

January 6, 2006

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Use of Ozone Depleting Propellants; Removal of Essential Use Designation for Over-the-Counter Epinephrine Metered-Dose Inhalers (MDIs)

To Whom It May Concern:

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

The National Association of Chain Drug Stores (NACDS) is providing comments on the agency's plans to address the continued need for the designation of over-the-counter (OTC) epinephrine metered-dose inhalers (MDIs) for the treatment of asthma as an "essential use" of ozone-depleting substances (ODSs). NACDS is the nation's largest community pharmacy organization, representing close to 200 chain pharmacy companies operating nearly 32,000 retail community pharmacies. Our member pharmacies serve as the largest providers of outpatient prescription medications in the nation, filling over 70 percent of the more than 3 billion outpatient prescriptions dispensed annually in the United States.

The Montreal Protocol plans to eliminate products that contain ozone-depleting substances (ODSs), such as the chlorofluorocarbon (CFC) propellant within epinephrine metered-dose inhalers (MDIs). While NACDS understands and recognizes the need for eventual removal of harmful ODSs from all products, including CFCs in MDIs, the Protocol also allows "essential use" products to remain available on the market as long as there are no available alternatives and they are essential for certain manufacturing or medical purposes. No alternatives exist for over-the-counter epinephrine MDIs and this medication serves a significant medical purpose for patients in need of immediate treatment for asthmatic symptoms. For these reasons, NACDS believes this product should continue to be deemed an "essential use" product under the Montreal Protocol.

According to a Wyeth Consumer Healthcare Survey, about 30% or six million of all asthma sufferers use an OTC epinephrine mist.¹ If OTC epinephrine MDIs lose their "essential use" designation, NACDS is concerned that many asthmatic patients will not be adequately treated for their disease and therefore, could be placed at an increased risk for health complications. Additionally, this would increase cost to consumers, governments, and the overall health care system in general.

(703) 549-3001

Fax (703) 836-4869

www.nacds.org

¹ 2005 WCH Internet Asthma Omnibus Study by Market Tools, Nov. 2005.

No alternatives exist for OTC epinephrine MDIs

In 1999, the FDA issued a proposed rule which said that more than one CFC-free product alternative should be available with the active ingredient before MDIs containing these substances are phased out. Because MDIs containing epinephrine represent the only OTC rescue therapy for asthma currently on the market, we believe this medication should be permitted to remain available until alternatives are produced.

The role of OTC epinephrine MDIs in the treatment of asthma

Because asthmatic patients need regular attention from health care professionals, many have questioned the role of OTC rescue therapies in asthma. The Wyeth Consumer survey, mentioned above, states that as many as four million of the six million patients who use OTC epinephrine MDIs use them as a supplement to their prescription inhalers. This demonstrates that most patients using OTC epinephrine MDIs do so only when needed and have appropriate medical care under a physician. In addition, the FDA has approved Primatene® Mist, an OTC epinephrine MDI, as a safe and effective product indicated to relieve shortness of breath, tightness of chest and wheezing due to physician-diagnosed bronchial asthma. Because Primatene® Mist is safe and most often taken only as a supplement to other prescription therapies when needed, we believe OTC epinephrine MDIs play a significant role in the immediate management of asthmatic symptoms.

FDA criteria for “essential use” are met

FDA explains there are three criteria products must meet to continue ODS “essential use” designation. First, there must be “substantial technical barriers” to formulating the product with ODS. The manufacturer of Primatene® Mist, the only OTC epinephrine MDI currently available, has made public the following. “Wyeth Consumer Healthcare has made several attempts to reformulate Primatene® Mist since the 1987 Montreal Protocol. The product is complex and the chemistry of finding non-CFC alternatives that can be successfully combined with the active ingredients has been challenging. Wyeth Consumer Healthcare is working to reformulate the product using the propellant hydrofloroalkane (HFA), a non-ODS ingredient, to carry epinephrine into the lungs.” The Manufacturer of Primatene® Mist estimates it will take four years to bring a non-ODS alternative to market and we ask that the “essential use” designation be extended to allow sufficient quantities of this new product to be available.

Secondly, according to FDA criteria, the product “must provide an otherwise unavailable important public health benefit.” Because epinephrine MDIs are the only OTC rescue

therapy available for asthma, this product serves a significant need to patients who are unable to obtain prescriptions when pharmacies are closed or due to cost concerns.

Finally, to retain “essential use” designation, the FDA criteria state that the product should not “release cumulative significant amounts of ODS into the atmosphere or the release is warranted in view of the high probability of unavailable important public health benefit.” When taking into consideration the currently available medical products which contain ODS, the amount of CFC released by OTC epinephrine MDIs is significantly low. Therefore, we believe the release is warranted.

Cost considerations

Because OTC epinephrine MDIs are less costly than many prescription MDIs, they provide an option to patients without prescription coverage or those who cannot afford these more expensive therapies. At the current time, most prescription MDIs are available as brand name only products and therefore, create significant cost barriers. The removal of the only OTC rescue therapy will cause many patients to be unable to afford treatments for their asthma and put them at risk for serious health complications. Additionally, costs will be increased for the government and the health care system.

Conclusions and recommendations

For the reasons described above, NACDS requests the FDA to extend the “essential use” designation of OTC epinephrine MDIs to ensure patients have access to at least one over-the-counter rescue treatment for asthma until sufficient supplies of this ingredient are available in non-ODS MDIs.

We appreciate your consideration of our views.

Sincerely,



John M. Coster, Ph.D., R.Ph.
Vice President, Policy and Programs

