WELLPOINT

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December 17, 2001

Dr. Steven Galson
Acting Director
Center for Drug Evaluation and Research, Food and Drug Administration
c/o Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket # 01N-0397

Dear Sirs:

WellPoint Health Networks, a managed health care company covering more than 10 million medical members, appreciates the opportunity to comment on the potential for enhanced safety labeling of prescription and OTC drugs. Current labeling of potential cognitive impairment for OTC and prescription drugs is not provided in a consistent and well-marked manner and these warnings are often minimized and misunderstood by the medicine-consuming public. WellPoint supports the adoption of a standard pictogram advisory to consumers that would advise against potential cognitive impairment caused by the use of sedating OTC or prescription drugs.

While we wait for these important labeling actions to be taken, it is important to note that a significant opportunity to decrease the incidence of traffic related morbidity and mortality could be accomplished today. On May 11th 2001, the Nonprescription Drugs and Pulmonary and Allergy Drugs Advisory Committees of the U.S. Food and Drug Administration voted to switch the allergy drugs Claritin, Allegra and Zyrtec from prescription to over-the-counter (OTC) status. The OTC status of these antihistamines would create a safer alternative to the current portfolio of sedating antihistamines, reducing the risks of the 40 million allergy suffers from driving a car or operating heavy machinery while impaired. The enactment of the Nonprescription Drugs and Pulmonary and Allergy Drugs Advisory Committees recommendations of May 11th will decrease the potential for traffic-related morbidity and mortality secondary to the use of antihistamines.

WellPoint looks forward to the FDA acting on the recommendations of the Nonprescription Drugs and Pulmonary and Allergy Drugs Advisory Committees to increase access to these safer antihistamines.

Thank you for the opportunity to comment.

Sincerely,

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