

AGENDA

Microbiology Medical Devices Panel of the MEDICAL DEVICES ADVISORY COMMITTEE

Holiday Inn, Ballroom 2
2 Montgomery Village Ave.
Gaithersburg, MD

June 29, 2011

Panel Chairperson
Angela M. Caliendo, M.D.

Designated Federal Officer
Shanika Craig, MBA

Discussion and Recommendations Regarding the Classification of NAAT-based Rapid *M. tuberculosis* Diagnostics and the Classification of Interferon Gamma Release Assays

- 8:00 – 8:15 **Call to Order, Announcements**
Shanika Craig, Designated Federal Officer, Office of Device Evaluation, CDRH
- 8:15 – 8:30 **Introductions**
Sally Hojvat, Ph.D., Director, Division of Microbiology Devices, Office of In Vitro
Diagnostic Device Evaluation and Safety, CDRH
Alberto Gutierrez, Ph.D., Director, Office of In Vitro Diagnostic Device Evaluation
and Safety, CDRH
- 8:30 – 8:50 **FDA Reclassification Process**
Marjorie Shulman, Acting Director, Premarket Notification Staff, Office of Device
Evaluation, CDRH
- Questions from the Panel*
- 8:50 – 10:00 **FDA Presentations**

Current FDA Regulation of Tuberculosis Diagnostics
Steven Gitterman, M.D., Ph.D., Medical Officer, DMD/OIVD/CDRH

Current Tuberculosis Diagnostics: The Role of Diagnostic Tests for Latent and Active
Tuberculosis
William Burman, M.D., Interim Director, Denver Public Health
- 10:00 – 10:10 **Break**
- 10:10 – 11:00 **FDA Presentations (Cont'd)**

The Public Health Implications of Reclassification
Kenneth Castro, M.D., Director, Tuberculosis Elimination Program, CDC
- Questions from the Panel*

*** 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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11:00 – 12:00	Open Public Hearing
12:00 – 1:00	Lunch
1:00 – 1:15	FDA Questions Sally Hojvat, Ph.D.
1:15 – 3:00	Panel Deliberations
3:00- 3:15	Break
3:15- 4:15	Panel Deliberations (Continued)
4:15- 4:30	Break
4:30 – 5:00	Summary and Next Steps Committee Chair and Sally Hojvat, Ph.D.
5:00	Adjourn

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