



Asthma and Allergy
Foundation of America



June 16, 2020

Dr. Peter Marks
Dr. Prabhakara Atreya
Director, Division of Scientific Advisors & Consultants
Center for Biologics Evaluation & Research
Food and Drug Administration (FDA)
5001 Campus Drive
College Park, MD 20740

Re: FDA Review of New Drug Application for Peanut Allergy Treatment by DBV Technologies

Dear Sirs,

We are commenting today on behalf of the undersigned organizations regarding FDA's decision to cancel the May 15, 2020, the Center for Biologics Evaluation and Research's (CBER) Allergenic Products Advisory Committee (APAC) open session to discuss and make recommendations on the safety and efficacy of Peanut (*Arachis hypogaea*) Allergen Extract manufactured by DBV Technologies, S.A for treatment of patients 4 through 11 years old with a confirmed diagnosis of peanut allergy.

We acknowledge that the COVID-19 pandemic may impact FDA's ability to a timely review and the hosting of a traditional open public hearing on this matter; however, we feel strongly the community deserves a formal opportunity to be heard regarding this important topic. We would greatly appreciate an update on the status of the new drug application and respectfully request a listening session to ensure the patient voice is fully considered.

Significant unmet need remains for the 3 million Americans living with peanut allergy. As peanut allergy prevalence continues to rise at alarming rates, it is imperative that FDA accelerate access to safe and effective treatments. Moreover, the 1.2 million children and teens living with peanut allergy deserve treatment options.

We look forward to a follow up conversation on this matter. Additionally, when the current COVID crisis subsides, we remain committed to work with FDA to advance the patient perspective and to promote the health and safety of all consumers with food allergies. Thank you in advance for your time and attention to this matter. Please feel free to contact Tonya Winders, CEO at twinders@AllergyAsthmaNetwork.org to discuss further.

Sincerely,

Allergy & Asthma Network
Asthma and Allergy Foundation of America
Food Allergy & Anaphylaxis Awareness Connection Team (FAACT)
Food Allergy Research & Education (FARE)