HEALTH REPORT

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"SINGULAIR®" PLACED UNDER INVESTIGATION FOR POSSIBLE LINK TO SUICIDE

Yet another drug is being placed under investigation by the U.S. Federal Drug Administration. This time it is the pharmaceutical drug Singulair manufactured by Merck & Co. Inc.

The FDA has received reports that the drug is responsible for causing behavior/mood changes, suicidality (suicide thinking and behavior) and suicide. The agency has issued a warning to healthcare professionals and users of the drug that it is conducting an investigation even though it is not telling people to immediately stop using the medication.

Singulair is a drug that is used to treat asthma and the symptoms of rhinitis – including runny nose, itching of the nose, sneezing and stuffy nose. It is also prescribed to prevent asthma that is induced by exercise.

Reports to the drug maker have already caused Merck to take action to update prescribing information to doctors and usage information to patients. These updates fall under the area of "post-marketing adverse effects."

Here are the adversely reported effects for which Merck already executed a series of informational updates in the past year for the prescribing of Singular:

- Tremor, March 2007.
- Depression, April 2007.
- Suicidality, October 2007.
- Anxiousness, February 2008.

The FDA has indicated that it may take up to 9 months to determine the results of this investigation. Regardless of the FDA's position on Singulair, it is warning both to doctors and to users to be alert to the risk of altered behavior and suicidal thinking.

Singular falls into a category of drugs known as "leukotriene receptor antagonists." (Leukotriene is a compound that works to regulate allergic and inflammatory reactions.) Additional leukotriene modifying medications include the drugs Accolate®, Zyflo® and Zyflo CR®.

According to the FDA, "Healthcare professionals and caregivers should monitor patients taking Singulair for suicidality and changes in behavior and mood."

Source: The U.S. Food and Drug Administration. "Early Communication about an Ongoing Safety Review of Singulair." April 2008. http://www.fda.gov/cder/drug/early_comm/montelukast.htm and http://www.fda.gov/medwAtch/safety/2008/safety08.htm#Singulair