Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
157th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

**October 9, 2019**

| **Committee Members** | **Temporary Voting Members** |
|---|---|
| Hana El Sahly, M.D., Chair | Steven A. Pergam, M.D., M.P.H.., FIDSA |
| Archana Chatterjee, M.D., Ph.D. + | |
| Hayley Gans, M.D. | **Temporary Non-Voting Members** |
| David Greenberg, M.D. + (IR) | David Wentworth, Ph.D. |
| Holly Janes, Ph.D. | |
| Michael Kurilla, M.D., Ph.D. | **Guest Speaker** |
| Myron Levine, M.D., D.T.P.H., F.A.A.P. + | David Wentworth, Ph.D. |
| H. Cody Meissner, M.D. | |
| Arnold Monto, M.D. + | **FDA Speaker** |
| Paul Offit, M.D. + | Jerry Weir, Ph.D. |
| Andrea Shane, M.D., M.P.H., M.Sc. + | |
| Paul Spearman, M.D. | |
| Geeta K. Swamy, M.D. | **FDA Participants** |
| Sheldon Toubman, J.D. (CR) | Marion Gruber, Ph.D. |
| Melinda Wharton, M.D., M.P.H. | Konstantin Chumakov, Ph.D. |
| | Zhiping Ye, M.D., Ph.D. |
| **Industry Representative** | |
| Lisa L. Bollinger, M.D., FAAP | |
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| **Designated Federal Officer (DFO)** | |
| CAPT Serina A. Hunter-Thomas, M.S.A., R.N. | |
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| **Committee Management Specialist(s)** | |
| Monique Hill, M.H.A. | |
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+ Not in attendance

These summary minutes for the October 9, 2019 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on _October 24_, 2019.

I certify that I participated in the October 9, 2019 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/
Hana El Sahly, M.D.
Chair

On October 9, 2019 at 8:30 a.m. Eastern Standard Time (EST), Dr. Hana El Sahly, VRBPAC Chair, called to order the 157th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss Topic I "Presentation of the Laboratory of Hepatitis Viruses (LHV) and the Laboratory of Vector-Borne Viral Diseases (LVVD), Division of Viral Products (DVP), Office of Vaccines Research and Review (OVRR) followed by Topic II "Strain Selection for the 2020 Southern Hemisphere Influenza Season." The Chair invited the committee members who joined via teleconference to introduce themselves, followed by the DFO's administrative remarks and reading of the Conflict of Interest (COI) statement into the public record. There were no waivers issued for conflicts of interest for this meeting. The meeting proceeded with Dr. Carolyn Wilson who gave an overview presentation of the research/site visit process. This was followed by Dr. Jerry Weir who provided a presentation titled "Overview of Division of Viral Products (DVP), Overview of Laboratory of Hepatitis Viruses (LHV) and Overview of Laboratory of Vector-Borne Viral Diseases (LVVD)." After Dr. Weir's presentation, the committee proceeded to take a 10-minute break, followed by the first Open Public Hearing session of the day. There were no public speakers for this portion of the meeting.

The meeting then proceeded on to Topic II: Strain Selection for the 2020 Southern Hemisphere Influenza Season. The VRBPAC Chair proceeded with roll call of the members, followed by the reading of the Conflict of Interest Statement by the DFO. Dr. Jerry Weir then provided the FDA "Introduction and Presentation of Questions" for Topic II, which was then followed by the Centers for Disease Control and Prevention's Dr. David Wentworth, who provided a presentation on "Global Surveillance and Virus Characterization." Dr. Wentworth's presentation was followed by a lunch break, which was then followed by an Open Public Hearing session. There were no registered speakers for this portion of the meeting; therefore the meeting progressed on to the committee discussion, voting and recommendations.

After the discussion, the committee proceeded with a vote for Topic II. There were two voting questions presented to the committee for Topic II:

1. For the composition of trivalent 2020 SH formulations of influenza vaccines, does the committee recommend:
    A. Inclusion of an A/Brisbane/02/2018 (H1N1)pdm09-like virus
    B. Inclusion of an A/South Australia/34/2019 (H3N2)-like virus
    C. Inclusion of a B/Washington/02/2019-like virus (B/Victoria lineage)

2. For quadrivalent 2020 SH formulations influenza vaccines, 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

For Question 1 the committee voted as follows: 11 Yes, 0 No, 0 Abstain
For Question 2 the committee voted as follows: 11 Yes, 0 No, 0 Abstain

The meeting was then adjourned on October 9, 2019 at 1:39PM 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://collaboration.fda.gov/p00bn3m9i56e/**
**https://collaboration.fda.gov/p1ccjjqefzg3/**
**https://collaboration.fda.gov/pgbqkn52tz3l/**