

**FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE**

July 26-27, 2001

Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, Maryland

AGENDA

Thursday, July 26

9:00 am **Session 1 - CLOSED SESSION**

10:35 **Session 2 - OPEN Session**
Aviron's Influenza Virus Vaccine, Trivalent, Types A & B, Live, Cold Adapted
FluMist™

10:35 **Call to Order,**
 Introductions, Administrative Matters

Dr. Robert S. Daum,
Committee Chair

10:45 **Introduction to Session and Summary**
 of Prior VRBPAC Deliberations

Dr. Peter Patriarca, FDA

11:15 **Overview of Development of Cold Adapted,**
 Live Attenuated Influenza Vaccines; Basis for
 Attenuation; and Potential for Reassortment
 with Wild-type Viruses in Nature

Dr. Brian Murphy, NIH

12:00 **Q&A on Dr. Murphy's Presentation**

12:15pm **Lunch**

1:15 **Sponsor's Presentation with Q&A**

2:45 **Break**

3:00 **FDA Presentation with Q&A**

Dr. Chrisanna Mink, FDA

4:15 **Adjourn for the Day**

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AGENDA, continued

Friday, July 27

Session 2 – continued

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8:30 am	Call to Order, Administrative Matters	Dr. Robert S. Daum, Committee Chair
8:40	Summary of Issues and Presentation of Questions to and Discussion Points for the Committee	Dr. Roland Levandowski, FDA
9:00	Open Public Hearing	
10:15	Committee Discussion and Voting	
12:00 noon	Lunch	
1:00	Committee Discussion and Voting, continued	
3:30 pm	Adjourn	