



April 11, 2001

Food and Drug Administration
Center for Drug Evaluation and Research (HFD-21)
ATTN: Sandra Titus
5630 Fishers Lane
Rockville, MD 20857

Dear Ms. Titus:

On July 6, 1998, I submitted a petition requesting the Food and Drug Administration to convert Allegra/Allegra-D, Claritin/Claritin-D and Zyrtec to over-the-counter status. The petition was assigned docket number 98P-0610/CP. I would like to ensure that the attached Quality-Adjusted Life Year (QALY) summary entitled "Cost-Effectiveness of Converting Non-Sedating Antihistamines from Prescription to Over-the-Counter Status" be included in my petition.

If you have any questions, please feel free to contact me.

Respectfully,

A handwritten signature in black ink, appearing to read "R. Seidman".

Robert C. Seidman, Pharm.D., M.P.H.
Vice President
Blue Cross of California Pharmacy

Cost-Effectiveness of Converting Non-Sedating Antihistamines from Prescription to Over-the-Counter Status

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By Michael B. Nichol, Ph.D. and Patrick Sullivan

Purpose: To evaluate the cost-effectiveness of converting non-sedating antihistamines from prescription status to over-the-counter (OTC).

Methods: A decision analytic model from a societal perspective was developed for two separate comparisons. First, a comparison was made between chlorpheniramine (OTC) and loratadine (OTC). A second model comparing prescription loratadine to loratadine OTC was estimated. Health benefits were measured as quality-adjusted life years saved, and were based on changes in the rate of motor vehicle accidents. Financial benefits were measured as potential costs averted due to reductions in medical and property damage due to motor vehicle accidents. The impact of the prescription status change on loratadine pricing was also estimated.

Results: The base case analysis of the chlorpheniramine to loratadine model resulted in an overall savings of \$45,777 per quality-adjusted life year (QALY). Key parameters in the analysis were varied by 10% and the resulting sensitivity analysis shows savings to society ranging from \$23,077 to \$21,272 per QALY.

The base case analysis of prescription loratadine to loratadine OTC resulted in an overall savings of \$68,553 per QALY. Key parameters were varied by 10% and the resulting sensitivity analysis shows savings to society ranging from \$151,128 to \$35,696.

Conclusion: This study demonstrates that the conversion of prescription loratadine to over-the-counter status is not only cost-effective to society, it is cost-saving. It is important to realize that this analysis only includes the impact of the conversion on motor vehicle accidents, and does not count savings due to increased productivity in the workplace.