

FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

1509 00 MAY 8 10:05

May 11-12, 2000
Holiday Inn, 8777 Georgia Avenue
Silver Spring, Maryland

AGENDA

Thursday, May 11

DRAFT

REVISED
5-5-00

- 8 AM Session 1 – CLOSED Session
- 9:15 Session 2 – Open Session
Update on Activities in the Office of Vaccines Research and Review
- 9:15 Call to Order, Introductions, Administrative Matters
9:30 Update on Activities Dr. William Egan, FDA
- 10:00 **Open Public Hearing**
- 10:20 Session 3 – Open Session
Rotavirus Vaccine and Associated Intussusception
- 10:20 Overview Dr. Kathryn Carbone, FDA
10:25 Clinical Diagnosis and Treatment of Intussusception Dr. W. Shiels
10:55 Update on CDC Rotavirus vaccine-Intussusception Investigation Dr. Melinda Wharton, CDC
11:15 Introduction of Clinical Concerns/Unknowns for RV Vaccine and Intussusception Dr. Kathryn Carbone, FDA
11:50 Updates on RV Vaccine-Intussusception pathogenesis/research issues Dr. C. D. Atreya, FDA
- 12:20 **Open Public Hearing**
- 12:30 Committee Discussion
- 1:00 Lunch
- 1:45 Session 4 – CLOSED Session

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Friday, May 12

- 8 AM Session 5 – CLOSED Session
- 9:15 Session 6 – Open Session
Use of Neoplastic Cells as Substrates for Vaccine Manufacture
- 9:15 Call to Order, Introductions, Administrative Matters
- 9:30 **Open Public Hearing**
- 10:00 Introduction and Interim Policy Dr. Andrew Lewis, FDA
- 10:30 Coffee Break
- 10:45 CBER Research Related to Neoplastic Cell Lines
Dr. Philip Krause, FDA
- 11:15 Committee Discussion
- 12:00 Lunch
- 1:00 History and Characterization of Vero Cells
Dr. Rebecca Sheets, FDA
- 1:30 Committee Discussion
- 2:45 Adjourn