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FDA NEWS RELEASE

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FDA: Over-the-counter asthma inhalers containing chlorofluorocarbons (CFCs) will no longer be made or sold after Dec. 31 2011

Users of Primatene Mist will need a prescription product to treat their asthma

The U.S. Food and Drug Administration says users of epinephrine inhalers containing chlorofluorocarbons (CFCs) should plan now to get a prescription for a replacement product because these inhalers will not be made or sold after Dec. 31, 2011.

Epinephrine inhalers, marketed by Armstrong Pharmaceutical Inc. as Primatene Mist, are the only FDA-approved inhalers for the temporary relief of occasional symptoms of mild asthma that are sold over-the-counter in retail stores without a prescription. The product uses CFCs to propel the medicine out of the inhaler so that consumers can breathe it into their lungs.

However, Primatene Mist will no longer be available by year's end because no CFC-containing epinephrine inhalers can be made or sold after Dec. 31, 2011, to comply with obligations made under the Montreal Protocol on Substances that Deplete the Ozone Layer. This is an international agreement signed by the United States, in which countries agreed to phase-out substances that deplete the ozone layer, including CFCs, after certain dates.

"If you rely on an over-the-counter inhaler to relieve your asthma symptoms, it is important that you contact a health care professional to talk about switching to a different medicine to treat your asthma," said Badrul Chowdhury, M.D., director of the Division of Pulmonary, Allergy and Rheumatology Products in the FDA's Center for Drug Evaluation and Research.

The FDA began public discussions about the use of CFCs in epinephrine inhalers in January 2006. The FDA finalized the phase-out date for using CFCs in these inhalers and notified the public in November 2008. Many manufacturers have changed their inhalers to replace CFCs with an environmentally-friendly propellant called hydrofluoroalkane (HFA). There is currently no HFA version of epinephrine inhalers.

There are, however, many other safe and effective inhalers to treat asthma symptoms. All of these inhalers require a prescription, which must come from a licensed health care professional (physician, physician's assistant or nurse practitioner). Current epinephrine inhaler users that don't have a health care professional to write them a new prescription can ask a family member or friend what doctor they use and would recommend, or they can visit a federally-qualified health center, local clinic, community health center, or minute-clinic (sometimes located in pharmacies) to see a health care professional and get a prescription.

Primatene Mist already carries a prominent notice about the phase-out date on its product label, and the FDA encourages Armstrong Pharmaceutical to further educate consumers as the deadline approaches to ensure an incident-free transition. The agency also will continue to work with retailers and pharmacies to facilitate a smooth phase-out of this CFC product and is prepared to review applications for replacement products.

For more information:

- [Phase Out of Epinephrine CFC Metered-Dose Inhalers](#)¹
- [Epinephrine CFC Metered-dose Inhalers - Questions and Answers](#)

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- [Consumer Update: Primatene Mist with Chlorofluorocarbons No Longer Available After Dec. 31, 2011](#)

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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