

AGENDA  
Meeting of the  
MICROBIOLOGY DEVICES PANEL MEETING  
Friday, October 12, 2001

*Panel Chair: Michael L. Wilson, M.D.*  
*Executive Secretary/ Chief, Bacteriology Branch: Freddie M. Poole*  
*Division Director: Steven I. Gutman, M.D., M.B.A.*

**9:00 CALL TO ORDER**

Opening Remarks.....Executive Secretary  
Introduction of Panel.....Panel Chair

**9:20 NEW BUSINESS**

**9:30 PREMARKET APPROVAL APPLICATION: *Cellestis Limited, QuantiFERON-TB. An in vitro diagnostic device for measuring the release of gamma-interferon from sensitized lymphocytes in PPD-stimulated whole blood. Intended as an aid in the diagnosis of latent tuberculosis infection, and to aid in the evaluation of individuals suspected of having M. tuberculosis infection.***

**MANUFACTURER'S PRESENTATION:**

**10:30 FDA PRESENTATION**

**QFT Performance Characterization..... Roxanne G. Shively, MS**  
Senior Scientific Reviewer, Bacteriology Devices Branch, Division of Clinical Lab. Devices

**Statistical Analyses of Data .....John L. Dawson, MS. JD**  
Mathematical Statistician, Division of Biostatistics, Office of Surveillance & Biometrics, CDRH

**Clinical Use of QFT Results ..... Leonard V. Sacks, M.D.**  
Senior Staff Fellow, Division of Special Pathogens and Immunologic Drug Products, CDER

**11:30 OPEN PUBLIC HEARING**

*Public Attendees who have contacted the Executive Secretary prior to the meeting, will address the panel and present information relevant to devices indicated to aid in the diagnosis of latent TB infection. Speakers are to state whether or not they have any financial involvement with manufacturers of these devices.*

**12:00 LUNCH BREAK**

**1:00 OPEN COMMITTEE DISCUSSION**

*This portion of the meeting is open to public observers. However, public observers may not participate except at the specific request of the Chairperson.*

**3:00 BREAK**

**3:15 OPEN PUBLIC HEARING**

*This portion of the meeting is open for comments from the public to comment on related issues.*

**3:30 INDUSTRY RESPONSE**

*This portion of the meeting is open for comments from the sponsor to respond to any issues presented.*

**3:35 FDA RESPONSE**

*This portion of the meeting is open for comments from the FDA to respond to any issues presented.*

**3:40 FINAL RECOMMENDATIONS AND VOTE**

*The Panel will provide final recommendations to the FDA and vote on Quanti-FERON-TB*

**4:30 ADJOURN**