

FDA panel says no to over-the-counter allergy drug singulair

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Experts expressed relief at the decision, citing safety concerns.

(HealthDay)—A panel of expert advisors to the U.S. Food and Drug Administration on Friday voted overwhelmingly against moving the allergy drug Singulair from prescription to over-the-counter status.

The panel voted 11-to-4 against the sale of the popular medication without a doctor's approval, the *Associated Press* reported.

According to the *AP*, many on the FDA panel felt there were still questions over the safety of making Singulair available without a prescription, especially because some patients would be using it for "off-label" treatment of conditions such as asthma.

The FDA does not have to follow the advice of its expert panels, but it usually does.

Two experts in the care of respiratory illness were happy with the panel's vote.

"My discomfort about Singulair being sold over the counter mirrors the FDA's concern that it may be used inappropriately for the treatment of asthma," said Dr. Andrew Ting, an assistant professor of pediatrics, pulmonary and critical care at The Mount Sinai Hospital in New York City.

"The selection of Singulair over an [inhaled corticosteroid](#) for asthma prevention is a decision that should only be made by trained medical professionals," he said. "The risk of asthmatics using Singulair as a rescue medication or in place of an oral corticosteroid such as prednisone could lead to a significant delay in appropriate treatment for exacerbations."

Ting also noted that "Singulair has possible side effects such as headache, bed wetting and behavioral changes that should be addressed with the patient before beginning the medication."

Dr. Harlan Weinberg is director of pulmonary medicine and pulmonary rehabilitation at Northern Westchester Hospital in Mt. Kisco, N.Y.

"A major concern would be for this medication's inappropriate use in children as well as patients self-medicating their asthma," he said. And Weinberg added that "medication interactions are always a concern and your use of Singulair with other prescription medications must be reviewed with your physician.

Finally, he said, "there are no well-controlled studies in pregnant women or with breast-feeding, for determining fetal or infant risk."

More information: Find out more about a range of allergy and asthma

medications at the [American Academy of Allergy Asthma & Immunology](#).

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