



January 25, 2019

Troyden Brennan, Chief Medical Officer
CVS Health
One CVS Drive
Woonsocket, Rhode Island 02895

Dear Mr. Brennan,

On behalf of the below signed patient and medical professional organizations, we strongly urge you to consider keeping Primatene Mist HFA “behind the counter” to help reduce inappropriate use of this medication and to protect patients from adverse events.

The Food and Drug Administration recently approved inhaled epinephrine (Primatene Mist HFA) as over-the-counter (OTC) treatment for patients with mild, intermittent asthma. We are concerned by FDA’s decision and believe steps should be taken to reduce the potential severe adverse outcomes that will likely result from the return of inhaled epinephrine to the U.S. market.

As you may know, the use of inhaled epinephrine is NOT considered appropriate treatment for the management of asthma – regardless of the level of asthma severity. Several expert panels have produced evidence-based recommendations on the treatment of asthma. None of these guidelines recommend the use of inhaled epinephrine to treat asthma. In fact, the National Asthma Education and Prevention Program (NAEPP), an expert panel convened by the National Institutes of Health, issued treatment guidelines for the management of asthma. NAEPP recommends **against** the use of epinephrine for treating asthma exacerbations, stating:

The less beta2-selective agents (isoproterenol, metaproterenol, isoetharine, and **epinephrine**) are not recommended due to their potential for excessive cardiac stimulation, especially in high doses.” (*emphasis added*)

Without pharmacists' guidance, unlimited access to inhaled epinephrine will jeopardize patient safety. Asthma is a serious respiratory condition and even patients with mild or intermittent asthma can experience life-threatening asthma exacerbations. We are concerned that many of the 25 million Americans with asthma will view inhaled epinephrine as an "equivalent substitute" for more effective prescription drugs to manage their asthma. Those who choose to treat their asthma with over-the-counter products will not have the benefit of more appropriate asthma medications that have been proven to reduce asthma exacerbations, improve symptom control, and have fewer side effects.

Placing inhaled epinephrine behind the counter will give pharmacists the opportunity to counsel patients on the risks and limitations of using inhaled epinephrine to treat asthma symptoms and, when appropriate, guide patients to primary care providers or appropriate specialists to prescribe patients safer and more effective medications.

The Food and Drug Administration does not have the authority to require an OTC drug to be placed behind the counter. The limited instances of products being held behind the counter (i.e., pseudoephedrine/Sudafed) are based on the Drug Enforcement Agency or state law authority to limit the sales of products that may be used to create illicit drugs. While FDA does not have the authority to require that OTC drugs be held behind the counter, pharmacies do have discretion to hold these products behind the counter in the interests of patient health and safety. We urge you to use your discretion and place inhaled epinephrine behind the counter to help best serve the needs of your customers who have asthma.

We would be happy to answer any questions you may have.

Sincerely,

Advocacy Council of the American College of Allergy, Asthma & Immunology
Allergy and Asthma Foundation of America
Allergy and Asthma Network
American Academy of Allergy, Asthma & Immunology
American Academy of Otolaryngic Allergy
American Academy of Pediatrics
American Association of Respiratory Care
American College of Allergy, Asthma and Immunology
American College of Chest Physicians (CHEST)
American Lung Association
American Thoracic Society
Society of Critical Care Medicine

ⁱ National Asthma Education Prevention Program– Expert Report 2 (1997) p. 64 figure 3-2.