Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
160th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

October 2, 2020

Committee Members
Hana El Sahly, M.D., Chair
Tammy Beckham, D.V.M., Ph.D.
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
Sheldon Toubman, J.D. *

Designated Federal Officer (DFO)
Kathleen Hayes, M.P.H.

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

Temporary Non-Voting Member & Speaker
David Wentworth, Ph.D.

FDA Speakers
Jerry Weir, Ph.D.

FDA Participants
Marion Gruber, Ph.D.

+ Not in attendance
< Alternate Industry representative

These summary minutes for the October 2, 2020 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on _____, 2020.

I certify that I participated in the October 2, 2020 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

_____	_____
Kathleen Hayes, M.P.H.	Hana El Sahly, M.D.
Designated Federal Officer	Chair

On October 2, 2020 at 11:00 a.m. Eastern Standard Time (EST), the 160th 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 2020-2021 southern hemisphere influenza season.

Dr. Hana El Sahly, the 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 waivers were issued for conflicts of interest for this meeting.

Dr. Jerry Weir of FDA provided an introductory presentation titled "Influenza Virus Vaccine Strain Selection – 2021 Southern Hemisphere." This was followed by a presentation by Dr. David Wentworth from the Centers for Disease Control and Prevention entitled, "Information for the Vaccine and Related Biological Products Advisory Committee, CBER, FDA: Global Influenza Virus Surveillance and Characterization."

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

Therefore, the Committee immediately proceeded with discussions followed by voting. There were two voting questions presented to the Committee:

1) For the composition of egg-based trivalent 2021 SH formulations of influenza vaccines, does the committee recommend:

- Inclusion of an A/Victoria/2570/2019 (H1N1)pdm09-like virus
- Inclusion of an A/Hong Kong/2671/2019 (H3N2)-like virus
- Inclusion of a B/Washington/02/2019-like virus (B/Victoria lineage)

For question 1, the Committee voting results are as follows: 15 Yes, 0 No, 0 Abstain

2) For quadrivalent 2021 SH formulations of influenza vaccines, 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 2, the Committee voting results are as follows: 15 Yes, 0 No, 0 Abstain

The meeting was then adjourned on October 2, 2020 at 1:50 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/p4yhx5uMg5k