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

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  Jennifer Goode (FDA)
Corrosion  David Saylor, PhD (FDA)
Preclinical Issues  Nadim Hallab, PhD (Rush University)
Laura Santambrogio, MD/PhD (Weill Cornell)
Clinical Non-Orthopedics  Stephen Weber, MD (FDA)
Ben Fisher, PhD (FDA)
Clinical Orthopedics  Young-Min Kwon, MD (Harvard University)
Diagnostics  Alfred Franzblau, MD (University of Michigan)
Summary/Gap Analysis  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  Michael Adjodha, MChE (FDA)
Summary of FDA Scientific Review  Lisa Torosyan, MD/PhD (FDA)
Biomarkers of Exposure  Alfred Franzblau, MD (University of Michigan)
Summary/Gap Analysis  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.
Immunology Devices Panel of the MEDICAL DEVICES ADVISORY COMMITTEE

Doubletree by Hilton DC North/Gaithersburg,
620 Perry Pkwy, Gaithersburg, MD  20877
November 14th, 2019

Panel Chairperson
Raj Rao, MD

Designated Federal Officer
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)

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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