

**FOOD AND DRUG ADMINISTRATION  
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH  
DRAFT AGENDA** (revised 2/9/04)

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE  
**February 18 & 19, 2004**

**Sheraton Four-Points Hotel, 8400 Wisconsin Ave., Bethesda, Maryland**

**Wednesday, February 18, 2004**

**8:30 a.m. Call to Order**

Dr. Gary Overturf, Chair

8:35 Administrative Matters

Dr. Bill Freas

8:40 Presentation of Plaques to Retiring Members

Dr. Karen Midthun

**8:50 OPEN Session**

**Strain Selection for Influenza Virus Vaccine for the 2004-2005 Season**

8:50 Introduction

Dr. Roland Levandowski, FDA

9:50 Vaccine Effectiveness

Dr. Carolyn Bridges, CDC  
Col. James Neville, DOD  
Dr. Antoine Flahault, INSERM, Paris

11:20 Break

11:30 U.S. Surveillance

Ann Moen, CDC

**12:00 p.m. Lunch**

**1:00 Open Public Hearing**

1:30 World Surveillance and Strain Characterization  
Strain Characterization

Dr. Nancy Cox, CDC

2:00 Additional Reports

Linda Canas, DOD  
Dr. Maria Zambon, HPA, UK

**3:00 Break**

3:30 Vaccine Responses

Dr. Roland Levandowski, FDA

4:00 Availability of Strains and Reagents

Dr. Zhiping Ye, FDA

4:15 Comments from Manufacturers

**5:00 Update on H5**

Dr. Nancy Cox, CDC  
Dr. Phil Minor, NIBSC  
NIH Speaker (TBA)

**7:00 p.m. Adjourn**

**AGENDA (Continued)**  
**VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE**

**Second Day**

**Thursday, February 19, 2004**

**8:30 a.m. Call to Order**

8:35 Announcements

**OPEN Session**

**Strain Selection for Influenza Virus Vaccine for the 2004-2005 Season**

**8:45 Open Public Hearing**

9:15 Options for Strain Selection Dr. Roland Levandowski, FDA

**9:35 Committee Discussion and Recommendations**

**10:45 Break**

**11:00 Mammalian Tissue Culture Used in Vaccine Preparation**

FDA Perspective

Dr. Zhiping Ye, FDA

NIBSC Perspective

Dr. Phil Minor, NIBSC

**1:00 p.m. Adjourn**