

Long Acting Bronchodilators (LABAs)

On February 18, 2010, the US Food and Drug Administration (FDA) announced that LABAs (salmeterol and formoterol) should never be used alone in the treatment of asthma. They also issued a class label change for these products, thus mandating that manufacturers include this warning in their labeling.

These new requirements are based on FDA analysis of clinical trials showing that use of LABAs has been associated with worsening of asthma symptoms, leading to hospitalization and in very rare cases, death. The drugs involved are salmeterol (Serevent™) and formoterol, (Foradil™) which are available as single agents and in combination with inhaled corticosteroids in the form of Dulera, Symbicort and Advair.

LABAs have previously been approved for chronic therapy of COPD, and intermittent use prior to exercise to protect against exercise-induced bronchoconstriction, but this FDA warning does not readdress these indications.

It is very important to know that the FDA has not banned the use of these medications; rather, they have outlined specific guidelines to be considered when using them.

These guidelines include:

- Patients who are currently taking LABAs should not discontinue their treatment without first consulting a physician. Abruptly stopping medications may result in acute loss of asthma control, which may be life-threatening.
- LABAs should only be used in combination with an asthma controller medication, such as an inhaled corticosteroid. In other words, LABAs should **not** be used alone in treating asthma.
- LABAs should only be used long-term in patients whose asthma cannot be adequately controlled when using asthma controller medications alone.
- If possible, LABAs should only be used for the shortest duration of time required to achieve control of asthma symptoms.
- Pediatric and adolescent patients who require long-term use of LABAs, in addition to an inhaled corticosteroid, should use products containing both agents (Dulera, Advair, or Symbicort) to ensure compliance with both medications.

The Physicians of Colorado Allergy and Asthma Centers have been actively involved in much of the research and debate that surrounds the LABA issue. We agree with the FDA that these medications should be used judiciously and when clinically warranted. Many of us have been treating asthma for over 25 years and have seen first-hand what the addition of these medications have done to benefit our asthmatic patients. In addition, none of us has ever seen a serious reaction associated with the use of LABAs. **If your doctor has prescribed Dulera, Advair or Symbicort, rest assured that all of the above guidelines have been carefully considered.**

Untreated or under-treated asthma poses a much greater risk than using long-acting bronchodilators. We are therefore recommending that you **do not stop your asthma medication without first consulting your physician.** .