



THE SENIORS COALITION

Working for a Responsible America

May 10, 2001

Sandra Titus
Health Science Administrator
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
5630 Fishers Lane
Mail Stop HFD-21, Room 1093
Rockville, MD 20857

Dear Ms. Titus:

The Seniors Coalition (TSC), on behalf of its four million members nationwide, would like to register its opinion regarding tomorrow's joint meeting of the Nonprescription Drugs Advisory Committee and the Pulmonary-Allergy Drugs Advisory Committee to discuss a Citizen Petition submitted by Blue Cross of California requesting that the Food and Drug Administration (FDA) convert several nonsedating antihistamines to over-the-counter (OTC) status. The Seniors Coalition believes that reclassifying nonsedating antihistamines will compromise patient safety and counteract the purpose of insurance coverage, which is to guard patients from the high costs of medical care.

Seniors are counted among the millions of Americans that suffer from allergies. Despite public perception, many allergies constitute serious medical conditions that can be life threatening. Accordingly, allergy sufferers often must see a trained physician for a proper evaluation of their symptoms and the prescribing of an appropriate mode of treatment. In many cases, physicians prescribe nonsedating antihistamines to alleviate, and sometimes eliminate, a patient's symptoms. The FDA, in its power to assess the safety and efficacy of all drugs, has determined that all the nonsedating antihistamines available on the market are to be prescription drugs, and in effect controlled substances. Reclassifying these drugs as OTC flies in the face of the FDA's original determination that these drugs cannot, and should not, be dispensed to patients without a doctor's evaluation and signature. It follows that, given the inherent dangers posed by the improper use of prescription drugs, patients should not be free to self-medicate. TSC fears that seniors, a population that tends to take numerous drugs simultaneously, will be even more susceptible to adverse drug interactions if this class of drugs is reclassified as OTC.

Furthermore, reclassifying nonsedating antihistamines as OTC would not be consumer-friendly. As do other Americans, seniors rely on their health insurance plans to cover a majority of the cost of their prescription drug expenditures. The seniors that do have prescription drug coverage through former employers, Medicare HMOs, Medicaid, state-sponsored low-income plans, and other sources are responsible for a nominal co-pay ranging from \$5 to \$20 per prescription. If the

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FDA decides to meet the terms of Blue Cross of California's Citizen Petition, it will in effect discontinue insurance coverage for the reclassified drugs. This would not be a problem but for the fact that the OTC cost of the various nonsedating antihistamines would be much more than a nominal co-pay. In a time when seniors are already having trouble affording their medicines, TSC is concerned that seniors would be paying substantially more out-of-pocket for these important drug treatments.

Ostensibly, the impetus behind Blue Cross of California's Citizen Petition is to cut costs. But Blue Cross of California is ignoring the fact that, according to the National Bureau of Economic Research, every \$1 spent on prescription drugs is associated with a decrease of \$4 in other health care expenses. These nonsedating antihistamines are reducing the need for more expensive medical attention – such as a hospital stay – that can result from a serious allergic reaction. Is it good policy on the FDA's part to open the door to cost-cutting that will only bring short-term savings? Moreover, should such cost-cutting be allowed to occur at the expense of patient safety?

There is no compelling health or economic reason for the FDA to meet the terms of Blue Cross of California's Citizen Petition. Moreover, TSC is very concerned that reclassifying these drugs will set a dangerous precedent that could further erode patient safety and financial security. Therefore, TSC strongly recommends to the joint meeting of the Nonprescription Drugs Advisory Committee and the Pulmonary-Allergy Drugs Advisory Committee to reject this Citizen Petition on behalf of the safety and financial well-being of seniors and other Americans.

Sincerely,



Mary M. Martin
Chairman of the Board
Executive Director