FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
30th Meeting of the Allergenic Products Advisory Committee
FDA White Oak Campus, Building 31, Great Room
Salon B & C
Silver Spring, MD
September 13, 2019
AGENDA
Meeting Link:

https://collaboration.fda.gov/apac091319/

Topic: The committee will meet in open session 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.

Note: Committee members are participating in person.

Time	Presentation/Presenter
8:30 AM	**Opening Remarks: Call to Order, Introduction of Committee** **Paul A. Greenberger, M.D.** Chair, APAC **Administrative Announcements, Conflict of Interest Statement** **Serina Hunter-Thomas, M.S.A., R.N.** Designated Federal Officer, VRBPAC CBER, FDA
8:45 AM	**FDA Introduction/Presentation of Questions** **Peanut (*Arachis hypogaea*) Allergen Powder: Palforzia** Taruna Khurana, Ph.D. Regulatory Biologist Division of Vaccines and Related Product Applications (DVRPA) Office of Vaccines and Related Research (OVRR) Center for Biologics Evaluation and Research (CBER)
8:50 AM	**Guest Presentation** **The Current State of Treatment for Food Allergy** Pamela A. Guerrerio, M.D., Ph.D. Chief, Food Allergy Research Unit (FARU) Laboratory of Allergenic Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health
9:40 AM	**Break**

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
30th Meeting of the Allergenic Products Advisory Committee
FDA White Oak Campus, Building 31, Great Room
Salon B & C
Silver Spring, MD
September 13, 2019
AGENDA

9:50 AM	**Sponsor Presentation** (90 minutes) **AR101 (Palforzia) for Patients with Peanut Allergy** Aimmune Therapeutics Louise Peacock, VP Global Regulatory Affairs, Aimmune Therapeutics James Baker, M.D., Director, Mary H. Weiser Food Allergy Center, Ruth Dow Doan Professor of Biologic Nanotechnology, Professor Emeritus of Internal Medicine, Medical School and Biomedical Engineering, College of Engineering University of Michigan Stephen Dilly, M.B.B.S., Ph.D., Clinical Science Advisor, Aimmune Therapeutics Daniel Adelman, M.D., Chief Medical Officer, Aimmune Therapeutics A. Wesley Burks, M.D., Dean of the UNC School of Medicine, Vice Chancellor for Medical Affairs, and CEO of UNC Health Care
12:00 PM	**Lunch**
1:00 PM	**Open Public Hearing** (90 minutes)
2:45 PM	**FDA Presentation** **Peanut, *Arachis hypogaea*, Allergen Powder for Oral Administration (Palforzia): Review of Efficacy and Safety** Kathleen S. Hise, M.D. Medical Officer Division of Vaccines and Related Product Applications (DVRPA) Office of Vaccines and Related Research (OVRR) Center for Biologics Evaluation and Research (CBER)
3:30 PM	**Committee Discussion, Voting, and Recommendations**
4:35 PM	**Adjourn Meeting**