Food and Drug Administration, Center for Biologics Evaluation and Research
Vaccines and Related Biological Products Advisory Committee Meeting
February 27 – 28, 2007
Hilton Hotel, Washington DC North/Gaithersburg
620 Perry Parkway, Gaithersburg, MD 20877
DRAFT AGENDA

Day 1 – February 27, 2007

Open Session

8:00 a.m.	Call to Order and Opening Remarks	Ruth A. Karron, M.D., Chair
8:05	Administrative Matters	Christine Walsh, R.N., FDA

Topic 1: Safety and Effectiveness of an H5N1 Inactivated Influenza Vaccine Manufactured by Sanofi Pasteur

8:15 a.m.	FDA Introduction	Norman Baylor, Ph.D., FDA
8:20	Sanofi Pasteur Introduction	Kenneth P. Guito, MBA, SP
8:25	Overview of DHHS Procurement of Sanofi Pasteur's H5N1 Inactivated influenza Vaccine	Robin Robinson, Ph.D., DHHS
8:35	Introduction to NIH's Clinical Study	Linda Lambert, Ph.D., NIH
	NIH Presentation of H5N1 Study Results	John Treanor, M.D., URMC
8:50	FDA Presentation of Immunogenicity and Safety Data	Andrea James, M.D., FDA
9:05	Questions/Clarifications	
9:20	CDC – Post Marketing Safety Monitoring During an Influenza Pandemic	Robert L. Davis, M.D., M.P.H., CDC
9:35	CDC – Post Marketing Collection of Effectiveness Data	David K. Shay, M.D., M.P.H., CDC
9:50	Sanofi Pasteur Presentation of Pharmacovigilence Plan	Patrick Caubel, M.D., Ph.D., SP
10:05	FDA Comments on Sanofi Pasteur Pharmacovigilence Plan	Robert Ball, M.D., M.P.H., Sc.M., FDA
10:20	Questions/Clarifications	
10:30	**Break**	

Food and Drug Administration, Center for Biologics Evaluation and Research
Vaccines and Related Biological Products Advisory Committee Meeting

Agenda (con't)

10:45	**Open Public Hearing**	
11:15	FDA Presentation of Questions	Andrea James, M.D., FDA
	Committee Discussion/Recommendations	
1:00	**Lunch**	

Open Session
Topic 2: Clinical Development of Influenza Vaccines for Pre-Pandemic Uses

2:00 p.m.	Introduction	Jesse Goodman, M.D., M.P.H., FDA
2:10	Scientific Data Needed to Support Pre-Pandemic Uses	Joseph Toerner, M.D., M.P.H., FDA
2:30	Boosting Study Results	John Treanor, M.D., URMC
2:45	**Open Public Hearing**	
3:15	**Break**	
3:30	Committee Discussion	
5:30	Adjourn for the day	

Food and Drug Administration, Center for Biologics Evaluation and Research
Vaccines and Related Biological Products Advisory Committee Meeting

Agenda (con't)

Day 2 – February 28, 2007
Open Session

8:00 a.m.	Call to Order and Opening Remarks	Ruth A. Karron, M.D., Chair
8:05	Administrative Matters	Christine Walsh, R.N., FDA

Topic 3: Strain Selection for the Influenza Virus Vaccine for the 2007 – 2008 Season

8:15 a.m.	Introduction	Rakesh Pandy, Ph.D., FDA
8:30	U.S. Surveillance	Joseph Bresee, M.D., CDC
8:50	World Surveillance/Strain Characterization	Nancy Cox, Ph.D., CDC
9:10	Vaccine Effectiveness Report – DOD	Angela Owens, M.P.H., DOD/ Luke Daum, Ph.D., DOD
9:25	Vaccine Responses	Zhiping Ye, M.D., Ph.D., FDA
9:45	Availability of Strains and Reagents	Zhiping Ye, M.D., Ph.D., FDA
10:00	**Break**	
10:20	Comments from Manufacturers	Albert Thomas, Sanofi Pasteur
10:40	**Open Public Hearing**	
11:10	Strain Selection Options/ Committee Discussion and Recommendations	Rakesh Pandy, Ph.D., FDA
11:55	Influenza A (H5N1) Viruses Update	Nancy Cox, Ph.D. CDC
12:25	**Lunch**	

Food and Drug Administration, Center for Biologics Evaluation and Research
Vaccines and Related Biological Products Advisory Committee Meeting

Agenda (con't)

Open Session
Topic 4: Influenza Type B Strain – Discussion on Circulating Lineages

1:25	Introduction	Jerry Weir, Ph.D., FDA
1:35	Background and Presentation of Possible Vaccine Options	Robert Couch, M.D., BCM
2:15	Regulatory Implications for Alternative Vaccine Options	Sara Gagneten, Ph.D., FDA
2:30	Comments from Manufacturers	Tony Colgate, Novartis
2:50	**Open Public Hearing**	
3:20	Committee Discussion	
4:15	Adjourn Meeting	