

**Food and Drug Administration
Center for Biologics Evaluation and Research**

**SUMMARY MINUTES
31st MEETING ALLERGENIC PRODUCTS ADVISORY COMMITTEE**

October 28, 2021

Committee Members

David Peden, M.D., M.S., Chair
Amal Assa'ad, M.D.
Carla Davis, M.D.
Mark Dykewicz, M.D.
Paul Greenberger, M.D.
Corinne Keet, M.D., Ph.D.
Sohelia Maleki, Ph.D.
Judith Woodfolk, M.B.Ch.B., Ph.D.

FDA Participants

Drusilla Burns, Ph.D.
Konstantin Chumakov, Ph.D. (Speaker)
Karen Elkins, Ph.D. (Speaker)
Peter W. Marks, M.D., Ph.D.
Ronald Rabin, M.D. (Speaker)
Jay Slater, M.D.
Celia Witten, Ph.D., M.D.

Industry Representatives

Hendrik Nolte, Ph.D. <

Consumer Representative

Jay Portnoy, M.D. *

Designated Federal Officers (DFO)

Kathleen Hayes, M.P.H.
Prabhakara Atreya, Ph.D

Committee Management Specialist

Monique Hill, M.H.A.

Division Director

Prabhakara Atreya, Ph.D

* Consumer Representative

+ Not in attendance

< Alternate Industry representative

These summary minutes for the October 28, 2021 Meeting of the Allergenic Products Advisory Committee were approved on November 17, 2021.

I certify that I participated in the October 28, 2021 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

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

-S-

 David Peden, M.D., M.S.
 Chair

On October 28, 2021 at 9:30 a.m. Eastern Standard Time (EST), the 31st Meeting of the Allergenic Products Advisory Committee (APAC) took place in open session to hear an overview of the research programs in the Laboratory of Immunobiochemistry (LIB), Division of Bacterial, Parasitic, and Allergenic Products (DBPAP), Office of Vaccines Research and Review (OVR), Center for Biologics Evaluation and Research (CBER).

Dr. David Peden, the APAC 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 conflicts of interest waivers were issued under 18 U.S. Code 208 in connection with the meeting.

Dr. Karen Elkins, Acting Associate Director for Research, Center for Biologics Evaluation and Research (CBER), FDA provided an overview of the research and the site visit process with a presentation titled "Overview of CBER Research Programs." Dr. Konstantin Chumakov, Associate Director of Research, Office of Vaccines Research and Review (OVR), CBER, FDA then provided an overview presentation titled "Overview of the Office of Vaccines Research and Review (OVR) & the Division of Bacterial, Parasitic and Allergenic Products (DBPAP)." This was followed by a presentation by Dr. Ronald Rabin, Chief of the Laboratory of Immunobiochemistry (LIB), DBPAP, OVR titled "Overview of Laboratory of Immunobiochemistry (LIB) Research Programs." Following their presentations, the Committee was released for a 10-minute break. After the 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 the closed session for the Site Visit report discussions followed by a vote.

Following the discussion, the Committee members provided rationale for their vote and/or any final remarks. Dr. David Peden then handed the meeting over to the DFO who adjourned the meeting on October 28, 2021 at 12:35 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/OHRWDuihDns>