FDA panel backs Glaxo inhaler for adults, not adolescents

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Government health advisers say a once-a-day respiratory inhaler from GlaxoSmithKline appears safe and effective for adults with asthma, but not for adolescents.

The Food and Drug Administration panel of experts voted 18-2 that evidence submitted by the British drugmaker for its Breo Ellipta inhaler does not support its use in asthma patients ages 12 to 17. That followed a positive vote of 16-4 supporting the drug's use in asthma patients 18 and up.

The FDA is not required to follow the recommendations of its experts, though it often does.

Breo Ellipta is already approved in the U.S. for a type of chronic lung disease, but Glaxo is hoping to expand the drug's use to the much larger patient population of roughly 37 million Americans with asthma.

Like several other respiratory drugs, Breo Ellipta combines two inhalable drug ingredients: a steroid and a long-acting beta agonist, or LABA for short. LABA-containing drugs have been subject to FDA warnings for several years and their current labeling warns doctors that they should only be prescribed to asthma patients who can't control their condition with other medications—and then only for the shortest time possible. While LABA drugs can be helpful in preventing day-to-day symptoms for some asthma patients, their use can also mask inflammation that builds up in the lung's airways. That means patients may not realize a

serious asthma attack is brewing until they're gasping for air.

In 2010, FDA required manufacturers of LABA-steroid combination drugs, including Glaxo, to conduct large safety studies measuring rates of hospitalization and death. Results of those studies aren't expected until 2017.

The FDA's panel voted Thursday that Glaxo should be required to conduct a separate large safety study of Breo Ellipta in both adults and adolescents.

LABA drugs do not carry the same risks for patients with other respiratory diseases, and Breo Ellipta was previously approved by the FDA for chronic obstructive pulmonary disorder, or COPD, which can cause chronic bronchitis and emphysema.

Breo Ellipta is one of several drugs Glaxo is counting on to replace deteriorating sales of its best-selling product, Advair, which uses an older combination of LABA and steroid drugs. Sales of Advair, which is approved for both asthma and COPD, fell nearly 20 percent last year to $6.9 billion, according to sales tracker GlobalData. U.S. sales of Advair and other asthma drugs have been squeezed by pharmacy benefit managers, who are increasingly seeking steeper discounts from drugmakers in return for placing their products on formulary lists of preferred medications. Additionally, Advair faces generic competition in some European countries.

London-based Glaxo pays royalties on Breo Ellipta to co-developer Theravance Inc., which is based in San Francisco.

Glaxo said in a statement: "We will continue to work closely with the FDA while it considers the committee's recommendations and our aim is to answer any outstanding questions."