FDA: Get Ready For Phasing Out Of CFC Inhalers

BY JEFF EVANS
Senior Writer

In a public health advisory, the Food and Drug Administration urged health care professionals and their patients and caregivers to switch to hydrofluoroalkane-propelled albuterol inhalers before chlorofluorocarbon-propelled inhalers are taken off the market Jan. 1, 2009.

Chlorofluorocarbon (CFC)-propelled albuterol inhalers will not be produced or sold in the United States in 2009 and beyond in order to meet mandates authorized by the Clean Air Act and an international environmental treaty, the Montreal Protocol on Substances That Deplete the Ozone Layer. CFCs contribute to the depletion of the ozone layer.

Three hydrofluoroalkane (HFA)-propelled albuterol inhalers have been approved by the FDA: Proair HFA Inhalation Aerosol, Proventil HFA Inhalation Aerosol, and Ventolin HFA Inhalation Aerosol. An inhaler containing levalbuterol (similar to albuterol) is available as Xopenex HFA Inhalation Aerosol. HFA-propelled albuterol inhalers are not currently available in generic forms.

"Manufacturers of the HFA versions have created financial assistance programs and eased income restrictions for low-income patients. Physician, pharmacy, and manufacturer's Web sites are also offering coupons for those who face a higher co-pay for these products," said Deborah Henderson, senior adviser in the Office of Executive Programs at the FDA's Center for Drug Evaluation and Research.

The spray from HFA-propelled inhalers may taste and feel different than CFC-propelled inhalers. The properties of HFA and the weaker force of its spray from the inhalers make it "important to clean and prime the inhalers in order for the right dose of medicine to be delivered. Patients should be reinforced with the knowledge that they need to follow the directions very carefully," Ms. Henderson said in a press teleconference.

The changes do not affect the medication's safety or effectiveness, she noted.

In the beginning of 2008, HFA-propelled albuterol inhalers composed only 5%-10% of albuterol inhaler sales in the market—even though the FDA in 2005 had finalized the end date for the sale of CFC-propelled albuterol inhalers. HFA-propelled albuterol inhalers now account for about 65% of the market, according to Dr. Badrul Chowdhury, director of the Division of Pulmonary and Allergy Products at the FDA's Center for Drug Evaluation and Research.

About 52 million albuterol metered-dose inhalers are prescribed in the United States each year, making them among the top 10 prescribed medications in the country, Dr. Chowdhury said during the teleconference.

Over the years, many manufacturers have stopped producing CFC-propelled albuterol inhalers. Currently, only one company, Armstrong Pharmaceuticals Inc., manufactures generic CFC-propelled albuterol inhalers, he said. ■

Resistance Thwarts Asthma Control

BY NANCY WALSH
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TORONTO — Steroid resistance is increasingly being recognized as a factor contributing to uncontrolled asthma and progression of lung disease, according to a pediatric allergy/immunology expert.

Resistance to inhaled corticosteroids is more common than was previously recognized, and can be found in 25%-35% of patients with asthma.

"In general, steroids are extremely effective in asthma, and really are the most effective anti-inflammatory drugs we have; but in any study of inhaled steroids in asthma, there is remarkable variability in response," said Dr. Donald Y.M. Leung, head of pediatric allergy and immunology at the National Jewish Medical and Research Center, Denver.

Multiple factors can contribute to steroid resistance, including genetics and ethnicity, with blacks being affected more commonly than whites, he said at an international conference of the American Thoracic Society. Allergen exposure, smoking, and obesity also have been implicated.

Steroid sensitivity is defined as a greater-than-20% improvement in FEV_1 (forced expiratory volume in 1 second) from baseline after a week of treatment with oral prednisone in doses of 20 mg twice a day, whereas steroid resistance is a less-than-15% improvement, Dr. Leung said.

Investigations of patients who are