

**Food And Drug Administration  
Center For Biologics Evaluation And Research  
Vaccines And Related Biological Products Advisory Committee Meeting  
March 15, 2005  
Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD 20814**

**AGENDA**

<b>8:30 a.m.</b>	<b>Call to Order</b>	Gary Overturf, M.D., Chair
8:35	Administrative Matters	Christine Walsh, R.N., FDA

**Session 1 – Open Committee Discussion – Safety and Immunogenicity for Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap) manufactured by GlaxoSmithKline Biologicals**

8:45	Tdap Introduction/Background/ Presentation of Questions	Theresa Finn, Ph.D., FDA
9:00	Clarifications/Questions	
9:05	GSK Tdap/Boostrix™	GlaxoSmithKline
10:05	Clarifications/Questions	
10:15	Break	
10:30	FDA Presentation	Ann Schwartz, M.D., FDA
11:00	Clarifications/Questions	
11:10	Open Public Hearing	
11:40	Committee Discussion and Recommendations	
12:40 p.m.	Lunch	

**Session II – Open Committee Discussion – Safety and Immunogenicity data for Tdap vaccine manufactured by Aventis Pasteur, Ltd.**

1:45	ADACEL™ Introduction	Martha Monser, FDA
1:55	AP Tdap/ADACEL™	Aventis Pasteur, Ltd.
2:55	Clarifications/Questions	

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|------|---|---------------------------|
| 3:05 | Break                                   |                           |
| 3:20 | FDA Presentation                        | ChrisAnna Mink, M.D., FDA |
| 4:00 | Clarifications/Questions                |                           |
| 4:10 | Open Public Hearing                     |                           |
| 4:40 | Committee Discussion and Recommendation |                           |
| 5:40 | Adjourn Meeting                         |                           |