

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

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

**February 20, 2003
Holiday Inn, 8120 Wisconsin Ave., Bethesda, Maryland**

Thursday, February 20, 2003

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|-----------------|---|-----------------------------|
| 8:30 AM | Call to Order | Dr. David Stephens, Chair |
| 8:35 | Administrative Matters | Dr. Jody Sachs, FDA |
| 8:40 | <u>Session 1 – OPEN Session</u>
<u>Strain Selection for Influenza Virus Vaccine for the 2003-2004 Season</u> | |
| 8:40 | Introduction | Dr. Roland Levandowski, FDA |
| 8:55 | U.S. Surveillance | Dr. Keiji Fukuda, CDC |
| 9:15 | World Surveillance and Strain Characterization | Dr. Nancy Cox, CDC |
| 9:35 | Molecular Characterization of Strains | Dr. Alexander Klimov, CDC |
| 10:00 | Break | |
| 10:20 | Additional Surveillance Reports | Linda Canas, DOD |
| 10:35 | Vaccine Responses | Dr. Roland Levandowski, FDA |
| 10:55 | Availability of Strains and Reagents | Dr. Zhiping Ye, FDA |
| 11:10 | Comments from Manufacturers | Dr. Sam Lee, Aventis |
| 11:30 | Options for Strain Selection | Dr. Roland Levandowski, FDA |
| 12:00 PM | Lunch | |
| 1:00 | Open Public Hearing | |
| 1:30 | Committee Discussion and Recommendations | |
| 2:30 | <u>Session 2 – OPEN Session</u>
<u>Laboratory of Bacterial Polysaccharides</u> | |
| 2:30 | Overview of Division of Bacterial, Parasitic, & Allergenic Products | Dr. Richard Walker, FDA |
| 2:40 | Overview of Laboratory of Bacterial Polysaccharides | Dr. Carl Frasch, FDA |
| 2:50 | Open Public Hearing | |
| 3:20 | <u>Session 2 – CLOSED Session</u> | |
| 4:30 | Adjournment | |