



March 4, 2025

Dr. David Kaslow
Director, Office of Vaccines Research and Review
U.S. Food and Drug Administration
10903 New Hampshire Avenue
WO71-7232
Silver Spring, MD 20993

RE: Support of the Viaskin® Peanut Patch Treatment Option in 4 – 7 Year Olds with Peanut Allergy to Address the Urgent Unmet Medical Need

Dear Dr. Kaslow,

In August 2024, we wrote to you in support of the Viaskin® peanut patch in toddlers 1 – 3 years old living with a confirmed peanut allergy. Today, the undersigned organizations write to you again on behalf of the food allergy community, representing more than 20 million Americans living with life-threatening food allergies in support of the Viaskin peanut patch in children 4 – 7 years old living with a confirmed peanut allergy.

The Viaskin Peanut patch is a hopeful advancement in the treatment of peanut allergies in children. The Viaskin Peanut patch has been well-studied, and we are

desperately in need of additional approved medical treatment options for families.

This past weekend we attended the American Academy of Allergy, Asthma and Immunology (AAAAI) 2025 annual meeting, a joint congress this year with World Allergy Organization (WAO). DBV hosted a product theater presentation with Drs Hugh Sampson, MD, Helen Brough, MBBS, and Doug Mack, MSc, MD, where 327 practicing allergists, immunologists, advocates, investors, media, and more attended to learn about the epicutaneous immunotherapy that the Viaskin peanut patch would bring to patients. DBV's compelling long-term data were recognized by congress organizers through selection for an oral abstract presentation in which Dr. David Fleischer shared the 5-year efficacy results of the Viaskin peanut patch in children ages 4 – 11 years in the Phase 3 PEOPLE study. Most notably from the PEOPLE data, approximately 2/3 of study subjects reached an eliciting dose (ED) of 1,000 mg or more of peanut protein at month 60. This means study subjects could tolerate up to the equivalent of 3-4 peanut kernels before having an allergic reaction. The treatment compliance also remained high, 93 percent out to five years, a testament to how well this practical therapy could fit into the daily lives of children with minimal disruption. It's concerning that a treatment option proven to be well tolerated and clinically beneficial in multiple clinical trials faces obstacles that could delay its availability to patients. We recognize the FDA's commitment to safety and efficacy, but we urge a more streamlined approach to ensure that promising therapies reach those in need without unnecessary delays.

Based on the unmet need and promise of this new kind of therapy, the undersigned organizations helped recruit families with children for this therapy's clinical trials. We promoted advertisement of DBV's VITESSE Phase 3 clinical study in 4 – 7 year olds with peanut allergy. We are proud to have supported the enrollment of 654 subjects into what is now the largest and most robustly designed clinical study ever conducted in peanut allergy. Many of us also participated in the recruitment for the REALISE and PEPITES Phase 3 clinical studies in the Viaskin Peanut patch ages 4 – 11 years. Combined, these studies have generated data in approximately ~1200

subjects across 1 million patches. In considering the fastest path to market for the Viaskin Peanut patch, it is curious why the additional COMFORT Children safety study in 4 – 7 year olds is required.

We formally request FDA to explain why the VITESSE Phase 3 data combined with the cross-over patients in the VITESSE open-label extension (OLE) cannot suffice for a Biologic License Application (BLA). Specifically, we would like to know what safety signal the FDA has identified that warrants an additional supplemental safety study to be conducted in an additional 240 subjects. When it comes to food allergy treatments, we consider the historical lack of urgency from the FDA a detriment to the patients and families who are eager to see the Viaskin peanut patch approved. The data from all forms of food allergy immunotherapy are more and more clear that the optimal time to intervene is early in life, and while the FDA hesitates, these patients grow older. Peanut allergy is often a lifelong disease, with only 20% of patients naturally developing tolerance over time. We support DBV's intent to submit a BLA for the Viaskin Peanut patch in children 4 – 7 years with the VITESSE data, the OLE crossovers, and, if necessary, using supplemental data from REALISE and PEPITES, and let the patient community and industry expert panelists weigh in on the value, efficacy, and safety of such a therapy at an Advisory Committee hearing.

The patient community recognizes that the continued development and availability of the Viaskin peanut patch depends on sustained external support of investors. Without continued investment, this promising treatment may never reach the patient population who need it. The uncertainty surrounding its future also raises broader concerns about the innovation ecosystem for food allergy therapies. People with milk, egg, tree nut, shellfish, fish, wheat, soy, sesame and other food allergies are waiting for successful peanut allergy treatments to open the door for hope in the development of treatments for their allergies. A lack of investment in this space could discourage other companies from pursuing much-needed advancements, limiting future treatment options for millions living with food allergies.

The evidence presented at AAAAI's annual meeting continues to demonstrate that the Viaskin Peanut patch offers a well-tolerated, safe, and efficacious product to peanut allergic children. We urge the FDA to collaborate with DBV on a timely path forward, that can be communicated publicly to all external stakeholders that are anxiously awaiting updates on DBV's future. We believe that the completion of the VITESSE trial and the significant amount of safety data accumulated over the years from prior studies should be more than sufficient to support a BLA application in 4-7-year-olds. We look forward to the opportunity to share the patient voice of the food allergy community during the review process. Thank you in advance for your time and consideration.

Sincerely,

Allergy & Asthma Network
AllergyStrong
Asthma and Allergy Foundation of America
Elijah-Alavi Foundation
Food Allergy & Anaphylaxis Connection Team

Submitted via EMAIL to

david.kaslow@fda.hhs.gov ;
peter.marks@fda.hhs.gov ; and
patientaffairs@fda.hhs.gov