



NATIONAL CONSUMERS LEAGUE

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BY ELECTRONIC MAIL

<http://www.fda.gov/dockets/ecomments>

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852
RE: Docket Number 2005N-0374 - Use of Ozone-Depleting substance

Dear Sir or Madam:

The National Consumers League (NCL) is a private, nonprofit advocacy group representing consumers on marketplace and workplace issues. We are the nation's oldest consumer organization. NCL provides government, businesses, and other organizations with the consumer's perspective on concerns including child labor, privacy, food safety, and healthcare, including medication information. Our mission is to protect and promote social and economic justice for consumers and workers in the United States and abroad.

NCL has long been involved in issues of healthcare - monitoring rulemaking and legislation involving health, providing and participating in patient education on medication and disease awareness, and researching factors that influence the provision of medical services to patients. NCL also recognizes that environmental health considerations are an important dimension of overall consumer health, and generally supports efforts to improve consumer access to clean air and water. On rare occasions, tensions between these two interests become apparent and require deeper consideration of a broader benefit/risk profile.

One such example is the desire to maintain consumer access to important "rescue" asthma medications while limiting environmental degradation through release of chlorofluorocarbons (CFCs). NCL is aware that, while many newer prescription asthma agents are now manufactured with alternate

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propellants, older products still require the use of CFCs to deliver the active ingredient to the lungs. NCL also recognizes that CFC emissions are known to have negative environmental effects and have, for this reason, been banned in industrial countries with some exceptions (including medical use). Given the prevalence of bronchial asthma in the United States, the nature of the disease, and the implications of inadequate or non-treatment, NCL is concerned about potential FDA actions that could limit the availability of an OTC inhaled option for immediate symptom relief.

In its Final Rule issued on essential use in 2002, the FDA indicated that it would review all essential use medical products using CFCs to determine whether products should continue to receive this designation - thereby permitting the products to be manufactured and used in their current form. In 2005 the FDA reviewed the essential use status for prescription inhalers releasing CFCs, and NCL is aware of plans for FDA to undertake a similar review process for OTC inhalers releasing CFCs. In this process, NCL encourages the FDA to carefully consider the possible implications of eliminating consumer access to OTC bronchial inhalers for any period of time.

It is NCL's understanding that, should the essential use designation petition for the OTC inhalant be denied, consumers could be exposed to a temporary or permanent lapse in product availability. This could have serious health consequences for the millions of people who rely on OTC access to bronchial inhalers for temporary relief from asthma attacks. Ultimately, it would be ideal if all asthma sufferers had access to routine medical care and appropriate resources for managing their conditions with the aid of clinical care and prescription medications. This ideal scenario, however, is not reflected in reality. Millions of Americans lack insurance (both for care and prescription drug coverage), and many more are simply accustomed to relying on OTC medications as a "last resort" option should a prescription product – for any number of reasons – not be available.

To deny consumers access to a clinically proven, safe, well known, widely used, and much-needed therapeutic alternative would – from NCL's perspective – be a grave mistake. Certainly, product manufacturers should be compelled to reformulate and market non-CFC products with all expediency. In the interim period, however, asthma sufferers should not be the ones to pay the price. Thank you for your consideration of this important issue.

Sincerely,

LINDA F. GOLODNER
President,
National Consumers League

