

FDA approves first peanut allergy drug for children

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A new drug is expected to lessen the severity of children's allergic reaction to peanut and is the first of its kind.

The Food and Drug Administration (FDA) has approved the use of Palforzia from Aimmune Therapeutics to treat peanut allergy in children ages 4-17 years.

"The fact there is now a treatment that can potentially provide an extra level of protection for peanut allergic individuals will be tremendously helpful to improve day-to-day functioning and potentially relieve some of the anxiety and quality-of-life effects that come along with the peanut allergy diagnosis," said Julie Wang, M.D., FAAAAI, FACAII, FAAP, chair of the AAP Section on Allergy and Immunology Executive Committee.

About 1 million U.S. children have peanut allergy, and only about 20% outgrow it, according to the FDA.

Children undergoing the treatment will be exposed to small levels of peanut powder that will increase over several months under a doctor's supervision. The treatment will "effectively teach the immune system to be less reactive to peanut," said Dr. Wang, professor of pediatrics at Icahn School of Medicine at Mount Sinai.

Before receiving FDA approval, Palforzia was tested in a randomized, double-blind, placebo-controlled study with about 500 people who are allergic to peanut. After six months of maintenance treatment, about two-thirds were able to tolerate a 600-milligram dose of peanut protein without a severe reaction compared to 4% of a placebo group.

Dr. Wang stressed the need for children on the treatment to continue to avoid all other exposure to peanut and to be prepared for a possible reaction by carrying epinephrine at all times.

The treatment is not appropriate for children with uncontrolled asthma or a history eosinophilic esophagitis or other eosinophilic gastrointestinal disease. It will be available via specially certified clinicians and requires an FDA Risk Evaluation and Mitigation Strategy program to educate health care workers, patients and their families about the risk of anaphylaxis.

The most common side effects, in addition to anaphylaxis, are abdominal pain, vomiting, nausea, tingling in the mouth, itching, cough, runny nose, throat irritation and tightness, hives, wheezing and shortness of breath. Those findings came from two double-blind, placebo-controlled studies that included about 700 people with peanut allergy.

In 2017, [AAP-endorsed guidelines](#) recommended early introduction of peanut to prevent an allergy for infants who are at increased risk. Palforzia differs in that it is intended as a treatment for children who are

older and already have been diagnosed.

“This is a very exciting new development in the field of food allergy,” Dr. Wang said. “... There are a lot of therapies that are in the pipeline such that additional food and/or different approaches to treating food allergies will hopefully be available in the coming years as well to address the larger food allergic population.”

Resources

- [FDA news release on Palforzia](#)
- [Full prescribing information](#)
- [AAP clinical report "Guidance on Completing a Written Allergy and Anaphylaxis Emergency Plan"](#)
- [AAP clinical report "Epinephrine for First-aid Management of Anaphylaxis"](#)
- [Web-based learning tool, Managing Allergy and Anaphylaxis in the Pediatric Clinic and Beyond](#)
- [Information for parents from HealthyChildren.org on anaphylaxis](#)
- [Information for parents from HealthyChildren.org on how to use an epinephrine auto-injector](#)

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