QUICK SUMMARY

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

February 18 & 19, 2004

The Vaccine and Related Biological Products Advisory Committee meeting was called to order by the Chair, Dr. Gary Overturf, on February 18, 2004 at 8:30 a.m. EST. Dr. Roland Levandowski, FDA discussed last year's selection of the components of the influenza vaccine and the constraints, importance and deadlines for selection of this year's vaccine components. Subsequent presentations included vaccine effectiveness, U.S. and world surveillance of influenza activity, strain characterization, vaccine responses, availability of strains, comments from manufacturers, and an update on influenza A(H5N1) activity in Asia. An Open Public Hearing was announced. No public comment was offered. The Chair adjourned the first day of the meeting at 6:10 p.m. EST.

The Chair called the second day of the meeting to order at 8:30 a.m. EST. An Open Public Hearing was announced. No public comment was offered. The panel heard an overview of their options for strain selection of the components of next season's influenza vaccine. After discussion, the committee made the following recommendations for the influenza virus strains to be included in vaccine for use during the 2004-2005 season in the United States. Based on information about the appearance and epidemiology of new influenza virus strains, responses to current vaccines, and the availability of new candidate strains for manufacturing, the committee recommended:

- The Committee unanimously recommended (17 votes in favor, 0 against, and 0 abstained) retaining the 2003-2004 influenza A H1N1 component, New Caledonia 20/99, for the 2004-2005 season.
- The Committee unanimously recommended (17 votes in favor, 0 against, and 0 abstained) changing the influenza A H3N2 component of the influenza vaccine to the A/Fujian-like strain for the 2004-2005 season.
- The Committee recommended (16 votes in favor of a change or provisional change, 1 vote to defer and 0 abstained) a change of the 2003-2004 influenza B component to a Yamagata lineage, B/Shanghai – like strain for the 2004-2005 season with a provision to meet via teleconference on March 17, 2004, review any further data gathered in the interim period, and make their decision final at that time if no new information would contradict the recommendation.

The panel heard presentations from both the FDA and National Institute for Biological Standards and Control (NIBSC) UK and had discussions on the use of mammalian cell lines for the use in preparation of reference influenza viruses.

This completed the committee discussion and recommendations and the meeting was adjourned at 12:20 p.m. EST