

AGENDA
HEMATOLOGY AND PATHOLOGY DEVICES PANEL MEETING
Hilton Washington DC North, Gaithersburg, MD
July 18, 2008

Panel Chairperson
Dorothy Adcock, M.D.

Executive Secretary
Louise E. Magruder

8:00 – 8:15 a.m. Opening Remarks – Introduction

8:15 – 9:15 a.m. 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. The Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.

9:15 – 9:25 a.m. FDA Introduction
Josephine Bautista, M.S., MT (ASCP)

9:25 – 10:15 a.m. FDA Speakers
CLIA Waiver – Carol Benson, M.A.
CLIA Waiver, Demonstrating Accuracy – Marina Kondratovich, Ph.D.

10:15 - 10:30 a.m. Break

10:30 – 11:20 a.m. FDA Speakers
Laboratory and Clinical Issues in CLIA Waiver for CBC/ADCC Devices –
Robert L. Becker, Jr., M.D., Ph.D.
CLIA Waiver Statistical Issues for CBC/ADCC Devices – Estelle Russek-Cohen, Ph.D.

11:20 – 11:35 a.m. FDA Summary – Josephine Bautista, M.S., MT (ASCP)

11:35 – 11:50 a.m. Panel Questions for FDA speakers

11:50 – 1:00 p.m. LUNCH

1:00 – 1:30 p.m. Guest Speaker
Judy Yost, M.A., MT.,(ASCP)
Centers for Medicare and Medicaid Systems

1:30 – 1:35 p.m. Panel Questions for Guest speaker

1:35 – 1:50 p.m. Panel General Discussion

1:50 – 3:00 p.m. Display of Questions and Discussion

3:00 –3:15 p.m. Break

3:15 – 5:00 Questions Discussion and Recommendations
Adjournment