Patch to treat peanut allergies to get expedited FDA review

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A medical skin patch tested by Seattle-area doctors and families to treat dangerous peanut allergies in children will receive accelerated regulatory review, officials said Thursday.

The Viaskin Peanut patch made by the French biotech firm DBV Technologies was granted a breakthrough therapy designation by the federal Food and Drug Administration.

That status is granted to expedite development and review of drugs or biological products that demonstrate substantial improvement over other therapies in treating serious or life-threatening diseases or conditions. Further study is pending before the FDA's final review.

In the case of the Viaskin patch, it's the first breakthrough designation aimed at a drug to treat food allergies, which affect about 15 million people in the U.S., company officials said.

The new status was based on the results of a recent Phase IIb multicenter clinical trial that showed that the immunotherapy patch boosted the amount of peanut protein it took to elicit an allergic reaction by at least tenfold, particularly in children younger than 12.

Dr. James Tilles, a physician partner at Northwest Asthma & Allergy Center in Seattle, oversaw the study in 11 area participants. He works with the Seattle Food Allergy Consortium, or SeaFAC, which works to bring allergy-related clinical trials to the area.

"To me, the significance is that the FDA is encouraged that there may be an approved treatment for peanut allergy in the near future and they don't want to have logistical hurdles get in the way," Tilles said.

The latest trial tested the safety and effectiveness of the adhesive patches infused with doses of 50 micrograms, 100 micrograms or 250 micrograms of peanut protein. The patches work by administering small amounts of peanut protein in the outer layers of the skin, activating an immune response, but without releasing antigens into the bloodstream, where they can trigger allergic shock.

It's a new kind of treatment that potentially poses fewer challenges and dangers than allergy shots or oral immunotherapy, which are now available.

The 250-microgram patch was the most effective, the study found, with more than half the children ages 6 to 11 responding to the medication.

DBV Technologies is preparing to launch a Phase III clinical trial in children, the last step before the product will be submitted to the FDA for review.

If all goes well, the peanut patch could be commercially available by 2018, Tilles said.