FDA removes boxed warning from certain asthma medications

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(HealthDay)—New evidence regarding safety is spurring the U.S. Food

and Drug Administration to remove a Boxed Warning from certain inhaled medications used to treat asthma and chronic obstructive pulmonary disease.

The decision applies to long-acting beta agonists (LABAs) used in combination with inhaled corticosteroid (ICS) medications. Brand names for these products include Advair, Airduo, Breo, Dulera, and Symbicort.

In 2011, the FDA told makers of such medicines to conduct large safety trials to assess the risk of serious side effects such as hospitalization, intubation, and death among asthma patients. A review of data from those trials found that treating asthma with LABAs in combination with ICS medicines "does not result in significantly more serious asthma-related side effects than ICS alone. Based on these results, the FDA has approved changes to the labeling of these products removing the Boxed Warning about asthma-related death," the FDA said.

However, the agency said that "using LABAs alone to treat asthma without an ICS to treat lung inflammation is associated with an increased risk of asthma-related death. Therefore, the Boxed Warning stating this will remain in the labeling of all single-ingredient LABA medicines." The FDA also noted that labeling on medicines that contain both an ICS and LABAs will still have a Warning and Precaution about the risk of using LABAs without an ICS for asthma and will provide information on the completed safety trials.

More information: More Information