

**Immunology Devices Panel
of the
MEDICAL DEVICES ADVISORY COMMITTEE**
Doubletree by Hilton DC North/Gaithersburg
620 Perry Pkwy, Gaithersburg, MD 20877
November 13th, 2019

Panel Chairperson
Raj Rao, MD

Designated Federal Officer
Aden S. Asefa, MPH

08:00	a.m.	Call to Order Conflict of Interest Deputization to Voting Member Status Statements Panel Introductions	Raj Rao, MD (Chair) Aden Asefa, MPH (FDA)
08:15	a.m.	Welcome & Introduction	Aron Yustein, MD (FDA)
08:25	a.m.	Introduction to Immunology Basics	Dori Germolec, PhD (NIH)
08:40	a.m.	FDA and Invited Speaker Presentations: Metal Implants (Incl. 15 Minute break) FDA Guidance/Biocompatibility Corrosion Preclinical Issues Clinical Non-Orthopedics Clinical Orthopedics Diagnostics Summary/Gap Analysis	Jennifer Goode (FDA) David Saylor, PhD (FDA) Nadim Hallab, PhD (Rush University) Laura Santambrogio, MD/PhD (Weill Cornell) Stephen Weber, MD (FDA) Ben Fisher, PhD (FDA) Young-Min Kwon, MD (Harvard University) Elizabeth Stafford, PhD (FDA) Lisa Torosyan, MD/PhD (FDA)
10:00	a.m.	Panel Clarifications/Deliberation	
11:30	a.m.	Lunch	
12:30	p.m.	FDA and Invited Speaker Presentations: Dental Amalgam Background Summary of FDA Scientific Review Biomarkers of Exposure Summary/Gap Analysis	Michael Adjodha, MChE (FDA) Lisa Torosyan, MD/PhD (FDA) Alfred Franzblau, MD (University of Michigan) Lisa Torosyan, MD/PhD (FDA)
01:45	p.m.	Panel Clarifications/Deliberations	
02:15	p.m.	Break	
02:30	p.m.	Open Public Hearing	
05:00	p.m.	Chair Summary/Adjourn	

* **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. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.

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Raj Rao, MD

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Aden S. Asefa, MPH

08:00	a.m.	Call to Order Conflict of Interest and Deputization to Voting Member Status Statements Panel Introductions (Asefa, FDA)	Raj Rao, MD (Chair) Aden Asefa, MPH (FDA)
08:10	a.m.	Open Public Hearing	
10:15	a.m.	Break	
10:30	a.m.	General Panel Deliberations	
11:15	a.m.	Panel Questions	
12:50	p.m.	Lunch	
01:40	p.m.	Panel Questions cont.	
03:00	p.m.	Break	
03:15	p.m.	Panel Questions cont.	
04:15	p.m.	Summary	Raj Rao, MD (Chair)
04:30	p.m.	Adjourn	

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