

**FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

**November 28-29, 2001
Holiday Inn, Bethesda**

AGENDA

Wednesday, November 28, 2001

8:30 AM Session 1, 2, 3 - CLOSED SESSIONS

**12:30 PM Session 4 - OPEN Session
Efficacy Trial Endpoints for Vaccines for the Prevention of Human Papilloma Virus**

12:30	Call to Order, Introductions, Administrative Matters	Dr. Robert S. Daum, Committee Chair
12:45	Introduction to Session and Presentation of Questions	Dr. Karen Goldenthal, FDA
1:00	Natural History and Virology	Dr. Beth Unger
1:45	Clinical Management/Natural History of Cervical Dysplasia and Related Findings	Dr. Edward Wilkinson
2:30	Break	
2:45	Endpoints Re-introduction of Questions and Q & A	Dr. Karen L. Goldenthal, FDA
3:30	Open Public Hearing	
4:45	Adjourn for the Day	

*This is the final Agenda
3805 A -*

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Thursday, November 29, 2001

8:30 AM Session 4 – Open Session -- Continued

8:30 Call to Order Dr. Robert S. Daum

8:40 Committee Discussion and Recommendations

12:00 noon Lunch

1 PM Session 5 – Open Session

Briefing on Activities in the Laboratory of Bacterial Toxins

1:00 Organizational Structure and Overview of Dr. Richard Walker, FDA
Research and Regulatory Responsibilities in the
Division of Bacterial, Parasitic and Allergenic Products

1:10 Organizational Structure and Overview of Regulatory Dr. Willie Vann, FDA
Responsibilities in the Laboratory of Bacterial Toxins

1:15 Description of Research Activities Dr. Willie Vann, FDA

1:25 Description of Research Activities Dr. Michael Schmitt, FDA

1:35 End of Open Sessions

1:45 Session 6 – CLOSED SESSION

2:30 End of Closed Session; Adjournment of Meeting