Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
144th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

October 13, 2016

Committee Members
Kathryn Edwards, M.D., Chair †
Hana El Sahly, M.D. †
Janet Englund, M.D. +
Leonard Friedland, M.D. *†
Bruce Gellin, M.D. †
David Greenberg, M.D.** +
Holly Janes, Ph.D. †
Karen Kotloff, M.D. †
Ofer Levy, M.D., Ph.D. +
Sarah Long, M.D. †
Ruth Lynfield, M.D. †
Pamela McInnes, D.D.S., MSc. (Dent) †
Arnold Monto, M.D. †
Patrick Moore, M.D., M.P.H. †
Mark Sawyer, M.D. †
Melinda Wharton, M.D., M.P.H. †

Temporary Voting Members
Jack Bennink, Ph.D. †
Vicky Pebsworth, Ph.D***†

Speakers
Jerry Weir, Ph.D
Jacqueline Katz, Ph.D. †#

FDA Participants
Marion Gruber, Ph.D.

Designated Federal Officer
Sujata Vijh, Ph.D.

Committee Management Specialists
Rosanna Harvey
Joanne Lipkind, M.S.
Denise Royster

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

These summary minutes for the October 13, 2016 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on October 31, 2016.

I certify that I participated on the October 13, 2016 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

/s/	/s/
Sujata Vijh, Ph.D.	Kathryn Edwards, M.D.
Designated Federal Officer	VRBPAC Chair

On October 13, 2016 at 1:00 p.m. Eastern Standard Time (EST), the Chair, Dr. Kathryn Edwards, called to order the 144th Meeting of the Vaccines and Related Biological Products Advisory Committee to discuss the topic "Selection of strains to be included in an influenza virus vaccine for the 2017 southern hemisphere influenza season". The meeting was held in an open session with members participating via teleconference. The Chair invited the members and temporary members to introduce themselves. The Designated Federal Officer (DFO) invited the FDA staff seated at the table to introduce themselves and made administrative remarks. The DFO also read the Conflict of Interest statement for the public record announcing that the meeting participants were screened for financial conflicts of interests and that no waivers were issued to any meeting participant. After the Conflict of Interest statement was read, the FDA and non-FDA speaker presentations began.

An introduction and overview of the topic along with the two voting questions was presented by Dr. Jerry Weir, Director of 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). This was followed by a presentation on Global Surveillance and Virus Characterization by Dr. Jacqueline Katz, of the Centers for Disease Control. Subsequently, clarifying questions were asked and discussed by the committee members.

After a brief break, the committee reconvened for the Open Public Hearing (OPH) session. As there were no members of the public wishing to make oral comments, the committee proceeded to make recommendations and final voting.

The Committee (12 regular members plus 2 temporary voting members, total 14) voted electronically on the following two questions regarding the strain composition for the 2017 southern hemisphere influenza season.

1. For the composition of trivalent 2017 SH formulations of influenza vaccines, does the committee recommend:

    a. Inclusion of an A/Michigan/45/2015 (H1N1)pdm09-like virus
    b. Inclusion of an A/Hong Kong/4801/2014 (H3N2)-like virus
    c. Inclusion of a B/Brisbane/60/2008-like virus (B/Victoria lineage)

2. For quadrivalent 2017 SH formulations influenza vaccines, does the committee recommend:
    A. Inclusion of a B/Phuket/3073/2013-like virus (B/Yamagata lineage) as the 2nd influenza B strain in the vaccine

For Question 1, the committee voted unanimously (14 Yes, 0 No, 0 Abstention) to include an A/Michigan/45/2015 (H1N1)pdm09-like virus, an A/Hong Kong/4801/2014 (H3N2)-like virus, and a B/Brisbane/60/2008-like virus (B/Victoria lineage).

For Question 2, 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 the composition of trivalent 2017 SH formulations of influenza vaccines, the committee recommended:

a. Inclusion of an A/Michigan/45/2015 (H1N1)pdm09-like virus
b. Inclusion of an A/Hong Kong/4801/2014 (H3N2)-like virus
c. Inclusion of a B/Brisbane/60/2008-like virus (B/Victoria lineage)

For quadrivalent 2017 SH formulations influenza vaccines, the committee recommended:

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

The meeting was adjourned at 3:27 p.m. on October 13, 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