DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

June 11, 2008

Dear Colleague,

The Food and Drug Administration (FDA) is seeking your help in communicating an important child health safety issue to schools throughout the United States. We hope you will share the following information with teachers, school nurses, and administrators in order to keep children with asthma safe at school.

On May 30, 2008, FDA issued a public health advisory alerting patients, caregivers, and healthcare professionals to important information about albuterol inhalers that are used to treat bronchospasm (wheezing) in patients with obstructive airways disease, such as asthma. Albuterol inhalers that use CFCs (chlorofluorocarbons) are being phased out and will no longer be available after December 31, 2008. Children who now use albuterol inhalers containing CFCs will need to transition to alternative albuterol inhalers which contain a propellant called HFA. There are currently three approved HFA propelled albuterol inhalers: Proair HFA Inhalation Aerosol, Proventil HFA Inhalation Aerosol, and Ventolin HFA Inhalation Aerosol. In addition, an HFA propelled inhaler containing levalbuterol, the active ingredient of albuterol, is available as Xopenex HFA Inhalation Aerosol. Albuterol HFA inhalers are used in the same way as albuterol CFC inhalers and give the same dose of albuterol as the CFC inhalers.

CFCs and HFAs are the propellants that move the albuterol medicine out of the inhaler into the lungs. CFCs are harmful to the environment and can have negative effects on health. The national transition from CFC propelled to hydrofluoralkane (HFA) propelled albuterol inhalers is due to an international environmental treaty. Under this treaty, the United States has agreed to phase out production and importation of Ozone Depleting Substances (ODS), including CFCs. Healthcare professionals have already started transitioning patients to the HFA propelled albuterol inhalers.

Because Albuterol HFA inhalers have to be cleaned and primed to work in the right way and give the right dose of medicine, it is important to note the following:

- HFA inhalers may taste and feel different than the CFC inhalers. Notably, the force of the spray of an HFA propelled inhaler may feel softer than that of a CFC propelled inhaler.

- Patients should be reassured of the drug's effectiveness, even though the spray may taste different or not feel as strong as that from a CFC inhaler.

- The actuator of an HFA inhaler must be cleaned under warm running water once a week; if it is not kept clean, it can become clogged and the albuterol will not be delivered to the lungs. Each HFA inhaler has different cleaning and drying instructions. Therefore, it is important to read and understand the instructions that come with each of the HFA inhalers before using.

- The HFA inhaler needs to be “primed” before initial use. Each HFA inhaler has different priming instructions. Therefore, it is important to read and understand the instructions that come with each of the HFA inhalers before using.

Additional information, including a Podcast, question and answer sheet, consumer article, and public service announcement can be found on FDA’s website at http://www.fda.gov/cder/mdi/albuterol.htm. The question and answer sheet and consumer article are available in both English and Spanish. To learn more about the transition and get answers to many frequently asked questions, you may also visit the Environmental Protection Agency (EPA) website at http://www.epa.gov/ozone/title6/exemptions/inhalers.html.

If you have questions, please contact Andrea Furia, Health Programs Coordinator or me at (301) 827-4460 or by email at Theresa.Toigo@fda.hhs.gov or Andrea.Furia@fda.hhs.gov.

Thank you for your support of FDA and its public health mission.

Sincerely,

Theresa Toigo, RPh, MBA
Director, Office of Special Health Issues
Food and Drug Administration