FDA Updates U.S. Product Labels for LABA-Containing Medications Including AstraZeneca's SYMBICORT

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WILMINGTON, Del., June 2 /PRNewswire-FirstCall/ -- Today, the U.S. Food and Drug Administration (FDA) released final label revisions for respiratory medications that contain an active ingredient known as a long-acting beta-agonist (LABA). This follows the FDA communication on 18 February 2010 requesting all manufacturers of LABA-containing medications to undertake class-labeling changes.

(Logo: http://www.newscom.com/cgi-bin/prnh/20091027/PH99766LOGO [1])

The FDA made label revisions to both single ingredient and combination LABA-containing medications. For the treatment of asthma, single ingredient LABAs should only be used with an asthma controller medication such as an inhaled corticosteroid (ICS), they should not be used alone. SYMBICORT® (budesonide/formoterol fumarate dihydrate) is an asthma combination medication that contains both an ICS (budesonide) and a LABA (formoterol).

The updated label for combination asthma medications, including SYMBICORT, provides guidance on how these products should be prescribed to treat asthma, including:

- SYMBICORT should only be used for patients not adequately controlled on a long-term asthma control medication such as an inhaled corticosteroid or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and LABA.
- Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g. disco
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