American Association of
HEALTH PLANS®

May 2, 2001

Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane, Room 1093
Rockville, Maryland 20857

Attn: Ms. Sandra L. Titus

Re: Citizen Petition 98P-0610/CP1

Dear Ms. Titus:

The American Association of Health Plans (AAHP), the national trade organization for HMOs, PPOs and similar health plans, representing over 1000 health plans providing health care and pharmacy coverage to over 150 million enrollees, appreciates the opportunity to comment on the petition filed by Blue Cross of California to convert cetrizine hydrochloride (Zyrtec), fexofenadine hydrochloride (Claritin) and loratidine (Allegra) to over-the-counter (OTC) status. AAHP believes that the evidence presented by Wellpoint in its petition satisfies the scientific criteria established by the FDA for changing these specific drugs to over-the-counter status.

We urge the agency in evaluating this matter to use an evidence-based process with the objective of promoting appropriate access to safe and effective drugs for allergy sufferers. We recognize that The Code of Federal Regulations allows the agency to grant over-the-counter status for particular pharmaceuticals when the following criteria are met: patients are able to safely diagnose the relevant condition; patients understand the drug regimen; and the drug being considered lacks significant side effects. We hope the agency will evaluate the Wellpoint petition in this light.

A majority of individuals with allergies – particularly seasonal allergies – routinely use OTC medications. While these medications meet the FDA criteria for OTC use, some studies have shown that many of these medications cause certain side effects for some individuals. Many of these side effects can be avoided with the newer non-sedating antihistamines, contributing substantially to allergy suffers' quality of life.

There are compelling data supporting the safe and effective over-the-counter use of non-sedating antihistamines. We appreciate