

AGENDA

GENERAL HOSPITAL AND PERSONAL USE DEVICES PANEL

Medical Device Supply Chain Resiliency and Shortages & Proposed 506J Device List

February 6, 2024

Panel Chairperson William R. Jarvis, MD **Designated Federal Officer** Jarrod Collier, MS

- 9:00 AM Call to Order Panel Introductions Conflict of Interest Statements
- 9:20 AM Opening Remarks Suzanne Schwartz, MD, MBA Director, Office of Strategic Partnerships and Technology Innovation
- 9:30 AM FDA Presentation and Questions for FDA Tammy Beckham, DVM, PhD Associate Director, Resilient Supply Chain Program

10:15 AM Break

 10:30 AM
 Stakeholder Presentation: Medical Device Manufacturers

 Mark B. Leahey
 President and CEO, Medical Device Manufacturers Association (MDMA)

Abby Pratt Senior Vice President, Global Strategy and Analysis Advanced Medical Technology Association (AdvaMed)

10:45 AM	Stakeholder Presentation: Healthcare Systems Paul D. Biddinger, MD, FACEP <i>Chief Preparedness and Continuity Officer, Mass General Brigham</i>
	Ann L. Prestipino, MPH Endowed Chair in Emergency Preparedness
	Director, Center for Disaster Medicine, Massachusetts General Hospital Department of Emergency Medicine
	Director, Harvard T.H. Chan School of Public Health Emergency Preparedness Research, Evaluation and Practice (EPREP) Program
11:00 AM	Stakeholder Presentation: Healthcare Providers Jacob F. Collen, MD, FACP, FCCP, FAASM, COL, MC, USA Pulmonary, Critical Care and Sleep Medicine Professor of Medicine, Uniformed Services University

Internal/Confidential/Deliberative



11:15 AM	Questions to Stakeholders
11:30 AM	Open Public Hearing*
12:30 PM	Lunch
1:10 PM	Working Session 1 – FDA Questions to the Panel
2:30 PM	Break
2:45 PM	Working Session 2 – FDA Questions to the Panel
3:30 PM	Panel Deliberations
4:30 PM	FDA Summations
5:00 PM	Adjournment

* Open Public Hearing – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. The Chair will then recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.