

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
DRAFT AGENDA

8:00 a.m. Call to Order Ruth A. Karron, M.D., Chair
Presentation of Appreciation Plaques to
To retiring members Norman Baylor, Ph.D., FDA

8:05 Administrative Matters Christine Walsh R.N., FDA

Session 1 – Open Committee Discussion – Safety and Immunogenicity of Diphtheria & Tetanus Toxoids & Acellular Pertussis Adsorbed , Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine Combined (DTaP-IPV/Hib), Pentacel™, manufactured by Sanofi Pasteur Limited

8:10 a.m. Introduction/Background/DTaP-IPV/Hib Theresa Finn, Ph.D., FDA
Presentation of Questions

8:15 DTaP-IPV/Hib / (Pentacel™) Luc Kuykens, M.D., MPH, SP
Michael Decker, M.D., MPH, SP
Scott Halperin, M.D., SP
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

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, MD, FDA

2:15 Clarifications/Questions

2:20 Overview Office of Vaccines Research
And Review Norman Baylor, Ph.D, FDA

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	<u>Session III - Closed Session</u>	
5:00	Adjourn Meeting	