

Stronger Warnings Advised on Asthma Drug

By REUTERS Published: November 29, 2007 (Reuters) -- Federal regulatory advisers on Wednesday recommended strengthening safety warnings on GlaxoSmithKline's asthma drug Serevent amid reports of deaths in children taking the treatment.

The Food and Drug Administration expert panel on drugs for children reviewed nine adverse-event reports of children taking the inhaled treatment, including five deaths in about a year, among other studies. "The data is very troubling because both the increase in hospitalization and in mortality is so different" from what doctors currently believe, said Dr. Thomas B. Newman, a panel member and an epidemiologist at the University of California, San Francisco. Serevent's use has fallen significantly since reports of asthma deaths came to light a few years ago. But it is an ingredient in Glaxo's blockbuster asthma drug Advair. The new worries could hurt sales of Advair, which were \$6.8 billion in 2006. At least two panel members said Serevent should be taken off the market. The F.D.A. said it would consider the safety of all drugs in the class, called long-acting beta agonists, at a future meeting. "The members of this committee think this is an urgent public health issue," said the panel chairwoman, Dr. Marsha Rappley, a neurology and psychiatry specialist at Michigan State University. Advair contains Serevent and a steroid. One theory suggests that the steroid provides a protective effect against the negative impact of Serevent, but panel members rejected that idea. The group said the label needed to better display the risk of asthma-related deaths. It also said the label needed to show more prominently that the drug was recommended only when other treatments had failed. The F.D.A. typically accepts the recommendations of these advisory panels. Glaxo presented data rebutting the negative reports. Kathy Rickard, vice president for respiratory clinical development at Glaxo, said the company believed that the data showed no increased risk of hospitalization and mortality for Advair.