Food and Drug Administration
Center for Biologics Evaluation and Review

SUMMARY MINUTES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

February 28-29, 2012
FDA White Oak Campus, Bldg. 31, Great Room
Silver Spring, MD

Committee Members
Dr. Robert Daum, Chair
Dr. Ambrose Cheung
Dr. Anna Durbin
Dr. Gregory Gray
Dr. Gary Schoolnik
Dr. Carol Tacket +
Dr. Gillian Air
Dr. Edgar Marcuse
Dr. Kent Kester
Dr. Michael Hudgens
Dr. Pedro Piedra

FDA Participants
Dr. Marion Gruber
Dr. Jerry Weir
Dr. Carolyn Wilson
Dr. Jay Slater
Dr. Sheldon Morris
Dr. Zhiping Ye
Dr. Rajesh Gupta
Dr. Theresa Finn

Temporary Voting Members
Dr. Bruce Gellin
Dr. Pamela McInnes
Dr. Melinda Wharton
Dr. Vicky Debold*
Dr. Kathryn Edwards
Dr. Theodore Eickhoff
Dr. Roland Levandowski
Dr. Scott Stanek

Speakers
Dr. Ronald Burke (DoD)
Dr. Nancy Cox (CDC)
Dr. Lisa Grohskopf (CDC)
Dr. Robin Robinson (HHS)
Dr. Elisabeth Neumeier (GSK)
Dr. Penny Heaton (Novartis)
Ms. Katalin Abraham (GSK)

Temporary Non-Voting Member
Dr. Nancy Cox

Industry Representative
Dr. Theodore Tsai**

Designated Federal Official
Donald Jehn, M.S.

Committee Management Specialist
Denise Royster

* Acting Consumer Representative
** Acting Industry Representative
+ Did not attend

These summary minutes for the February 28-29, 2012 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on March 13, 2012.

I certify that I participated in the February 28-29, 2012 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

/// original signed ///
Donald Jehn, M.S.
Designated Federal Official

/// original signed ///
Robert Daum, M.D.
Chair

The Chair, Dr. Robert Daum, called the Meeting of the Vaccines and Related Biological Products Advisory Committee to order at 8:00 a.m. EST on February 28, 2012. Following administrative remarks and reading of the conflict of interest statement, Topic I presentations began. Topic I of the meeting addressed the October 28, 2011 site visit of the intramural research programs of the Laboratory of Mycobacterial Diseases and Cellular Immunology (LMDCI), Division of Bacterial, Parasitic, & Allergenic Products (DBPAP), Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER).

Following Topic I, additional conflict of interest statements were read.

During Topic II, the Committee received presentations by FDA, CDC, DoD and manufacturers on seasonal influenza strains for subsequent selection. There was also an update on surveillance for influenza viruses with pandemic potential and candidate vaccine viruses.

An Open Public Hearing was announced. There were four public comments from Novartis, GSK, Sanofi Pasteur, and MedImmune. The meeting adjourned for the day at approximately 4:00 p.m.

On February 29, 2012, Dr. Daum called the meeting to order at 8:00 a.m. Following administrative remarks and reading of the conflict of interest statement, Topic III presentations began. Topic III was a discussion on licensure pathways for pandemic influenza vaccines.

An Open Public Hearing was announced. There were two public comments from Barbara Loe Fisher and Chris Downey.

Proceedings were adjourned at approximately 12:50 p.m.

Following is a summary of the discussion. Additional information and specific details may be obtained for the transcript and the webcast of the meeting. The transcript may be viewed on the World Wide Web at: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/ucm288695.htm.

Open Session

After opening administrative remarks on February 28, 2012, the Committee listened to updates of CBER, DBPAP and LMDCI during Topic I.

During Topic II, the Committee was briefed on the strain selection for the influenza virus vaccine for the 2012-2013 influenza season. The topic was introduced by FDA, followed by presentations on U.S. and world surveillance by CDC. Vaccine effectiveness report was provided by DoD and FDA provided presentations on vaccine responses and availability of vaccine viruses and reagents.

The Committee was asked to vote on options for strain composition for 2012-2012 trivalent influenza vaccines:

- Influenza A (H1N1)
  - Retain current vaccine strain A/California/7/2009 (H1N1)-like virus
  - Replace current vaccine strain with an alternative vaccine virus
- Influenza A (H3N2)
  - Replace current vaccine strain with an A/Victoria/361/2011 (H3N2) - like virus
  - Replace current vaccine strain with another candidate vaccine virus or retain current vaccine strain A/Perth/16/2009 (H3N2)-like virus
- Influenza B
  - Replace current vaccine strain with B/Wisconsin/1/2010 - like virus (B/Yamagata lineage)
  - Replace current vaccine strain with another candidate vaccine virus or retain current B/Brisbane/60/2008-like virus (B/Victoria lineage)

The Committee voted unanimously (18 votes) to retain current strain A/California/7/2009 (H1N1)-like virus and the Committee voted unanimously (18 votes) to replace current vaccine strain with an A/Victoria/361/2011 (H3N2) – like virus.
The Committee voted 17 Yes, 1 No to replace the current strain with B/Wisconsin/1/2010 –like virus (B/Yamagata lineage).

The Committee was asked to vote on options for strain selection for the 2nd influenza B strain if a quadrivalent influenza vaccine were available.

- Influenza B
  - Include current vaccine strain B/Brisbane/60/2008-like virus (B/Victoria lineage)
  - Include another candidate vaccine virus of the B/Victoria lineage

The Committee voted 17 Yes, 1 No to include vaccine strain B/Brisbane/60/2008 – like virus (B/Victoria lineage).

After opening administrative remarks on February 29, 2012, the Committee was briefed on licensure pathways for pandemic influenza vaccines. The topic was introduced by FDA and followed by a presentation from BARDA and another FDA presentation. GlaxoSmithKline and Novartis then provided the Committee with their presentations on this topic.

The Committee was then asked to discuss:

1. To infer effectiveness of an adjuvanted pandemic influenza A subtype vaccine, please discuss the use of:
a) clinical endpoint efficacy data accrued with a U.S.-licensed unadjuvanted seasonal vaccine made by the same manufacturer and process, and
b) observational effectiveness data accrued during the H1N1 2009 pandemic for a non-U.S.-licensed adjuvanted monovalent vaccine made by the same manufacturer and process.

2. Please discuss approaches to infer effectiveness for pandemic influenza vaccines that are manufactured using a process not licensed in the U.S.:
a) pandemic influenza vaccines dependent on an HA antibody response
b) pandemic influenza vaccines with protective mechanisms that are not dependent on an HA antibody response.

With regard to item 1, the committee consensus stated that it important to have safety and immunogenicity data accrued with the adjuvanted pandemic vaccine and it was reasonable to infer effectiveness of the pandemic influenza vaccine from the efficacy of the seasonal influenza vaccine made by the same manufacturer and process. Some members of the committee expressed reservations regarding the use of observational effectiveness data and a preference for use of efficacy data accrued with the seasonal vaccine. However, others noted that observational data "span a spectrum" and the acceptability of these data to infer effectiveness would be dependent on review of the data. The committee suggested that if reference sera were available that may help reduce variability between serology data generated in different studies.

With regard to item 2a the committee the committee noted that if a manufacturer made a seasonal vaccine that effectiveness could be inferred as for item 1a. The committee stated that it was premature to discuss item 2b.

Closed Session

On February 28, 2012 before the conclusion of Topic I, there was a closed session of this meeting in order to discuss the report of the intramural research programs and make recommendations regarding personnel staffing decisions.