



**Allergy & Asthma Network**

Mothers of Asthmatics

4054 '02 JAN 15 A9:46

1/10/2002

Dockets Management Branch (HFA 305)  
Food and Drug Administration  
5630 Fishers Lane  
Rockville, MD 20857

Re: Docket No. 01D-0510

On behalf of patients with asthma and allergies who depend on orally inhaled metered dose inhaler medications to breathe, Allergy & Asthma Network Mothers of Asthmatics enthusiastically applauds FDA's *Draft Guidance for Industry on Integration of Dose-Counting Mechanisms Into MDA Drug Products: Availability*.

The *Guidance* document accurately characterizes the problems patients face and presents reasonable recommendations to ensure patients can use inhaled medications with confidence and have a visible means of knowing when to refill prescriptions.

Section C Other Considerations, line three makes reference to *rescue* bronchodilators. Because patients depended on bronchodilators to prevent rescue situations as well as at the first sign of symptoms, we suggest replacing *rescue* with *rapid acting* or deleting use of either word.

Finally, I see no mention of intranasal metered dose inhalers in your draft document. The technology for orally inhaled metered dose inhalers is easily transferred to intranasal devices and would aid patients in knowing when to refill these important medications.

Thank you for your attention to this important and long overdue subject. It will be interesting to see what impact this makes on morbidity and mortality rates.

Sincerely,



Nancy Sander  
President

**01D-0510**

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2751 Prosperity Avenue, Suite 150  
Fairfax, VA 22031



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