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

Preliminary AGENDA

Thursday, July 26

9:00 am Session 1 - CLOSED SESSION

10:15 <u>Session 2 - OPEN Session</u>

	10:30	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	TBD
2:45		Break	
	3:00	FDA Presentation with Q&A	Dr. Chris Mink, FDA
4:15		Adjourn for the Day	

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Preliminary AGENDA, continued

Friday, July 27

Session 2 -continued

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		