

**FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY
COMMITTEE**

DRAFT AGENDA

November 16 - 17, 2005 8:30 AM EST

Holiday Inn Select, 8120 Wisconsin Avenue, Bethesda, MD 20814

Day 1

Open Session

8:30 a.m.	Call to Order and Opening Remarks	Gary D. Overturf, M.D., Chair
8:35	Administrative Matters	Christine Walsh, R.N., FDA

Use of MDCK Cells for Manufacture of Inactivated Influenza Virus Vaccines

8:45 a.m.	Introduction and Overview	Philip Krause, M.D., FDA
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9:30	Tumorigenicity Presentation	Andrew Lewis, M.D., FDA
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10:15 Break

10:30	Adventitious Agent Presentation	Arifa Khan, Ph.D., FDA
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11:15	Issues Associated with Residual Cell Substrate DNA	Keith Peden, Ph.D., FDA
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12:00 noon Lunch

1:00 p.m. Open Public Hearing

1:30	Manufacturer's Presentation	Rina Rappuoli, Ph.D. Chiron Corporation
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2:15	Manufacturer's Presentation	Jeroen Medema Solvay Pharmaceuticals, Inc.
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3:00 Break

3:15	Committee Discussion	
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5:15 p.m. Adjourn for the day

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Day 2

8:30 a.m. **Closed Session**

Open Session

10:00 a.m. Call to Order and Opening Remarks Gary D. Overturf, M.D., Chair
10:05 Administrative Matters Christine Walsh, R.N., FDA

Developing New Pneumococcal Vaccines for U.S. Licensure for Adults

10:20 a.m.	FDA Presentation Presentation of Questions	Douglas Pratt, M.D., M.P.H., FDA
10:50	Opsonophagocytic Activity (OPA) Assays	Sandra Steiner, Ph.D., CDC
11:20	Epidemiology of Invasive Pneumococcal Disease in Adults	Matthew R. Moore, M.D., M.P.H., C.D.C.
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
1:30	Presentation	Jan Poolman, Ph.D. GlaxoSmithKline, Inc.
2:00	Presentation	George Siber, M.D. Wyeth
2:40	Presentation	Louis Fries, M.D. ID Biomedical Corporation
3:10	FDA Presentation of Questions	Marion Gruber, Ph.D., FDA
3:15	Break	
3:30	Committee Discussion of FDA Questions/ Committee Recommendations	

5:30

Adjourn Meeting