

Questions: Salmeterol

The committee has been provided background information on safety issues related to salmeterol, including previous deliberations by the Pulmonary Advisory Committee of June 2005 in relationship to the class labeling box warning for asthma-related deaths and that salmeterol only be used as additional therapy for patients not adequately controlled on other asthma-controller medications. Since this meeting, there has been additional safety information concerning the pediatric population, and the Office of Surveillance and Epidemiology has provided an analysis of the available observational pharmacoepidemiology studies and a subgroup analysis of the pediatric populations in clinical trials.

1

Questions: Salmeterol

In view of the evolving issue of risks for the pediatric population, the Agency thinks further assessment of the role of this product in the treatment of pediatric asthma is warranted and plans to bring this issue to a future advisory committee. In the interim please address the following questions:

2

Questions: Salmeterol

1. Pending the completion of further analyses regarding the risks and benefits of salmeterol in pediatric patients, please discuss whether the current labeling and MedGuide adequately communicate the potential risks in children. Please include in your discussions whether the present warning on asthma deaths is adequate for the pediatric population. Also, please address the observed signal of increased pediatric hospitalizations and whether the current labeling adequately addresses this issue.

3

Questions: Salmeterol

2. Please discuss whether the current labeling and MedGuide are clear in the recommendation that salmeterol only be used as additional therapy for patients not adequately controlled on other asthma-controller medications (e.g., low-to-medium dose ICS) or whose disease clearly warrants treatment with two maintenance therapies. In particular, please comment on whether the current labeling and MedGuide clearly communicate that there is no clear evidence that ICS mitigates the risk of asthma-relegated deaths in patients receiving salmeterol.

4