Statement of the American Pharmacists Association (APhA)
to the Food and Drug Administration's
Nonprescription Drugs Advisory Committee and the
Pulmonary-Allergy Drugs Advisory Committee
Use of Ozone-Depleting Substance:
Essential-Use Determination of OTC Epinephrine Metered Dose Inhalers
January 24, 2006

Thank you for the opportunity to comment on the continued need for the designation of over-the-counter (OTC) epinephrine-metered dose inhalers for the treatment of asthma as an essential use of ozone-depleting substances. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 53,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

The Food and Drug Administration (FDA) first announced its intention to amend its regulations to remove the essential-use designation for self-pressurized inhalers that contain chlorofluorocarbons (CFCs) in 1997. The Agency proposed this action to reduce the amount of ozone-depleting CFCs released into the Earth's atmosphere and to comply with the Montreal Protocol which directs developed countries to identify a date by which the country will stop seeking essential-use exemptions for CFCs. APhA understands the important environmental concerns motivating the Agency's actions and the Association's comments on this issue mirrors our position on the essential use designation for prescription inhalation products – our position is applicable to OTC products as well. There is clearly a need to rid the environment of CFCs that damage the Earth's ozone layer and increase the risk of health conditions such as cancer and cataracts. The question is not whether the essential-use designation should be removed, but when and how that transition should occur.

The transition from epinephrine-metered dose inhalers (MDIs) to non-CFC MDIs must be carefully designed to ensure that consumers' medical needs are adequately met. Obstructive lung diseases, including asthma, affect consumers of all ages, and inhalation therapies are the primary method of treating and controlling these conditions. A phase-out of CFC propellants used in OTC epinephrine MDIs could have a significant impact on the treatment of consumers with mild to intermittent asthma. The Agency must consider the effects the transition will have on these consumers when considering the essential use designation at question.

The transition from epinephrine MDIs with CFC propellants may pose financial and logistical barriers for some consumers. Over 31 million children and adults have been diagnosed with asthma[1] and many of these individuals use an inhaler to treat sudden asthma symptoms. While there are a number of prescription MDIs available, CFC-containing epinephrine MDIs are the only OTC inhalers currently available which are approved for the treatment of asthma. The removal of the essential-use designation for epinephrine MDIs would result in the removal of <u>all</u>

[1] National Center for Health Statistics. National Health Interview Survey. 2001.

over-the-counter MDIs from the market. Consumers will be required to switch to a prescription product. Consumers forced to switch from a CFC-containing epinephrine MDI that is available as a OTC to a prescription medication can expect higher medication costs as well as increased costs for physician or emergency room visits. An increase in cost could decrease access to vital medications.

The switch from one MDI product to another may also create consumer anxiety. Modifying a consumer's therapy or switching to another medication, even if the new therapy is equally effective or superior to their current medication, may be difficult for the consumer. Consumers must feel confident that their new therapy provides the same therapeutic benefit. Some pharmacists have reported working with consumers who express concerns about new prescription inhalation therapies. For example, consumers who switch from a pressurized MDI to a dry-powder inhaler have questioned the quality of the spray from the device because it is different from what they are used to. Consumers have also questioned the variation in taste of the product. While these issues of preference are not insurmountable barriers to overcome, they could affect how non-CFC MDIs are accepted by patients.

As the Advisory Committees examine the continued need for the essential use designation for OTC epinephrine MDIs, APhA urges the Agency to weigh the public health benefits of the products. Specifically, the Agency should assess whether removal of the products from the marketplace would create significant financial and logistical barriers for consumers with asthma, and whether these barriers would prevent consumers from obtaining appropriate asthma treatment. While the Agency's ultimate decision should be based on the same criteria used during the evaluation of prescription MDIs that contain CFCs, there is one significant difference between the two categories of products that must be considered. Unlike prescription MDIs utilizing CFCs, which have a number of non-CFC alternatives available, there are no OTC alternatives available for epinephrine MDIs. In the Agency's decision last year to remove the essential use designation for the prescription product albuterol by December 2008, the FDA based its action on a number of factors including the availability of a sufficient number of alternatives with the same indication and approximate level of convenience.[2] Before removing the essential use designation for OTC MDI products, the same test should be met.

If OTC epinephrine MDIs are deemed non-essential, APhA requests that the Agency coordinate its efforts to communicate information about the product's removal from the market with pharmacists and other health care professionals. The key to consumer acceptance and a smooth transition process to a prescription inhalation device is education. Consumers must be informed about the CFC-transition issue, the reason for the transition, and the steps that the Agency is taking to ensure that safe, effective, and acceptable alternative therapies are available. This will require an effective communication strategy designed to reduce confusion, concern, and anxiety among patients. It is particularly important that when consumers learn that the transition is due to the harmful effects of the CFCs, that they are reassured that their current epinephrine MDIs are not flawed or doing them harm. The tremendous responsibility for educating consumers about the transition process, and counseling, observing, and ensuring proper use of alternative therapies, will fall on the nation's health professionals, including pharmacists.

[2] FDA "Questions and Answers on Final Rule of Albuterol MDIs". www.fda.gov/cder/mdi/mdifaqs.htm.

In conclusion, APhA reiterates its appreciation of the Agency's efforts to fully examine the issues related to the removal of the essential-use designation for OTC epinephrine MDIs. Both prescription and OTC MDIs play an important role in the treatment of consumers with asthma. The transition to other non-ozone-depleting therapies will not be easy; however, it is a necessary step to address important environmental concerns. As the FDA evaluates the essential use designation for epinephrine MDIs, we recommend that the Agency consider the effects the product's removal from the market will have on consumers – both financially and logistically – and the need to coordinate communication about the change with health care professionals. Carefully considering these factors will allow the Agency to develop a smooth transition process with the least detrimental impact on patients. APhA would be happy to offer our assistance to the Agency in this process.

Thank you for your consideration of the views of the nation's pharmacists.