Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
30th ALLERGENIC PRODUCTS ADVISORY COMMITTEE

September 13, 2019

Committee Members
Paul A. Greenberger, M.D., Temporary Chair
David Peden, M.D., Chair +
Amal H. Assa'ad, M.D. +
Ira Finegold, M.D., M.S. ^
Corinne A. Keet, M.D., Ph.D. +
Soheila Maleki, Ph.D., FAAAAI
Hendrik Nolte, M.D., Ph.D. (Alt. IR)
Jay Portnoy, M.D. (CR) +

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

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

Temporary Voting Members
Andrea Apter, M.D., M.Sc., M.A.
Erica Brittain, Ph.D.
Mark Dykewicz, M.D.
Randy Hawkins, M.D. **>
John Kelso, M.D.
Gailen Marshall, M.D., Ph.D., FACP

Speaker
Pamela Guerrerio, M.D., Ph.D.

FDA Speakers
Kathleen S. Hise, M.D.
Taruna Khurana, Ph.D.

FDA Participants
Marion Gruber, Ph.D.
Philip Krause, M.D.
Jay Slater, M.D.
Sofia Chaudhry, M.D.

+ Not in attendance
^ Via Teleconference
**>Consumer Representative - CTGTAC

These summary minutes for the September 13, 2019 Meeting of the Allergenic Products Advisory Committee were approved on September 24, 2019.

I certify that I participated in the September 13, 2019 Meeting of the Allergenic Products Advisory Committee and that these minutes accurately reflect what transpired.

/s/
Serina A. Hunter-Thomas
Designated Federal Officer

/s/
Paul A. Greenberger, M.D.
Temporary Chair

On September 13, 2019 at 8:30 a.m. Eastern Daylight Time (EDT), Dr. Paul Greenberger, Temporary APAC Chair, called to order the 30th Meeting of the Allergenic Products Advisory Committee (APAC) to discuss and make recommendations on the safety and efficacy of Peanut (*Arachis hypogaea*) Allergen Powder manufactured by Aimmune Therapeutics, Inc., indicated as an oral immunotherapy to reduce the incidence and severity of allergic reactions, including anaphylaxis, after accidental exposure to peanut in patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy. The Temporary Chair invited everyone around the table 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. Taruna Khurana who gave the FDA introductory presentation titled "Peanut (*Arachis Hypogaea*) Allergen Powder: PALFORZIA," followed by Dr. Pamela Guerrerio from the National Institutes of Health who gave a presentation titled "The Current State of Treatment for Food Allergy". She then answered questions from the panel. Following a short break, there was a presentation from the sponsor, Aimmune, whose presentation was titled "AR101 (Palforzia) for Patients with Peanut Allergy." The Committee then took a break for lunch and reconvened for the Open Public Hearing (OPH) session. After the OPH session, the next speaker to present was Dr. Kathleen Hise from FDA whose presentation was titled "Peanut, *Arachis hypogaea*, Allergen Powder for Oral Administration (Palforzia): Review of Efficacy and Safety."

Afterward, the committee proceeded with discussion and recommendations followed by a vote. There were two voting questions presented to the committee:

Q1. Are the available efficacy data adequate to support the use of Palforzia as a treatment to reduce the incidence and severity of allergic reactions, including anaphylaxis, after accidental exposure to peanut in patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy.

As part of a Risk Evaluation and Mitigation Strategy, the Agency will require the following to mitigate the risk(s) of systemic allergic reactions, including anaphylaxis, due to Palforzia:

a. Documentation that any patient prescribed Palforzia has a valid prescription for injectable epinephrine.
b. Caregivers/patients must attest to carrying injectable epinephrine while on Palforzia.
c. Initial dose escalation and the first dose of each up-dosing level must be administered in a certified facility capable of treating systemic allergic reactions.

Q2. Are the available safety data, in conjunction with additional safeguards, adequate to support the use of Palforzia in patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy.

For Question 1 the committee voted as follows: 7 Yes, 2 No, 0 Abstain
For Question 2 the committee voted as follows: 8 Yes, 1 No, 0 Abstain

After the results of each vote was posted on the screens, each voting committee member was called upon to discuss their rationales for voting as they did. This was followed by final comments from the Director of Office of Vaccines Research and Review, Dr. Marion Gruber, which was followed by discussion and adjournment.

The meeting was adjourned at 4:35pm EDT on September 13, 2019.

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/plmqc2quh8zc/
https://collaboration.fda.gov/pqby8mg3l8hg/
https://collaboration.fda.gov/pbb32ovhcthi/
https://collaboration.fda.gov/ptbxpgb3l2t1/