Qianni Wu, PharmD** Clinical Pharmacology Reviewer Division of Inflammation and Immune Pharmacology Office of Clinical Pharmacology Office of Translational Sciences, CDER, FDA
	Clinical Considerations and Risk/Benefit	**Jennifer Lan, MD**
12:25 p.m.	Clarifying Questions to the FDA	
12:45 p.m.	**LUNCH**	
1:30 p.m.	**OPEN PUBLIC HEARING**	
2:30 p.m.	Charge to the Committee	**Miya Paterniti, MD**
2:45 p.m.	Questions to the Committee/Committee Discussion	
3:20 p.m.	**BREAK**	
3:30 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	