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FDA strengthens warning about mental health side effects linked to montelukast

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The Food and Drug Administration (FDA) is advising clinicians not to prescribe asthma and allergy drug montelukast to patients with mild symptoms, due to the risks of serious behavior and mood-related issues.

Montelukast (Singulair and generics) already includes warnings about mental health side effects but the FDA decided to implement a boxed warning following continued reports of neuropsychiatric events such as agitation, depression, sleeping problems and suicidal thoughts and actions. It also will require patients with a prescription to be given a medication guide.

“With today’s action, the FDA aims to make sure patients and medical providers have the information available to make informed treatment decisions,” Sally Seymour, M.D., director of the Division of Pulmonary, Allergy and Rheumatology Products in the FDA’s Center for Drug Evaluation and Research said in a news release. “Importantly, there are many other safe and effective medications to treat allergies with extensive history of use and safety, such that many products are available over the counter without a prescription.”

The FDA recommends clinicians:

- ask patients about their history of psychiatric illness before prescribing montelukast;
- consider the risks and benefits of montelukast and review them with patients;
- advise patients to stop taking montelukast, and contact a health care professional immediately if they experience changes in behavior or new neuropsychiatric symptoms, suicidal thoughts or behavior;
- monitor all patients treated with montelukast for neuropsychiatric symptoms;
- encourage patients and their parents/caregivers to read the medication guide that explains safety risks; and
- report adverse events to the FDA’s MedWatch program, http://bit.ly/2ptaPRP.

The FDA’s full drug safety communication is available at http://bit.ly/2TJYR1x.