

AGENDA
Meeting of the
MICROBIOLOGY DEVICES PANEL MEETING
Thursday, October 11, 2001

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

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9:45 CALL TO ORDER Panel Chair
OPENING REMARKS.....Executive Secretary
INTRODUCTION OF PANEL..... Panel Chair

NEW BUSINESS:

PREMARKET APPROVAL APPLICATION: *Sepsis Inc., Endotoxin Activity. An in vitro diagnostic device for the determination of endotoxin activity in human blood samples, to rule out gram negative infection.*

10:00 MANUFACTURER'S PRESENTATION:

11:00 FDA PRESENTATION:

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

EAA Performance Characteristics **Marian H. Heyliger, MS**
Senior Scientific Reviewer, Bacteriology Devices Branch, DCLD

11:40 OPEN PUBLIC HEARING

(Public Attendees, who have contacted the Executive Secretary prior to the meeting, or any other interested parties, will address the panel and present information relevant to in vitro diagnostic devices that detect endotoxin activity. Speakers are to state whether or not they have any financial involvement with manufacturers of these devices.)

12:10 LUNCH BREAK

1:00 OPEN COMMITTEE DISCUSSION

(This portion of the meeting is open to public observers. Public observers may not participate except at the specific request of the Chairperson. The Panel discusses the FDA Questions and provides advice to the agency.)

2:50 BREAK

3:00 OPEN PUBLIC HEARING

(This portion of the meeting is open for comment from the public. Speakers are to state whether or not they have any financial involvement with manufacturers of this device.

3:10 SPONSOR RESPONSE

(The sponsor may provide comments to respond to any issue raised during the Committee Discussion.)

3:15 FDA RESPONSE

(The FDA may provide comments to respond to any issue raised during the Committee Discussion.)

3:20 VOTE AND RECOMMENDATIONS

(The Panel provides their recommendations and votes on the PMA.)

4:15 BREAK

4:25 RECONVENE

PREMARKET NOTIFICATION SUBMISSION : An *in vitro* diagnostic device for detecting and measuring urinary tract infection by semiquantitative analysis of volatile compounds released from urine samples.

4:25 SPONSOR PRESENTATION

5:15 FDA PRESENTATION

Osmetech UTI Performance Marian H. Heyliger, MS.
Senior Scientific Reviewer, Bacteriology Devices Branch, DCLD

5:25 OPEN PUBLIC HEARING

(Public Attendees who have contacted the Executive Secretary prior to the meeting, or any other interested parties, will address the panel and present information relevant to the use of detection and measuring of urinary tract infection by analysis of volatile organic compounds. Speakers are to state whether or not they have any financial involvement with manufacturers of these devices.)

5:30 OPEN COMMITTEE DISCUSSION

(This portion of the meeting is open to public observers. Public observers may not participate

except at the specific request of the Chairperson.)

6:30 FINAL RECOMMENDATIONS

(The Panel will provide final recommendations to the FDA.)

6:45 MEETING ADJOURN