



Death Risk Warning for Asthma Drugs

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New labels on asthma drugs Advair and Serevent warn patients that the drugs "may increase the risk of asthma-related death."

GlaxoSmithKline, which makes both Advair and Serevent, agreed to the new 'black box' warnings -- the strongest warning a drug label can carry. The agreement follows the FDA's November 2005 request for an update of the drugs' existing black box labels.

Advair and Serevent contain an active ingredient called salmeterol. The drugs are used by patients whose asthma cannot be controlled by steroid-based inhalers alone. While the drugs can reduce the number of asthma attacks, they can make asthma attacks worse when they do occur.

In clinical trials, there were more asthma deaths in patients taking salmeterol than in patients taking an inactive placebo. However, the total number of asthma-related deaths was small -- 13 deaths in 13,176 patients who took salmeterol for seven months.

"GSK has confidence in the proven safety profile of Serevent and Advair when these products are used appropriately," the company says in a news release. "There have been over 48 million prescriptions dispensed for Serevent since introduction in 1995 and over 62 million prescriptions dispensed for Advair since introduction in 2001."

GSK will also provide a new patient medication guide with Advair and Serevent prescriptions.

The FDA in November 2005 also asked drugmaker Novartis to put a similar black box label on its asthma drug, Foradil. The active ingredient in Foradil is in the same drug class as salmeterol. However, no new warning for Foradil has yet been announced.

FDA safety reviewer David Graham, MD, in November 2004 voiced concern about Serevent (and other nonasthma drugs) during congressional drug safety hearings. In July 2005, the FDA convened an expert panel to look at the safety of Serevent, Advair, and Foradil.

The panel recommended that all three drugs continue to be sold in U.S. pharmacies.

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