Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
165th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

March 5, 2021

Committee Members
Hana El Sahly, M.D., Chair
Archana Chatterjee, M.D., Ph.D.
CAPT. Amanda Cohn, M.D.
Hayley Gans, M.D.
Holly Janes, Ph.D.
Michael Kurilla, M.D., Ph.D.
Myron Levine, M.D., D.T.P.H., F.A.A.P.
H. Cody Meissner, M.D.
Paul Offit, M.D.
Steven Pergam, M.D., M.P.H.
Andrea Shane, M.D., M.P.H., M.Sc.
Paul Spearman, M.D.
Geeta K. Swamy, M.D.

Industry Representatives
Paula Annunziato, M.D.
Gregg Sylvester, M.D., M.P.H. <+

Consumer Representative
Jay Portnoy, M.D. * (Acting)

Designated Federal Officers (DFO)
Kathleen Hayes, M.P.H.
Prabhakara Atreya, Ph.D.

Committee Management Specialist(s)
Monique Hill, M.H.A.

* Consumer Representative
+ Not in attendance
< Alternate Industry representative

Temporary Voting and Non-Voting Members
COL Andrew Wiesen
David Kim, M.D., M.A.
David Wentworth, Ph.D. (TNVM)

Speakers and Guest Speakers
CAPT Lisa Grohskopf, M.D., M.P.H. - CDC
Jerry Weir, Ph.D. - FDA
Kathleen Creppage, DrPH, M.P.H. - DoD
Kevin Taylor, M.D., MTM &H - DoD
Lauren Parker, Ph.D. – AstraZeneca
Manju Joshi, Ph.D. - FDA

FDA Participants
Marion Gruber, Ph.D.
Philip Krause, M.D.
Peter W. Marks, M.D., Ph.D.
Celia M. Witten, Ph.D., M.D.
CDR. Valerie Marshall, M.P.H., P.M.P.

These summary minutes for the March 5, 2021 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on __3/26/2021_____.

I certify that I participated in the March 5, 2021 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

_____/s/_____
Kathleen Hayes, M.P.H.
Designated Federal Officer

_____/s/_____
Hana El Sahly, M.D.
Chair

On March 5, 2021 at 9:00 a.m. Eastern Standard Time (EST), the 165th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2021 – 2022 influenza season.

Dr. El Sahly, the VRBPAC Chair, called the meeting to order. The DFO made administrative remarks, conducted roll call and invited the committee members to introduce themselves, and read the Conflict of Interest (COI) statement into the public record. It was stated that no conflict of interest waivers were issued under 18 U.S. Code 208 in connection with the meeting.

Dr. Jerry Weir of FDA provided an introductory presentation titled "Influenza Virus Vaccine Strain Selection 2021-2022 Northern Hemisphere." This was followed by a presentation by Dr. Lisa Grohskopf with the Centers for Disease Control and Prevention (CDC) titled "U.S. Influenza Surveillance." Dr. David Wentworth, also with the CDC, then gave the presentation "Global Influenza Virus Surveillance and Characterization." Following this presentation, the Committee was released for a 10-minute break. After the break, LTC Kevin Taylor with the Department of Defense (DoD) presented "DoD Influenza Surveillance and Mid-Season Vaccine Effectiveness." Following his presentation, Dr. Manju Joshi with the FDA presented, "Candidate Vaccine Strains & Potency Reagents." The Manufacturer Representative, Dr. Lauren Parker with AstraZeneca, then shared Influenza Vaccine Manufacturing Industry Perspective for 2020-21 Northern Hemisphere Influenza Vaccine Supply.

After a 45-minute lunch break, the Open Public Hearing session was announced. However, there were no public speakers pre-registered for this portion of the meeting.

Therefore, the Committee immediately proceeded with discussions followed by voting for Topic **There were 4 (four) voting questions presented to the Committee for Topic 1:**

Question 1) For the influenza A (H1N1) component of the 2021-2022 influenza virus vaccines in the U.S., does the committee recommend:

- An A/Victoria/2570/2019 (H1N1)pdm09-like virus for egg-based vaccines
- An A/Wisconsin/588/2019 (H1N1)pdm09-like virus for cell- or recombinant-based vaccines

For question 1, the Committee voting results are as follows: 16 Yes, 0 No, 0 Abstain

Question 2) For the influenza A (H3N2) component of the 2021-2022 influenza virus vaccine in the U.S., does the committee recommend:

- An A/Cambodia/e0826360/2020 (H3N2)-like virus

For question 2, the Committee voting results are as follows: 16 Yes, 0 No, 0 Abstain

Question 3) For the influenza B component of the 2021-2022 trivalent and quadrivalent influenza virus vaccines in the U.S., does the committee recommend inclusion of a B/Washington/02/2019-like virus (B/Victoria lineage)

For question 3, the Committee voting results are as follows: 16 Yes, 0 No, 0 Abstain

Question 4) For quadrivalent 2021-2022 influenza vaccines in the U.S., does the committee recommend inclusion of a B/Phuket/3073/2013-like virus (B/Yamagata lineage) as the 2nd influenza B strain in the vaccine

For question 4, the Committee voting results are as follows: 16 Yes, 0 No, 0 Abstain

Following the vote, the Committee members provided rationale for their vote and/or any final remarks. Dr. El Sahly then handed the meeting over to the DFO who adjourned the meeting on March 5, 2021 at 2:40 PM EST.

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://youtu.be/dG_NjxSYBkA**