Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
153rd VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

October 3, 2018

Committee Members
Kathryn Edwards, M.D., Chair †
Hana El Sahly, M.D.+
Holly Janes, Ph.D. †
Michael Kurilla, M.D., Ph.D. †
Myron Levine, M.D., D.T.P.H. +
Ofer Levy, M.D., Ph.D. †
H. Cody Meissner, M.D. †
Arnold Monto, M.D. †
Paul Offit, M.D. †
Andrea Shane, M.D., M.P.H. †
Paul Spearman, M.D. †
Geeta Swamy, M.D. †
Melinda Wharton, M.D., M.P.H. †

Consumer Representative**†
Sheldon Toubman, J.D.

Industry Representative*†
David Greenberg, M.D.

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

FDA Speakers
Jerry Weir, Ph.D.

FDA Participants
Marion Gruber, Ph.D.
Zhiping Ye, M.D., Ph.D.

Administrative Team

Designated Federal Officer
CAPT Serina Hunter-Thomas, M.S.A., R.N.

Committee Management Specialist
Joanne Lipkind, M.S.

Director
Prabhakara Atreya, Ph.D.
Division of Scientific Advisors and Consultants

† Via Teleconference
+ Not in attendance
* Industry Representative
** Consumer Representative
# Temporary Non-Voting member and Speaker

These summary minutes for the October 3, 2018 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on December 4, 2018.

I certify that I participated on the October 3, 2018 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

/s/	/s/
Serina Hunter-Thomas	Kathryn Edwards, M.D.
Designated Federal Officer	Chair

On October 3, 2018 at 11:00 a.m. Eastern Standard Time (EST), the Chair, Dr. Kathryn Edwards, called to order the 153rd Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss and make recommendations on the strain selection for the 2019 Southern Hemisphere Influenza season. The entire meeting was held in open session. The Chair invited the members 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 two voting questions were presented by Dr. Jerry Weir from the Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA). The FDA overview was followed by presentation from Dr. Jacqueline Katz from the Centers of Disease Control on the "Global Surveillance and Virus Characterization – 2019 Southern Hemisphere Influenza Vaccine." Following Dr. Katz's presentation, the meeting progressed on to the Open Public Hearing (OPH) session. There were no public members who attended the OPH portion 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 2019 Southern Hemisphere Influenza season.

The Committee voted verbally on the following:

For the composition of trivalent 2019 SH formulations of influenza vaccines, does the committee recommend:

- Inclusion of an A/Michigan/45/2015 (H1N1) pdm09-like virus
- Inclusion of an A/Switzerland/8060/2017 (H3N2)-like virus

- Inclusion of a B/Colorado/06/2017-like virus (B/Victoria lineage)

The committee voted unanimously (12 Yes, 0 Abstention, 0 No) to include an A/Michigan/45/2015 (H1N1) pdm09-like virus, an A/Switzerland/8060/2017 (H3N2)-like virus, and a B/Colorado/06/2017 -like virus (B/Victoria lineage).

For quadrivalent 2019 SH formulations 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

The committee voted unanimously (12 Yes, 0 Abstention, 0 No) to include B/ Phuket/3073/2013-like virus (B/Yamagata lineage) as the 2nd influenza B strain in the vaccine.

The meeting was adjourned at 3:00 p.m. on October 3, 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/p997h7h5sex/
Part 2: https://collaboration.fda.gov/p352xquyo15/