

**Immunology Devices Panel Meeting
December 3, 2008**

Hilton Washington, D.C./North, 620 Perry Parkway, Gaithersburg, MD 20877
Tel 301-977-8900

**Panel Chair: George Netto, M.D.
Executive Secretary: Dai J. Li, M.D., M.S., Ph.D.**

**Fujirebio HE4 EIA and Risk of Ovarian Malignancy Algorithm (ROMA™)
(K080033)
Agenda***

- 8:30 – 8:45 **Call to Order**
- Opening Remarks.....Panel Chair
 - Introduction of PanelPanel Chair
 - Conflict of Interest Statement.....Executive Secretary
- 8:45- 9:15 **Open Public Hearing****
- 9:15-10:15 **Sponsor Presentation**
Fujirebio Diagnostics, Inc.
- 10:15 – 10:30 **Q & A**
- 10:30-10:45 **Break**
- 10:45-11:45 **FDA Presentation**
- FDA Reviewer (James Reeves, Ph.D.)
 - FDA Statistician (Marina Kondratovich, Ph.D.)
 - Robert L. Becker, M.D. Chief Medical Officer CDRH/OIVD
- 11:45 – 12:00 **Q & A**
- 12:00 -1:15 **Lunch Break**
- 1:15 – 3:15 **Panel Discussion**
- 3:15 -3:30 **Break**
- 3:30-4:00 **Open Public Hearing****
- 4:00-5:00 **Panel Deliberations and FDA Questions**
- 5:00. **Adjourn**

* All times are approximate

** **Open Public Hearings**-Interested persons may present data, information, or views, orally or in writing, on the meeting agenda. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, Dr. George Netto will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.