



AMERICAN ASSOCIATION FOR RESPIRATORY CARE
9425 N. MacArthur Blvd, Suite 100, Irving, TX 75063-4706
(972) 243-2272, Fax (972) 484-2720
<http://www.aarc.org>, E-mail: info@aarc.org

October 15, 2007

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

Docket No. 2007N-0262
(RIN number 0910-AF92)

To Whom It May Concern:

The American Association for Respiratory Care (AARC) welcomes the opportunity to comment on the Food and Drug Administration's (FDA) proposed rule: **Use of Ozone-Depleting Substances (ODS); Removal of Essential-Use Designation for Epinephrine used in Oral Pressurized metered-dose inhalers (MDIs).**

The AARC represents over 43,000 respiratory therapists who provide care for patients with a wide range of lung diseases. Respiratory therapists are the only health care profession that receives comprehensive formal education in all aspects of respiratory therapy.

The AARC continues to endorse the goals of the Montreal Protocols and the provisions of the Clean Air Act. Further, we continue to offer our support for the global transition away from CFC Metered Dose Inhalers (MDIs). One of the most important conditions that must be met to remove a CFC driven medication from the essential use list is that there must be a comparable substitute.

The FDA, in consultation with the Environmental Protection Agency (EPA) has determined that there are no substantial technical barriers to formulating epinephrine as a product that does not release oxygen depleting substances (ODS) into the environment. Therefore, the Agency has determined that within a very reasonable timeframe epinephrine will no longer be designated as an essential use medication and will be removed from the market.

The AARC is in support of this proposal.

We applaud the FDA and the measured assessment that that the Agency has provided for its proposed rule. The issues regarding the economic and clinical impact on patients, providers, and manufacturers that this proposal will engender have been clearly addressed in the proposed rule.

Concerns with OTC Bronchodilator Products

The AARC has, for many years, raised concerns with the availability of over the counter (OTC) epinephrine (in any formulation) and other OTC bronchodilator products. Our concerns, which we enumerated in a previous comment to the FDA (November 1, 2005 Docket No. 1995N-0205 (RIN number 0910-AF32) are the continued ease of the availability of these products without patient training and education in the use of these inhaled medications. These critical compliance components are absent when using OTC inhaled medications. Self-medication of any inhaled medication to treat respiratory conditions without any clinical input from health care clinicians to instruct and train the user can endanger the health of the patient/consumer.

Epinephrine medications are administered through MDIs, just as are prescription aerosolized medications. Unlike most forms of drug therapy, the success of aerosol therapy requires that the individual master a complex technique to inhale the drug deeply into the airways. Misuse or improper use (such as poor technique) of an MDI can severely compromise a patient's health and physical condition.

The AARC recognizes that epinephrine has been available OTC to the American consumer for many years, and that, if implemented this regulation will not be supported by certain stakeholders, including affected consumers.

We acknowledge as does the FDA that costs to the consumer will increase as a physician office visit will be required and the cost of obtaining a prescription medication in lieu of an OTC product will also be required. While we do not dismiss the immediate cost impact on the consumer, the offset in the potential decrease in emergency room visits, hospitalizations and improvement in a patient's lung health due to proper care, education and training instructions must be viewed as outweighing the financial impact on the individual.

We believe that the when implemented the FDA regulation regarding epinephrine will have positive impact on the health of the American public afflicted with lung disease. The AARC supports the FDA proposed regulation.

Sincerely,

A handwritten signature in black ink, appearing to read "Toni Rodriguez". The signature is fluid and cursive, with a large, stylized "R" and "z".

Toni Rodriguez, EdD, RRT
President