DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Services

Food and Drug Administration
Division of Drug Information
10903 New Hampshire Avenue
Silver Springs, MD 20993

August 29, 2008

Dear Colleague,

The Food and Drug Administration (FDA) is seeking your help in communicating an important patient health safety issue to pharmacists throughout the United States. The FDA recognizes that pharmacists are at the frontline regarding patient health. We hope you will share the following information with pharmacists in order to keep patients with asthma and COPD safe as well as informed of the changes regarding their medications.

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 and chronic obstructive pulmonary disease (COPD). Albuterol inhalers that use CFCs (chlorofluorocarbons) are being phased out and will no longer be available after December 31, 2008. Patients who now use albuterol inhalers containing CFCs will need to transition to alternative albuterol inhalers which contain a propellant called hydrofluoralkane (HFA).

There are currently three approved HFA propelled albuterol inhalers:

- **ProAir HFA Inhalation Aerosol**
- **Proventil HFA Inhalation Aerosol**
- **Ventolin HFA Inhalation Aerosol**

In addition, an HFA-propelled inhaler containing levalbuterol, an enantiomer 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.

Any of the three HFA-propelled products containing the active moiety albuterol (ProAir HFA Inhalation Aerosol, Proventil HFA Inhalation Aerosol, and Ventolin HFA Inhalation Aerosol) are adequate replacements for CFC-propelled products containing albuterol, but there are differences among these products that healthcare providers and pharmacists should be made aware. These three products are not generic products to CFC-propelled albuterol MDIs.

CFCs and HFAs are the propellants that move the albuterol medicine out of the inhaler so that patients can breathe the albuterol medicine 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.

The labeling for Proventil-HFA Inhalation Aerosol, Ventolin-HFA Inhalation Aerosol, Pro Air-HFA Inhalation Aerosol, and Xopenex HFA Inhalation Aerosol may be found at:

DRUGS@FDA: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm

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/phaseout/mdi/.

If you have questions, please contact the Division of Drug Information's toll free number 1-888-INFO-FDA (1-888-463-6332), or by email at druginfo@fda.hhs.gov.

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

Sincerely,

Barry W. Poole, RPh
Director, Division of Drug Information
Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration