

FDA panel considers first pill for ragweed allergy

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Placed under the tongue, it helps the body immunize itself against the offending plant.

(HealthDay)—There may be good news coming in the form of a pill for the millions of Americans who suffer from ragweed allergy.

On Tuesday, the U.S. Food and Drug Administration's Allergenic Products Advisory Committee will consider whether to recommend approval of the first pill to prevent this annual scourge.

Ragwitek, the brainchild of Merck & Co., is made of ragweed pollen and helps the body become immune to it. Patients begin taking the pill, which is placed under the tongue, 12 weeks before the ragweed pollen season begins and continue through the season's end. In the United States, the ragweed season usually starts in September and runs through the fall.



People suffering from ragweed <u>allergy</u> suffer stuffy noses with sneezing, itching and congestion, as well as itchy and watery eyes. These annoying symptoms can affect quality of sleep and hamper daily activities. Plus, these problems often precede the development of asthma.

Current treatments include a variety of nasal sprays, as well as shots specifically tailored to tame all of a patient's allergies.

Dr. Len Horovitz, a pulmonary specialist at Lenox Hill Hospital in New York City, has his doubts about the power of this new pill. He said people who are allergic to ragweed often are allergic to other plants as well.

"I am skeptical that the pill will work on these other plant allergies," he said.

Another expert, however, said he sees this as a first step in making this kind of allergy treatment a real possibility.

"The whole idea of [under-the-tongue] immunotherapy has been in the background for some time," said William Blouin, an allergy and immunology nurse practitioner at Miami Children's Hospital. "Until this point, immunotherapy has to be done as a series of injections."

A pill would make life simpler, he said, because it wouldn't require the inconvenience of weekly doctor visits or the pain of injections. Blouin said the new pill is intended only for ragweed, so if a person was allergic to other plants it would mean taking a separate pill for each one.

"I understand that there are one or two similar pills in the pipeline," he said.

Last December, the same FDA advisory committee voted unanimously



to recommend approval of a similar kind of pill for grass pollen allergies, known as Grastek. Merck is developing that pill in partnership with a European company.

"Conceptually, it's very desirable, especially for children," Blouin said. Although the pill has been tested only on adults, he said he expects it will be tested on teens and young children at some point.

During Tuesday's committee meeting, the panel will be asked whether the data supports the safety and effectiveness of Ragwitek for people aged 18 and older, and whether more studies are needed before making a recommendation to approve the product.

Merck's five trials showed both improvement in symptoms and in quality of life among those who were taking Ragwitek, the company said.

According to FDA documents, some patients experienced lip swelling, abdominal pain and diarrhea while taking the pill. Other side effects included swollen tongue, difficulty breathing and hives.

More information: Visit the <u>American College of Allergy</u>, <u>Asthma and Immunology</u> for more on ragweed allergy.

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