Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
142nd VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

March 4, 2016

Committee Members
Kathryn Edwards, M.D., Chair +
Ruth Lynfield, M.D., Acting Chair
Janet Englund, M.D. +
Karen Kotloff, M.D.
Ofer Levy, M.D., Ph.D. +
Sarah Long, M.D.
Arnold Monto, M.D.
Patrick Moore, M.D., M.P.H.
Mark Sawyer, M.D.
David Greenberg, M.D.* +

Temporary Voting Members
Gillian Air, M.D.
Jack Bennink, Ph.D.
Bruce Gellin, M.D., M.P.H.
Judith Goldberg, Sc.D. †
Pamela McInnes, D.D.S., M.Sc. (Dent.)
Scott Stanek, D.O., M.P.H.
Melinda Wharton, M.D., M.P.H.
Ellen Andrews, Ph.D. ***

Temporary Non-Voting Members
Jacqueline Katz, Ph.D. #
Filip Dubovsky, M.D., M.P.H., FAAP**

Speakers
Anissa Cheung, M.Sc.
CAPTAIN PHS Michael Cooper, Ph.D.
Matthew Downham, Ph.D.
Lisa Grohskopf, M.D., M.P.H. †
Manju Joshi, Ph.D.
Zhiping Ye, M.D., Ph.D
Jacqueline Katz, Ph.D.

FDA Participants
Marion Gruber, Ph.D.
Jerry Weir, Ph.D.

Designated Federal Officer
Sujata Vijh, Ph.D.

Committee Management Specialist
Denise Royster

† Via Teleconference
+ Not in attendance
# Temporary Non-Voting Member and Speaker
* Industry Representative
** Temporary Industry Representative
*** Acting Consumer Representative

These summary minutes for the March 4, 2016 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on March 23, 2016.

I certify that I participated on the March 4, 2016 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

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Sujata Vijh, Ph.D.	Ruth Lynfield, M.D.
Designated Federal Officer	Acting Chair

On March 4, 2016 at 8:30 a.m. Eastern Standard Time (EST), the Acting Chair, Dr. Ruth Lynfield, called to order the 142nd Meeting of the Vaccines and Related Biological Products Advisory Committee to discuss the topic "Strain Selection for the Influenza Virus Vaccines for the 2016-2017 Influenza Season". The meeting was held in an open session. The Chair invited the members, temporary members, and participants seated at the table to introduce themselves. The Designated Federal Officer (DFO) made administrative remarks and read the Conflict of Interest statement into the public record. There were no waivers for conflicts of interest for this meeting. After the Conflict of Interest statement was read for the public record by the DFO, the FDA and non-FDA speaker presentations began.

An introduction and overview of the topic along with the four voting questions was presented by Ms. Anissa Cheung from the Division of Viral Products (DVP) of the Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA). Dr. Lisa Grohskopf from the Centers for Disease Control (CDC) participated via teleconference and presented the U.S. Surveillance data using her presentation that was displayed via live webcast for public viewing. This was followed by a presentation on World Surveillance and Virus Characterization by Dr. Jacqueline Katz, also of the CDC. After a brief break, the Department of Defense (DoD) Influenza Surveillance and Vaccine Effectiveness report was provided by Captain Dr. Michael Cooper of the Armed Forces Surveillance Center. This was followed by a presentation on Influenza Vaccine Responses by Dr. Zhiping Ye of DVP/OVRR/CBER/FDA. Dr. Manju Joshi of the Division of Biological Standards & Quality Control**,** CBER/FDA, presented on Candidate Vaccine Strains and Potency Reagents for 2016-2017 Influenza Season. This was followed by a presentation on Influenza Vaccine Manufacturing process by Dr. Matthew Downham of AstraZeneca/MedImmune, who spoke on behalf of industry.

After lunch break, the committee reconvened for the Open Public Hearing (OPH) session. There was one oral comment from the public from Dr. Margaret Dayhoff-Brannigan, Patient Advocacy Project Manager at the National Center for Health Research.

At the completion of the OPH, the Committee proceeded with the discussion and subsequent voting on influenza strain selection for trivalent and quadrivalent influenza vaccines for the 2016-2017 influenza season.

The Committee (6 regular members plus 8 temporary voting members, total 14) voted electronically on the strain composition for 2016-2017 trivalent influenza vaccines.

1. For the trivalent influenza vaccine, the committee recommended the inclusion of the following strains:

   A. Inclusion of an A/California/7/2009 (H1N1)pdm09-like virus

   The committee voted unanimously (14 Yes, 0 Abstention, 0 No) to include an A/California/7/2009 (H1N1)pdm09-like virus.

   B. Inclusion of an A/Hong Kong/4801/2014 (H3N2)-like virus

   The committee voted unanimously (14 Yes, 0 Abstention, 0 No) to include an A/Hong Kong/4801/2014 (H3N2)-like virus.

   C. Inclusion of a B/Brisbane/60/2008-like virus (B/Victoria lineage)

   The committee voted unanimously (14 Yes, 0 Abstention, 0 No) to include a B/Brisbane/60/2008-like virus (B/Victoria lineage)

2. For the quadrivalent influenza vaccine, the committee was also asked to vote on the strain selection for inclusion of the 2nd influenza B strain:

   A. Influenza B

   Inclusion of a B/Phuket/3073/2013-like virus (B/Yamagata lineage) as the 2nd influenza B strain in the vaccine.

   The committee unanimously voted (14 Yes, 0 Abstention, 0 No) to include a B/Phuket/3073/2013-like virus (B/Yamagata lineage) as the 2nd influenza B strain in the quadrivalent influenza vaccine.

The final recommendations were as follows:

For trivalent influenza vaccines in the 2016-2017 season, the committee recommended the inclusion of the following three strains:

- A/California/7/2009 (H1N1)pdm09-like virus;
- Inclusion of an A/Hong Kong/4801/2014 (H3N2)-like virus;
- Inclusion of a B/Brisbane/60/2008-like virus (B/Victoria lineage).

For quadrivalent vaccines containing two B components in the 2016-2017 season, the committee recommended the inclusion of the following strain as the 2nd influenza B strain in addition to the above three strains that are included in the trivalent vaccine:

- A B/Phuket/3073/2013-like virus (B/Yamagata lineage)

The meeting was adjourned at 2:07 p.m. on March 4, 2016.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed at: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/ucm474746.htm