Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
151st VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

March 1, 2018

Committee Members
Kathryn Edwards, M.D., Chair
Hana El Sahly, M.D.
Ofer Levy, M.D., Ph.D. +
Holly Janes, Ph.D. ^
Pamela McInnes, D.D.S., M.Sc.
Arnold Monto, M.D.
Paul Offit, M.D.
Andrea Shane, M.D., M.P.H., M.Sc.
Melinda Wharton, M.D., M.P.H.

FDA Speakers
Anissa Cheung, M.Sc.
Manju Joshi, Ph.D.

Guest Speakers
Angelia Cost, Ph.D., Sc.M.
Lisa Grohskopf, M.D., M.P.H.^
Jacqueline Katz, Ph.D., CDC#
Penny Post, Ph.D.

Designated Federal Officer (DFO)
Serina A. Hunter-Thomas, M.S.A., R.N.

Committee Management Specialist
Rosanna Harvey

Temporary Voting Members
Jack Bennink, Ph.D.
Karin Bok, Ph.D.
Andrew Wiesen, M.D., M.P.H.

Consumer Representative
Sheldon V. Toubman, J.D.

Industry Representative
Leonard Friedland, M.D. ^^

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

FDA Participants
Marion Gruber, Ph.D.
Philip Krause, M.D.
Jerry Weir, Ph.D.

+ Not in attendance
# Temporary Non-Voting Member and Speaker
* Industry Representative
^^ Alternate Industry Representative
^ Via Teleconference

These summary minutes for the March 1, 2018 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on March 23, 2018.

I certify that I participated in the March 1, 2018 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

/s/
Serina A. Hunter-Thomas
Designated Federal Officer

/s/
Kathryn Edwards, M.D., Chair

On March 1, 2018 at 8:00 a.m. Eastern Standard Time (EST), the Chair, Dr. Kathryn Edwards, called to order the 151st Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss the Topic I "Presentation of the Laboratory of Mucosal Pathogens & Cellular Immunology (LMPCI), Division of Bacterial, Parasitic & Allergenic Products (DBPAP, Office of Vaccines Research and Review (OVRR)." Dr. Carolyn Wilson gave a presentation titled "Center for Biologics Evaluation and Research Overview" followed by Dr. Jay Slater, who provided an overview of the Office of Vaccines Research and Review, followed by an overview of the Laboratory of Mucosal Pathogens & Cellular Immunology by Dr. Scott Stibitz. Following the Open Public Hearing for this portion of the meeting and hearing none, on March 1, 2018 at 9:10 a.m. Eastern Standard Time (EST), the Committee met in the closed session which lasted until 9:45 a.m. Eastern Standard Time (EST).

At approximately 10:15 a.m. Eastern Standard Time (EST), the meeting proceeded on to Topic II, Strain Selection for the Influenza Virus Vaccines for the 2018-2019 Influenza Season. The meeting was held in its entirety in open session. The Chair invited the members, temporary members, and participants seated at the table to re-introduce themselves. The DFO made administrative remarks and read the Conflict of Interest (COI) statement into the public record. There were no waivers issued for conflicts of interest for this meeting.
After the COI statement was read 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. Influenza Surveillance and Interim Estimates of 2017-18 Vaccine Effectiveness data. This was followed by a presentation on Global Surveillance and Virus Characterization by Dr. Jacqueline Katz, also of the CDC. The Department of Defense (DoD) Influenza Surveillance and Mid-Season Vaccine Effectiveness report was provided by Dr. Angelia Cost of the Armed Forces Health Surveillance Center. After lunch break, the committee reconvened for the presentation on Candidate Vaccine Viruses and Potency Reagents for the 2018-2019 Influenza Season by Dr. Manju Joshi of the Division of Biological Standards & Quality Control**,** CBER/FDA. This was followed by a presentation on the Influenza Vaccine Manufacturing process by Dr. Penny Post of Protein Sciences Corporation, a Sanofi Company, who provided an industry perspective on the manufacturing process of the influenza vaccine.

This was followed by the Open Public Hearing (OPH) session. There were no speakers interested in making comments at 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 2018-2019 influenza season.

The Committee (9 regular members plus 3 temporary voting members, total 12) voted electronically on the strain composition for 2018-2019 trivalent influenza vaccines.

1. **For the composition of the trivalent 2018-2019 influenza virus vaccine in the U.S., does the committee recommend?**

    A. **Inclusion of an A/Michigan/45/2015 (H1N1) pdm09-like virus**
    The committee voted unanimously (12 Yes, 0 Abstention, 0 No) to include an A/Michigan/45/2015 (H1N1) pdm09-like virus.

    B. **Inclusion of an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus**
    The committee voted unanimously (12 Yes, 0 Abstention, 0 No) to include an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus.

    C. **Inclusion of a B/Colorado/06/2017-like virus (B/Victoria lineage)**
    The committee voted (11 Yes, 1 Abstention, 0 No) to include a B/Colorado/06/2017-like virus (B/Victoria lineage).

2. **For the quadrivalent influenza vaccine in the U.S., 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**
    The committee unanimously voted (12 Yes, 0 Abstention, 0 No) to include a B/Phuket/3073/2013-like virus (B/Yamagata lineage) in the quadrivalent influenza vaccine.

The final recommendations were as follows:

For trivalent influenza vaccines in the 2018-2019 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/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus;
- Inclusion of a B/Colorado/06/2017-like virus (B/Victoria lineage).

For quadrivalent 2018-2019 influenza vaccines in the U.S., the committee recommended the inclusion of the following strain in addition to the above three strains that are included in the trivalent vaccine:

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

The meeting was adjourned at 2:40 p.m. on March 1, 2018.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed at:
Part 1: https://collaboration.fda.gov/p1n796092m9/
Part 2: https://collaboration.fda.gov/p5thw2sxtz0/
Part 3: https://collaboration.fda.gov/p96ddbhfr2g/