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New Product Is First to Claim It May Reduce Peanut Allergies

By RONI CARYN RABIN SEPT. 14, 2017

A new powdered peanut product is the first food item allowed to claim it may reduce peanut allergies in infants, though parents of susceptible babies are urged to consult a doctor before trying it. The product, called Hello, Peanut, can be mixed into puréed baby food to expose infants to peanuts starting around five months old.

The Food and Drug Administration allowed the new item, developed by a physician, to make the claim just months after the nation's top allergy experts reversed longstanding advice on preventing peanut allergies, dropping recommendations to withhold all peanut-containing foods in early childhood in favor of early, frequent exposure, starting with peanut powder or extract for infants beginning to eat solid food. The label warns that evidence is limited.

While many foods like whole grains, nuts and supplements carry qualified health claims stating that they may reduce the risk of diseases like cancer or heart disease, this is the first time a food product label will be allowed to make a qualified claim that it reduces the risk of an allergy, officials said. A qualified claim means there is evidence supporting the claim, but it is not conclusive.

“This is a very important claim for us to allow to be incorporated into food labels,” said Dr. Scott Gottlieb, the commissioner of the F.D.A. “The guidelines

for how to approach allergens in children are changing, the science is changing, and it's important for parents to know.”

The product consists of packets of organic peanut and sprouted oat blends in powdered form that can be mixed into baby food starting at five months, or soon after an infant starts eating solids. It is meant to be phased in with an introduction kit of seven packets that increases the amount of peanut content every day for a week, starting with a packet for day one that contains 200 milligrams of peanut powder, which is less than a single peanut, and gradually increasing by day seven to 2 grams of peanut, the equivalent of three to seven peanuts. If a baby develops a reaction, such as flushing or hives, parents should stop feeding the child and contact their pediatrician; they should not continue the regimen.

That system can be followed by “maintenance” packets that continue with 2 grams of peanut powder, to be used until a toddler can eat peanut butter or is old enough to chew and swallow peanuts without choking. Studies indicate that regular consumption of peanuts is necessary to maintain the food tolerance.

Dr. David Erstein, an allergist who founded the company Assured Bites, which makes Hello, Peanut, said he hoped the limited health claim on the package will both raise awareness and increase parents' comfort level with the new recommendations.

“There are still a lot of skeptics and anxious parents who are nervous,” he said.

And though the research studies concentrated on high-risk kids, he said, “we think this should be helpful for the general population.”

The label cautions parents whose babies are at high risk for allergies because of eczema or an egg allergy to have their baby evaluated by a doctor and undergo skin or blood testing for peanut allergy before using the product.

“The danger is that someone will misinterpret how to use this product and give it to a child who's already allergic,” said Lianne Mandelbaum, who runs a website for people with food allergies. “People have already come up to me and said ‘this is great news, there's a cure for your son, you just need to feed him a

little of these products that are coming out and he won't be allergic anymore.' That could be potentially dangerous."

The powder is certified organic, dairy-free, kosher and free of genetically modified organisms. The introductory kit is \$25 and the maintenance kit costs \$20 for about three weeks.

Experts say a less expensive alternative for parents is to mix equal parts smooth creamy peanut butter and warm water to make a souplike baby food.

Smooth, creamy peanut butter, cereals and other products that fit the criteria will also be able to make the claim that they reduce the risk of developing a peanut allergy, F.D.A. officials said. Their availability should make it easier for parents to implement the new approach to preventing peanut allergies, which have increased in prevalence in recent years and are responsible for more deaths from anaphylaxis, or constriction of the airways, than any other food allergy.

"People who don't have children with these allergies don't always appreciate the very real danger of a deleterious event that might even lead to death, but even more important, the extraordinary anxiety that pervades the families of children with documented peanut allergies who are afraid of exposing their children," said Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, which is part of the National Institutes of Health. "This is not a trivial problem."

Consumer advocates stressed that parents need to understand that these new products do not treat or cure existing allergies, and emphasized that no peanut products should ever be given to someone who has an established peanut allergy.

"This not a treatment for peanut allergy and it's important that people understand that," said Dr. James R. Baker Jr., chief executive of Food Allergy Research & Education, a patient advocacy group. "If a child is allergic, they should not eat peanut under any circumstances."

But he said it is critical to reduce the development of peanut allergies, and "the easiest way to deal with a food allergy is to keep it from happening."

The new guidelines encouraging early exposure to peanut-containing foods were developed after several studies in recent years seemed to challenge the

advice to ban peanuts in infancy, and culminated in a large long-term clinical trial in England of hundreds of infants at high risk of developing a peanut allergy because of eczema or an allergy to eggs.

Babies who tested positive for an existing peanut allergy were excluded from the study, but the others were randomly assigned either to be fed peanut products regularly or to be denied all peanut-containing foods.

By the time they turned 5, only 1.9 percent of the 530 allergy-prone children who had been fed peanuts regularly since infancy had developed an allergy, compared with 13.7 percent of the children who had abstained from peanuts.

In the United States, the prevalence of peanut allergies among children has been climbing. A recent study by the independent nonprofit FAIR Health found that private insurance claims for anaphylactic reactions to all foods rose nearly 400 percent between 2007 and 2016, but peanuts were the most common food to cause the reaction, responsible for more than one-quarter of the claims. Insurance claims about anaphylactic reactions caused by peanuts increased by nearly 450 percent during the same time period. The analysis was based on FAIR Health's database of 23 billion privately billed health procedures.

Though many children outgrow food allergies, one-third of the claims involved adults over the age of 18, suggesting some allergies may be a lifelong problem.

“One of the reasons it is even more compelling to avoid the onset of peanut allergies is that other types of food allergies — egg, fish and some others — you often, though not always, outgrow the allergy with age,” Dr. Fauci said. “This is generally not the case with peanut at all. Once you get peanut allergies, you essentially have them forever, which is why it becomes even more important to do this prevention through early exposure.”