



PROVIDER *bulletin*

April 22, 2010

Dear Provider:

The FDA has issued an update to the phase out inhalers that deplete the ozone by CFCs. Please see the enclosed letter detailing the timelines and rationale. Action steps are also provided in the news release. Some products have already been discontinued by the manufacturer in anticipation of this action. Below are the KHS formulary products that will be affected and the alternative for your convenience.

Phased out inhaler

Alupent Inhalation Aerosol (metaproterenol)

Intal Inhaler (cromolyn)

Aerobid Inhaler System (flunisolide)

(budesonide)

propionate)

Combivent Inhalation Aerosol (albuterol and ipratropium)

Maxair Autohaler (pirbuterol)

Alternate inhaler

Ventolin HFA (albuterol)

QVAR (beclomethasone dipropionate)
Pulmicort Turbohaler/Flexhaler

Flovent HFA/Diskus (fluticasone

Ventolin HFA (albuterol)
Atrovent HFA (ipratropium bromide)

Ventolin HFA (albuterol)

Sincerely,

Bruce Wearda, R.Ph.
Corporate Pharmacist



FDA U.S. Food and Drug Administration

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News & Events

FDA NEWS RELEASE

For Immediate Release: Apr. 13, 2010

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Consumer Inquiries: 888-INFO-FDA

Asthma and COPD Inhalers That Contain Ozone-depleting CFCs to be Phased Out; Alternative Treatments Available

The U.S. Food and Drug Administration today announced, in accordance with longstanding U.S. obligations under the Montreal Protocol on Substances that Deplete the Ozone Layer, seven metered-dose inhalers (MDI) used to treat asthma and chronic obstructive pulmonary disease (COPD) will be gradually removed from the U.S. marketplace. These inhalers contain ozone-depleting chlorofluorocarbons (CFCs), which are propellants that move medication out of the inhaler and into the lungs of patients. Alternative medications that do not contain CFCs are available.

The affected products and their phase out schedule include:

Inhaler Medication	Last Date to be manufactured, sold or dispensed in U.S.	Manufacturer
Tilade Inhaler (nedocromil)	June 14, 2010	King Pharmaceuticals
Alupent Inhalation Aerosol (metaproterenol)	June 14, 2010	Boehringer Ingelheim Pharmaceuticals
Azmacort Inhalation Aerosol (triamcinolone)	Dec. 31, 2010	Abbott Laboratories
Intal Inhaler (cromolyn)	Dec. 31, 2010	King Pharmaceuticals
Aerobid Inhaler System (flunisolide)	June 30, 2011	Forest Laboratories
Combivent Inhalation Aerosol (albuterol and ipratropium in combination)	Dec. 31, 2013	Boehringer Ingelheim Pharmaceuticals
Maxair Autohaler (pirbuterol)	Dec. 31, 2013	Graceway Pharmaceuticals

Patients using the inhalers scheduled to be phased out should talk to their health care professional about switching to one of several alternative treatments currently available. Until then, patients should continue using their current inhaler medication.

CFCs are harmful because they deplete the ozone layer miles above the Earth that absorb some of the sun's harmful ultraviolet rays. The United States has banned the general use of CFCs in consumer aerosols for decades, and eliminated the production of CFCs in the United States as of Jan. 1, 1996, except for certain limited uses, such as MDIs.

"During this transition, FDA wants to ensure that patients have access to safe and effective alternative medications to treat their asthma or COPD," said Badrul Chowdhury, M.D., Ph.D., director of the Division of Pulmonary, Allergy, and Rheumatology Products in FDA's Center for Drug Evaluation and Research. "We are currently working with professional societies and patient organizations to make sure patients understand which products will no longer be available and have information on which alternative medication might work best for them."

The CFC phase out is part of an international agreement to ban substances that deplete the Earth's ozone layer. The Montreal Protocol on Substances that Deplete the Ozone Layer and the U.S. Clean Air Act aim to protect the public health and the environment from the potentially negative effects of ozone depletion. Bans on products containing CFCs began in the late 1970s.

The decision to phase out the products is the latest in a series of decisions related to the removal of CFC inhaler products from the market as required by the Clean Air Act. The agency proposed to phase-out the seven remaining products in 2007 and reached a final decision after reviewing more than 4,000 public comments and information submitted as part of a public meeting.

For more information:

- Seven Inhalers That Use CFCs Being Phased Out¹
- Phase Out of CFC Metered-Dose Inhalers²
- Metered-Dose Inhalers Clean Air Act Information³
- Drug Treatments for Asthma and Chronic Obstructive Pulmonary Disease that Do Not Use Chlorofluorocarbons⁴

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RSS Feed for FDA News Releases⁵ [what is RSS?⁶]

Links on this page:

1. <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm207864.htm>
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3. <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm071523.htm>
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