Food and Drug Administration
Center for Biologics Evaluation and Research

# SUMMARY MINUTES
# 145th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

**March 9, 2017**

**Committee Members**
Kathryn Edwards, M.D., Chair
Hana El Sahly, M.D.
Janet Englund, 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., M.Sc.
Arnold Monto, M.D.
Patrick Moore, M.D., M.P.H.
Mark Sawyer, M.D.+
Melinda Wharton, M.D., M.P.H.

**Speakers**
Anissa Cheung, M.Sc., FDA
Michael Cooper, Ph.D., DOD
Lisa Grohskopf, M.D., M.P.H., CDC
Manju Joshi, Ph.D., FDA
Jacqueline Katz, Ph.D#., CDC

**Designated Federal Officer**
Prabhakara Atreya, Ph.D.

**Committee Management Specialist**
Rosanna Harvey

+ Not in attendance
# Temporary Non-Voting Member and Speaker
* Industry Representative

**Temporary Voting Members**
Jack Bennink, Ph.D.
Scott Stanek, D.O., M.P.H.

**Temporary Voting Consumer Representative**
Cherise Scott, Ph.D., M.P.H

**Temporary Non-Voting Member**
Jacqueline Katz, Ph.D. #

**FDA Participants**
Jerry Weir, Ph.D.
Philip Krause, M.D.

These summary minutes for the March 9, 2017 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on April 7, 2017.

I certify that I participated on the March 9, 2017 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

/s/
Prabhakara, Ph.D. (Acting)
Designated Federal Officer

/s/
Kathryn Edwards, M.D. Chair

On March 9, 2017 at 8:30 a.m. Eastern Standard Time (EST), the Chair, Dr. Kathryn Edwards, called to order the 145th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss the topic "Strain Selection for the Influenza Virus Vaccines for the 2017-2018 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 issued 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) presented the U.S. Surveillance data. 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 Candidate Vaccine Strains and Potency Reagents for 2017-2018 Influenza Season by Dr. Manju Joshi of the Division of Biological Standards & Quality Control**,** CBER/FDA. This was followed by a presentation on Influenza Vaccine Manufacturing process by Dr. Beverly Taylor of Seqirus Vaccines Limited, United Kingdom who spoke on behalf of industry.

After lunch break, the committee reconvened for the Open Public Hearing (OPH) session. There were no comments for the OPH part of the meeting.

The Committee therefore proceeded with the discussion and subsequent voting on influenza strain selection for trivalent and quadrivalent influenza vaccines for the 2017-2018 influenza season.

The Committee (8 regular members plus 3 temporary voting members, total 11) voted electronically on the strain composition for 2017-2018 trivalent influenza vaccines.

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

    A. **Inclusion of an A/Michigan/45/2015 (H1N1)pdm09-like virus**
    The committee voted unanimously (11 Yes, 0 Abstention, 0 No) to include an A/Michigan/45/2015 (H1N1)pdm09-like virus.

    B. **Inclusion of an A/Hong Kong/4801/2014 (H3N2)-like virus**
    The committee voted (10 Yes, 1 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 (10 Yes, 1 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 2$^{nd}$ influenza B strain in the vaccine**.
    The committee unanimously voted (11 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 2017-2018 season, the committee recommended the inclusion of the following three strains:

- Inclusion of A/Michigan/45/2015 (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 2017-2018 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 2:00 p.m. on March 9, 2017.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed at: https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/ucm538209.htm