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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