



AMERICAN ASSOCIATION FOR RESPIRATORY CARE
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Division of Dockets Management
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket No. 1995N-0205 (RIN number 0910-AF32)

Proposed Amendment of Monograph for Over-the-Counter Bronchodilator Drug Products

Dear Sirs:

The American Association for Respiratory Care (AARC) a 38,000 member professional association of respiratory therapists welcomes the opportunity to comment on the Food and Drug Administration's (FDA) proposed revisions to the Monograph for over the counter (OTC) bronchodilator drug products.

Respiratory therapists comprise the only health care profession that receives comprehensive formal education in all aspects of respiratory therapy. These licensed professionals undergo rigorous validated competency testing over the full scope of practice which includes diagnosis, treatment, and management of all respiratory diseases and conditions. Patients who suffer from cystic fibrosis, asthma, emphysema, chronic obstructive pulmonary disease, lung cancer are cared for by the respiratory therapist. They are responsible for management of mechanically ventilated patients, administration of a wide range of prescription medications via aerosol therapy as well as all aspects of oxygen therapy including assessment of the patient's needs, titrating oxygen dosage and selection of the appropriate oxygen delivery devices.

The AARC has taken the lead at the national level in many asthma management education programs. Since its inception the AARC has been a key member of the National Asthma Education and Prevention Program. Respiratory therapists are recognized as essential health care practitioners in asthma management services.

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General Concerns with OTC Bronchodilator Products

While the AARC recognizes that bronchodilator medications and devices have been available OTC to the American consumer for many years, we have continuing concerns with the overall medical appropriateness and easy availability of these medications, absent clear patient education, training and instructions. Respiratory therapists are acutely aware of the necessity of proper use, proper training and proper instruction in the use of any medication that is inhaled, and the clinical result if the medication or devices are not used properly.

OTC bronchodilator medications are administered through metered-dose inhalers (MDIs), just as are prescription aerosolized medications. MDIs are the most common devices worldwide for therapeutic aerosol delivery and are the most common form of medication next to the pill or tablet. However, it is important for the FDA to realize that an inhaled medication, whether it is prescription or OTC, is not as simple as taking a pill or tablet.

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. Not only can a lack of instruction or even poor instruction compromise the patient's health, but also improperly administered medications can waste medication, which can prove costly to the consumer.

We would also warn that continued reliance or use of OTC bronchodilators to relieve asthma symptoms without the controller medications or seeking medical assistance is potentially dangerous.

With these above concerns in mind, the AARC offers the following comments.

Enhanced Warning Labels

The AARC recognizes that respiratory impaired patients, particularly those suffering from asthma have easy access to many over the counter bronchodilator drugs that can assist them. We have stated our concerns in the above paragraphs regarding the lack of formal patient instruction and education on the proper way to administer these medications to achieve the full benefit of the drugs.

Having stated this, the AARC does recognize that by its very nature OTC medications will contain only those instructions that are included in the product inserts. Education is essential for any medication or device that a patient may use to treat the symptoms of asthma. Given the fact that while these medications are indeed OTC, the implications if they are misused or improperly used makes enhancing and clarifying the warning labels on these products even more imperative. Improper use of a device or medication can immediately lead to serious and potentially life threatening complications.

The AARC supports the FDA's revisions to the content of the warning labels for bronchodilator products. We agree these changes will have the potential to provide for a safer and more effective use of all OTC bronchodilator medications.

We support the FDA's proposal to enhance the Asthma Alert warning requirements for epinephrine products for use in a hand-held rubber bulb nebulizer.

We support the inclusion of other medical conditions in Sections 341.76 (c) (1); (c) (4); and (c) (6) (iii), which directs the individual to consult a physician and not to use OTC medications without a physician's diagnosis of asthma.

We concur that revising the warning currently on the labels should be enhanced to clarify more specifically what reactions may occur, or more importantly, how taking the medication beyond the recommended dose could adversely affect the user.

The AARC supports the proposed revisions to enhance the warning labels on over the counter bronchodilator products. We do however, reiterate our concern that any inhaled medication, prescription or OTC, must include patient education and instruction. Bronchodilator products are meant to alleviate a medical event that could be life threatening if the medication is not properly taken. We would urge the FDA to consider assessing the appropriateness of permitting bronchodilator products to remain OTC, or what further requirements should be put in place when these products are sold to the public.

Sincerely,

A handwritten signature in cursive script that reads "John D. Hiser".

John D. Hiser, MEd., RRT, FAARC
President