

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

**VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE**

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

**DRAFT 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	<b>Call to Order,</b> Introductions, Administrative Matters	Dr. Robert S. Daum, Committee Chair
12:45	Introduction to Session and Presentation of Questions	Dr. Karen Goldenthal, FDA or Dr. Douglas Pratt, 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****

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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 Research and Regulatory Responsibilities in the Division of Bacterial, Parasitic and Allergenic Products	Dr. Richard Walker, FDA
1:10	Organizational Structure and Overview of Regulatory Responsibilities in the Laboratory of Bacterial Toxins	Dr. Willie Vann, FDA
1:15	Description of Research Activities	Dr. Willie Vann, FDA
1:25	Description of Research Activities	Dr. Michael Schmitt

**1:35              End of Open Sessions**

**1:45              Session 6 – CLOSED SESSION**

**2:30              End of Closed Session; Adjournment of Meeting**