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

DRAFT AGENDA

Day 1

8:30 a.m. 8:35	Call to Order Administrative Matters	Dr. Gary Overturf, Chair Christine Walsh R.N., FDA			
	Session 1 – Open Committee Discussion – Strain Selection for Influenza Virus for the 2005 – 2006 Season				
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. 8:35	Call to Order Announcements	Dr. Gary Overturf, Chair Christine Walsh, R.N.				
8:45	Open Public Hearing					
	Session II – Open Committee Discussion –	- FDA Critical Path				
9:15	Initiative Update Presentation to Committee	Dr. Mary Foulkes, FDA				
9:45	Q&A	Dr. Jerry Weir, FDA				
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				
10:35	Q&A	Dr. Richard Lastor, 1 D				
10:45	Overview - Laboratory of Pediatrics & Respiratory Viral Diseases	Dr. Jerry Weir, FDA				
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					