

**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**

DRAFT AGENDA

8:30 a.m. Call to Order 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/ Theresa Finn, Ph.D., FDA
Presentation of Questions

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, B.A., FDA

1:55 AP Tdap/Adacel Aventis Pasteur, Ltd.

2:55 Clarifications/Questions

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