American Latex Allergy Association

FDA Proposing Phase Out of CFCs in Metered-Dose Inhalers for Epinephrine

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The U.S. Food and Drug Administration today proposed a change to its regulation on the use of chlorofluorocarbons or CFCs in metered dose inhalers (MDIs) for epinephrine. The rule would remove the ?essential-use? designation that allows the use of CFCs in these medical devices.

Epinephrine MDIs are used for the temporary relief of occasional symptoms of mild asthma.

FDA has tentatively concluded that there are no substantial technical barriers to formulating epinephrine as a product that does not release CFCs. Under the proposed rule, epinephrine MDIs containing CFCs would be removed from the market by the end of 2010. A 60-day public comment period will commence following publication of the proposed rule in the Federal Register, and an open public meeting on the essential use of epinephrine will be held on a date to be announced later.

The Clean Air Act permits CFCs to be used in medical products, if the use is determined to be essential by FDA. The use of CFCs has been generally banned in consumer aerosols, such as hairspray, in the United States since 1978 because of adverse effects on stratospheric ozone levels.

The production of CFCs is being phased out worldwide under the terms of an international agreement called the Montreal Protocol on Substances that Deplete the Ozone Layer. Most MDIs available in the United States once contained CFCs; however most such products have recently been or are being reformulated to use other substances as propellants.

Epinephrine MDIs are the only devices currently marketed over the counter. Should this rule become final, epinephrine MDI users will have to obtain a prescription for alternative drug products if a non-CFC epinephrine inhaler still does not exist.

For more information, visit the link below.
Link to original article
http://www.fda.gov/OHRMS/DOCKETS/98fr/07-4663.htm [1]

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