

**Food And Drug Administration
Center For Biologics Evaluation And Research
Vaccines And Related Biological Products Advisory Committee Meeting
September 22 and 23, 2004
Holiday Inn, 8120 Wisconsin Ave., Bethesda, MD 20814**

Draft AGENDA

Day 1

8:15 AM **Closed Session**
9:45 AM Break/Adjourn Closed Session

Open Session

Presentation of Tetravalent Meningococcal Conjugate Vaccine
Sponsor: Aventis Pasteur Inc.
Product: Menactra

10:00 AM	Call to Order	Dr. Gary Overturf, Chair
10:05 AM	Announcements	Christine Walsh R.N., FDA
10:15 AM	Introduction to the License Application	Dr. Carl Frasch, FDA
	What is the product	
	Requested indication	
	Regulatory history	
10:30 AM	Clinical Data in Support of Menactra	Aventis Pasteur Representative
11:15 AM	Questions of Clarification for Applicant	
11:30 AM	Break	
11:45 AM	Clinical Review of Safety and Efficacy	Dr. Lucia Lee, FDA
12:30 PM	Questions of Clarification for FDA	
12:45 PM	Lunch	
2:00 PM	Open Public Hearing	
2:30 PM	Presentation of Questions for Committee	Dr. Carl Frasch, FDA
2:45 PM	Committee Discussion/Voting on Questions	
3:30 PM	Break	
3:45 PM	Continuation of Committee Discussion/Vote	
4:30 PM	Adjourn	

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Day 2

Open Session

Thailand HIV Vaccine Phase 3 Trial

Trial Sponsor: Office of the Surgeon General of the Army

Products: HIV-1 Recombinant Canarypox-Vectored Vaccine (ALVAC vCP1521)
[Aventis Pasteur], and Recombinant gp120 B/E (CHO cells) with Alum [VaxGen]

9:00 AM	Call to Order	Dr. Gary Overturf, Chair
9:05 AM	Announcements	Christine Walsh R.N., FDA
9:15 AM	Opening Remarks	Dr. Joseph Toerner, FDA
9:25 AM	Presentation by the Sponsor	LTC Brown, DoD
	Overview of Study RV144, Rationale for Proceeding with Phase III Study	
10:00 AM	Questions of Clarification from Committee	
10:15 AM	Open Public Hearing	
10:45 AM	Break/Adjourn Open Session	
11:00 AM	Closed Session	
12:15 PM	Adjourn	