



Sutter Health

0116 04 JUL 18 19:25

To: Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

From: Katherine Rix, Pharm.D. *KR*
Clinical Pharmacy Coordinator, Sutter Health
2200 River Plaza Drive, Sacramento, CA 95833

Subject: Docket No. 2003P-0029 – FDA Proposed withdrawing “essential-use” status for albuterol metered-dose inhalers using Chlorofluorocarbon (CFC) propellants.

To Whom It May Concern:

Upon the request of the Food and Drug Administration, I am writing to urge the FDA to not remove ‘essential-use’ status from albuterol metered dose inhalers using CFC propellants. Although the reasons for phase out of these products are convincing, the FDA must also weigh the potential public health impacts of such an action.

Currently, non-CFC products retail for \$36 - \$42.00 each. With market exclusivity, the prices of these products could be expected to increase. In comparison, comparable CFC-containing products retail for less than \$20.00. I, among many healthcare, community and social organizations, feel that this cost differential may inhibit some from obtaining the lifesaving medication needed in the event of breathing difficulties or an ‘asthma attack’. Discouraging persons with asthma or COPD who rely on ready access to life-saving medication and affordable health care may result in increased costs (emergency room visits, hospitalizations or lost productivity) and reduced quality of life or even death.

To ensure all persons with asthma and COPD can maintain access to affordable medications and healthcare, please support our need to maintain ‘essential-use’ designation on albuterol CFC-containing MDIs.

In closing, I would like to thank the FDA for their continued work on promoting and protecting the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use. Your commitment to protecting consumers and promoting public health is evident and appreciated.

Best regards,

Katherine Rix

2003P-0029

C 19