

**Food And Drug Administration
Center For Biologics Evaluation And Research
Vaccines And Related Biological Products Advisory Committee Meeting
February 16 - 17, 2005
Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD 20814**

AGENDA

Day 1

8:30 a.m. 8:35	Call to Order Administrative Matters	Dr. Gary Overturf, Chair Christine Walsh R.N., FDA
<u>Session 1 – Open Committee Discussion – Strain Selection for Influenza Virus for the 2005 – 2006 Season</u>		
8:45	Introduction	Dr. Roland Levandowski, FDA
9:45	U.S. Surveillance	Dr. Keiji Fukuda, CDC
10:15	Break	
10:30	World Surveillance and Strain Characterization	Dr. Nancy Cox, CDC
11:00	Additional Reports	Linda Canas, DOD
12:00	Lunch	
1:00	Open Public Hearing	
1:30	Vaccine Responses	Dr. Roland Levandowski
2:00	Availability of Strain and Reagents	Dr. Zhiping Ye, FDA
2:15	Comments from Manufacturers	Albert Thomas, sanofi pasteur
3:00	Break	
3:15	Options for Strain Selection	Dr. Roland Levandowski
3:30	Committee Discussion and Recommendation	
5:00	Adjourn for the day	

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Day 2

8:30 a.m.	Call to Order	Dr. Gary Overturf, Chair
8:35	Announcements	Christine Walsh, R.N.

8:45 Open Public Hearing

Session II – Open Committee Discussion – FDA Critical Path Initiative Update

9:15	Presentation to Committee	Dr. Mary Foulkes, FDA Dr. Jerry Weir, FDA
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9:45 Q&A

9:50 Break

Session III – Open Committee Discussion – Committee Presentation; Laboratory of Biophysics and Laboratory of Pediatrics & Respiratory Viral Diseases

10:05	Overview – Laboratory of Biophysics	Dr. Richard Walker, FDA/ Dr. Richard Pastor, FD
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10:35 Q&A

10:45	Overview - Laboratory of Pediatrics & Respiratory Viral Diseases	Dr. Jerry Weir, FDA
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11:15 Q&A

11:25 Break/Adjourn Open Session

12:00 p.m. **Closed Session I**

1:00 Break/Adjourn Closed Session 1

1:05 **Closed Session II**

2:05 Adjourn

