

US Food and Drug Administration

*Joint Meeting of the Pulmonary-Allergy Drugs
Advisory Committee, Drug Safety and Risk
Management Advisory Committee, and the
Pediatric Advisory Committee*

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Objective

- Discuss the risk-benefit of inhaled long-acting beta agonists (LABAs) bronchodilators for the treatment of asthma in adults and pediatric patients

Questions for Discussion and Voting

- Total of 10
- Questions 1-4 are by active LABA ingredient and by age group
- Questions 5-8 are in individual LABA-containing products and by age group
- Questions 5-8 require voting

Question 1

- Discuss the benefits of using salmeterol for the treatment of asthma in patients not adequately controlled on other asthma-controller medications (eg, low- to medium-dose inhaled corticosteroids) or whose disease severity clearly warrants initiation of treatment with two maintenance therapies, in each of the following age groups:
 - In adults [≥ 18 years of age]
 - In adolescents [12-17 years of age]
 - In children [4-11 years of age]

Question 2

- Discuss the benefits of using formoterol for the treatment of asthma in patients not adequately controlled on other asthma-controller medications (eg, low- to medium-dose inhaled corticosteroids) or whose disease severity clearly warrants initiation of treatment with two maintenance therapies, in each of the following age groups:
 - In adults [≥ 18 years of age]
 - In adolescents [12-17 years of age]
 - In children [5-11 years of age]

Question 3

- Discuss the risks of using salmeterol for the treatment of asthma in patients not adequately controlled on other asthma-controller medications (eg, low- to medium-dose inhaled corticosteroids) or whose disease severity clearly warrants initiation of treatment with two maintenance therapies, in each of the following age groups:
 - In adults [≥ 18 years of age]
 - In adolescents [12-17 years of age]
 - In children [4-11 years of age]

Question 4

- Discuss the risks of using formoterol for the treatment of asthma in patients not adequately controlled on other asthma-controller medications (eg, low- to medium-dose inhaled corticosteroids) or whose disease severity clearly warrants initiation of treatment with two maintenance therapies, in each of the following age groups:
 - In adults [≥ 18 years of age]
 - In adolescents [12-17 years of age]
 - In children [5-11 years of age] (Note that Symbicort is not indicated in this age group)

Question 5

- Do the benefits of Serevent (salmeterol xinafoate) outweigh its risks for the maintenance treatment of asthma in patients not adequately controlled on other asthma-controller medications (eg, low- to medium-dose inhaled corticosteroids) or whose disease severity clearly warrants initiation of treatment with two maintenance therapies, in the following age groups:
 - In adults [≥ 18 years of age] (Voting question)
 - In adolescents [12-17 years of age] (Voting question)
 - In children [4-11 years of age] (Voting question)

Question 6

- Do the benefits of Foradil (formoterol fumarate) outweigh its risks for the maintenance treatment of asthma in patients not adequately controlled on other asthma-controller medications (eg, low- to medium-dose inhaled corticosteroids) or whose disease severity clearly warrants initiation of treatment with two maintenance therapies, in the following age groups:
 - In adults [≥ 18 years of age] (Voting question)
 - In adolescents [12-17 years of age] (Voting question)
 - In children [5-11 years of age] (Voting question)

Question 7

- Do the benefits of Advair (fluticasone propionate; salmeterol xinafoate) outweigh its risks for the maintenance treatment of asthma in patients not adequately controlled on other asthma-controller medications (eg, low- to medium-dose inhaled corticosteroids) or whose disease severity clearly warrants initiation of treatment with two maintenance therapies, in the following age groups:
 - In adults [≥ 18 years of age] (Voting question)
 - In adolescents [12-17 years of age] (Voting question)
 - In children [4-11 years of age] (Voting question)

Question 8

- Do the benefits of Symbicort (budesonide and formoterol fumarate dihydrate) outweigh its risks for the maintenance treatment of asthma in patients not adequately controlled on other asthma-controller medications (eg, low- to medium-dose inhaled corticosteroids) or whose disease severity clearly warrants initiation of treatment with two maintenance therapies, in the following age groups:
 - In adults [≥ 18 years of age] (Voting question)
 - In adolescents [12-17 years of age] (Voting question)

Question 9

- Based on your discussion and votes above, are there further labeling changes or risk mitigation strategies for individual LABA products, or the class as a whole, that would be advisable?

Question 10

- What further studies, if any, would clarify important unanswered questions of safety and efficacy for individual LABA products or the class as a whole?

Thank You!