

**FDA Overview of Issues for the Joint Nonprescription Drugs Advisory Committee and the Pulmonary-Allergy Drugs Advisory Committee – May 11, 2001**

In June 1998, Blue Cross of California (now WellPoint Health Networks) filed a Citizen Petition with the Food and Drug Administration (FDA) requesting that three top-selling antihistamines be switched to over-the-counter status because the prescription requirement deprives patients of "ready access to quality medical care" afforded by these drugs. The drugs cited in the petition are the newer generation (sometimes called "second-generation") antihistamines: Claritin (loratadine), Allegra (fexofenadine), and Zyrtec (cetirizine). These drugs have been approved for marketing by prescription-only in the United States since 1993, 1996 and 1995 respectively. This meeting is to discuss the proposal that these products be switched to over-the-counter (OTC) status.

Historically, the majority of drugs which have been switched from prescription-only status to OTC marketing have been at the initiation of the sponsor. The Food, Drug and Cosmetics (FD&C) Act as amended restricts drugs to prescription-only status if a learned intermediary is required for the proper use of the drug. As written, the default assumption of the FD&C Act is for drugs to be marketed OTC without a prescription unless a decision is made that consumers are not able to appropriately diagnose their condition nor able to correctly choose the remedy and safely use it based on OTC labeling. Older generation antihistamines (such as chlorpheniramine and diphenhydramine) have a long history of OTC use for the treatment of allergic rhinitis and other related conditions. The issue with the newer generation antihistamines cited in the petition, then, is whether they are unique in terms of their marketing histories, their pharmaceutical properties or their safety profiles such that they need a learned intermediary for their proper use and therefore should remain prescription-only. Normally, in a sponsor-initiated OTC switch, the sponsor has to make an argument within a NDA for the appropriateness of the drug for OTC marketing for the indication(s) sought, the effectiveness of the drug with OTC use, and that the drug has a sufficient safety profile for OTC marketing (i.e., it can be safely used without a learned intermediary). In this case, the Citizen Petition requests the FDA to initiate this switch and therefore there is no marketing application supporting the OTC status for any of these agents. Since the efficacy of these drug products and the appropriateness of antihistamines in general for OTC marketing are not in question, the FDA presentation will focus on the safety experience with these drugs. It should be noted that the overall safety experience of the drugs post-marketing has been favorable and the FDA is not questioning the safety of these agents for marketing.

The Citizen Petition contains a variety of rationales for the proposed switching of these products to OTC status. The committees should be cognizant that the FDA is NOT seeking advice on economic considerations of a switch (as these are not the purview of the FDA) nor are we seeking debate on the regulatory and statutory basis for a FDA-initiated switch to OTC status. Rather, the FDA is seeking advice from the committees on whether these agents, given their marketing history, safety profiles, and the fact that they are in a class of drugs already accepted for OTC availability, could be used appropriately and safely by consumers without the intervention of a learned intermediary.