FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

January 30-31, 2001
Holiday Inn, 8120 Wisconsin Ave., Bethesda, Maryland

AGENDA

Tuesday, January 30

8:00		**Call to Order, Introductions, Administrative Matters**	Dr. Robert Daum
8:15		**Presentation of Plaques to Retiring VRBPAC Members**	Dr. Kathryn Zoon, FDA
8:30		**Session 1 – OPEN Session** **Strain Selection for Influenza Virus Vaccine for the 2001-2002 Season**	
	8:30	Introduction and Updates	Dr. Roland Levandowski, FDA Dr. Lance Rodewald, CDC Dr. Wendy Keitel
	9:30	U.S. Surveillance	Dr. Keiji Fukuda, CDC
	9:50	World Surveillance and Strain Characterization	Dr. Nancy Cox, CDC
	10:10	Molecular Characterization of Strains	Dr. Alexander Klimov, CDC
10:30		**Break**	
	11:00	Additional reports	Ms. Linda Canas, DOD Mr. Alan Hampson Dr. Joanna Ellis
	12:00	Vaccine Responses	Dr. Roland Levandowski, FDA
	12:20	Availability of Strains and Reagents	Mr. Zhiping Ye, FDA
	12:30	Comments from Manufacturers	Dr. Slusaw, PhRMA
12:45		**Lunch**	
	1:45	Options for Strain Selection	Dr. Nancy Cox, CDC
1:45		**Open Public Hearing**	
	2:30	Committee Discussion and Recommendations	
5:00		**Adjournment**	

FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

January 30-31, 2001
Holiday Inn, 8120 Wisconsin Ave., Bethesda, Maryland

AGENDA

Wednesday, January 31

9 AM		**Call to order; introductions; announcements**	
9:15		**Session 2 –– OPEN Session** **SmithKline Beecham's LYMErix™ Lyme Disease Vaccine Safety Update**	
	9:15	Introduction	Dr. Karen Midthun, FDA
	9:25	Sponsor's Presentation on Pre-licensure Safety Data	SmithKline Beecham
	9:55	Q&A – Clarifications of Sponsor's Presentation	
	10:05	FDA Presentation on Pre-licensure Safety Data	Dr. Patricia Rohan, FDA
	10:20	Q&A – Clarifications of FDA's Presentation	
10:30		**Break**	
	10:50	Sponsor's Presentation on Phase 4 Study	SmithKline Beecham
	11:10	Sponsor's Presentation on Additional Post-marketing Data	Smith Kline Beecham
	11:20	Q&A – Clarifications of Sponsor's Presentations	
	11:30	FDA Presentation on Post-licensure Safety Data	Dr. Robert Ball, FDA
	11:50	Q&A – Clarifications of FDA's Presentation	
12 noon		**Lunch**	
1:00		**Open Public Hearing**	
3:15		**Committee Discussion**	
5:30		**Adjournment**	