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

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
November 30, 2021

DRAFT AGENDA

The committee will discuss Emergency Use Authorization (EUA) 000108, submitted by Merck & Co. Inc., for emergency use of molnupiravir oral capsules for treatment of mild to moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and/or hospitalization.

9:00 a.m.	Call to Order	**Lindsey R. Baden, MD** Chairperson, AMDAC
9:10 a.m.	Conflict of Interest Statement and Introduction of Committee	**Joyce Yu, PharmD** Acting Designated Federal Officer, AMDAC
9:15 a.m.	FDA Introductory Remarks	**John Farley, MD, MPH** Director Office of Infectious Diseases (OID) Office of New Drugs (OND), CDER, FDA
9:25 a.m.	**SPONSOR PRESENTATIONS**	**Merck & Co., Inc.**
	Introduction	**Sean Curtis, MD, MPH** Senior Vice President Global Regulatory Affairs & Clinical Safety Merck & Co., Inc
	Mechanism of Action	**Daria J. Hazuda, PhD** Vice President, Infectious Disease and Vaccines Merck & Co., Inc
	Nonclinical Safety	**Kerry Blanchard, PhD** Senior Vice President, Preclinical Development Merck & Co., Inc
	Clinical Efficacy and Safety	**Nicholas Kartsonis, MD** Senior Vice President Clinical Research, Infectious Diseases/Vaccines Merck & Co., Inc
	Benefit-Risk Conclusion	**Nicholas Kartsonis, MD**
10:35 a.m.	**BREAK**	

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DRAFT AGENDA (cont.)

10:45 a.m.	**FDA PRESENTATIONS**	
	Emergency Use Authorization (EUA) Request 108 Molnupiravir (MOV) Capsules	**Aimee Hodowanec, MD** Senior Medical Officer Division of Antivirals (DAV) OID, OND, CDER, FDA
	Molnupiravir: Nonclinical Toxicology Findings	**Mark Seaton, PhD, DABT** Research Officer Division of Pharmacology/Toxicology-Infectious Diseases OID, OND, CDER, FDA
	Genotoxicity Safety Assessment of Molnupiravir	**Robert H. Heflich, PhD** Director Division of Genetic and Molecular Toxicology National Center for Toxicological Research Office of the Chief Scientist Office of the Commissioner, FDA
	Clinical Overview	**Aimee Hodowanec, MD**
	FDA Clinical Virology Review of Molnupiravir	**Patrick R. Harrington, PhD** Senior Clinical Virology Reviewer DAV, OID, OND, CDER, FDA
	Review Issues and Proposed Risk Mitigation Strategies	**Aimee Hodowanec, MD**
11:45 a.m.	Clarifying Questions for Presenters	
12:45 p.m.	**LUNCH**	
1:30 p.m.	**OPEN PUBLIC HEARING**	
2:30 p.m.	Charge to the Committee	**Debra Birnkrant, MD** Director DAV, OID, OND, CDER, FDA

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DRAFT AGENDA (cont.)

2:45 p.m.	Questions to the Committee/Committee Discussion
3:50 p.m.	**BREAK**
4:00 p.m.	Questions to the Committee/Committee Discussion (cont.)
5:00 p.m.	**ADJOURNMENT**