Food and Drug Administration Center for Biologics Evaluation and Research Vaccines and Related Biological Products Advisory Committee Meeting January 25, 2007

Doubletree Hotel, 8120 Wisconsin Ave., Bethesda, MD AGENDA

MODIUM				
8:00 a.m.	Call to Order Presentation of Appreciation Plaques to To Retiring Members	Ruth A. Karron, M.D., Chair Norman Baylor, Ph.D., FDA		
8:05	Administrative Matters	Christine Walsh R.N., FDA		
<u>Session 1 – Open Committee Discussion – Safety and Immunogenicity of Diphtheria</u> <u>& Tetanus Toxoids & Acellular Pertussis Adsorbed, Inactivated Poliovirus and</u> <u>Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine Combined (DTaP-IPV/Hib), Pentacel Manufactured by Sanofi Pasteur Limited</u>				
8:10 a.m.	Introduction/Background/DTaP-IPV/Hib Presentation of Questions	Theresa Finn, Ph.D., FDA		
8:15	DTaP-IPV/Hib / (Pentacel TM)	Luc Kuykens, M.D., MPH, SP Michael Decker, M.D., MPH, SP Scott Halperin, M.D. David Greenberg, M.D., SP		
9:30	Clarifications/Questions			
9:45	Break			
10:00	FDA Presentations	Karen Farizo, M.D., FDA Theresa Finn, Ph.D., FDA		
11:05	Clarifications/Questions	Theresa Film, Fil.D., FDA		
11:15	Open Public Hearing			
11:45	Committee Discussion and Recommendations			
1:00 p.m.	Lunch			
Session II – Open Committee Discussion - Overview Office Vaccines Research And Review, CBER				
2:00	Overview of CBER Research Programs	Kathryn Carbone, M.D., FDA		
2:15	Clarifications/Questions			
2:20	Overview Office of Vaccines Research And Review	Norman Baylor, Ph.D, FDA		

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(Agenda con't) 2:35	Clarifications/Questions	
2:40	Office of Vaccines Research and Review Research Program	Michael Brennan, Ph.D., FDA
2:55	Clarifications/Questions	
3:00	Break	
3:15	Overview Division of Viral Products	Jerry Weir, Ph.D., FDA
3:30	Clarifications/Questions	
3:35	Overview Division of Bacterial Parasitic And Allergenic Products	Richard Walker, Ph.D., FDA
3:50	Clarifications/Questions	
3:55	Open Public Hearing	
4:25	Session III - Closed Session	
5:00	Adjourn Meeting	