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

## VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

**December 17, 2002** 

## Bethesda Marriott Hotel 5151 Pooks Hill Road Bethesda, Maryland 20814

## Tuesday, December 17, 2002

| 8:30 am  |       | Call to Order,<br>Administrative Matters  | Dr. Robert S. Daum, Chair<br>Dr. Jody Sachs, FDA |
|----------|-------|---|--|
| 8:45     |       | Plaque Presentation of Retiring VRBPAC Members  | Dr. Kathryn Zoon, FDA                            |
| 9:00 am  |       | Session 1- Open Session<br>FluMist™ Influenza Virus Vaccine, Trivalent, Types A & B, Live, Cold Adapted |  |
|          | 9:00  | Overview of FluMist™ Issues   | Dr. ChrisAnna Mink, FDA                          |
|          | 9:15  | Sponsor's Presentation: Overview / Product Profile  | Dr. James Young<br>MedImmune Vaccines, Inc.      |
|          | 9:35  | Clinical Update / Summary   | Dr. Edward Connor<br>MedImmune Vaccines, Inc.    |
|          | 10:15 | Q & A   | wedinimune vaccines, inc.                        |
| 10:25    |       | Break   |  |
|          | 10:35 | FDA Presentation:<br>Review of Safety and Efficacy/Effectiveness of Flumist                             | Dr. ChrisAnna Mink, FDA                          |
|          | 11:35 | Q & A   |  |
| 12:00 pm |       | Lunch   |  |
|          | 1:00  | Open Public Hearing for Session 1   |  |
|          | 2:00  | Questions to the Committee  |  |
|          | 2:30  | Committee Discussion and Recommendations  |  |
| 5:00     |       | Adjourn for the Day   |  |