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CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

May 4, 2001

Sandra L. Titus
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5630 Fishers Lane (Room 1093)
Rockville, MD 20857

Re: Docket No. 98P-0610. Subject: Request for time to speak at the May 11, 2001, Joint Meeting of the Nonprescription Drugs Advisory Committee and Pulmonary-Allergy Drugs Advisory Committee

Dear Ms. Titus:

The Consumer Healthcare Products Association (CHPA) requests time on May 11, 2001 to address the joint meeting of the Nonprescription Drugs Advisory Committee and the Pulmonary-Allergy Drugs Advisory Committee with comment on the Citizen Petition 98P-0610/CP1 that was submitted by Blue Cross of California Wellpoint health Network. This Citizen Petition requests that FDA switch the following antihistamines to over-the-counter (OTC) status: Allegra (fexofenadine hydrochloride), Claritin (loratadine), and Zyrtec (cetirizine hydrocholoride).

CHPA is the 120-year-old trade organization representing the manufacturers and distributors of nonprescription medicines and dietary supplements. By sales, CHPA members represent over 95% of the nonprescription medicine marketplace. CHPA has had a long standing interest in the legislative and regulatory aspects of Rx-to-OTC switch and has commented to the agency on related matters on many occasions.

CHPA opposes the Blue Cross of California Citizen Petition for the following principal reasons, among others:

- The NDA holder has the most comprehensive knowledge about the Rx-to-OTC switch candidate. The NDA holder, who has undertaken and maintains the full clinical development of the Rx drug, is best positioned to understand the existing clinical and post-marketing surveillance data held in the NDA and undertake, if needed, additional studies, so as to ensure that the switched product meets the statutory standard that it can be labeled for OTC consumer use. It is therefore in the public interest for the NDA holder, not a third party which does not have access to the NDA database, to initiate switch.

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- Rx-to-OTC switch without the consent of the sponsor requires due process and protection of proprietary data. Under § 505(e) of the Act, formal notice and hearing is required to withdraw approval as a prescription drug. The switch regulation cited in the Blue Cross Citizen Petition cannot substitute for statutory hearing rights, and the switch regulation is not appropriate for modern switches, having not been used in 30 years.
- Comparative effectiveness evaluations are not appropriate criteria for switch. Under § 505(d) of the Act, comparative effectiveness is not a criterion for approval, and comparative safety may be relevant only in rare cases where a drug may have very serious/fatal side effects and has a clearly safer alternative.
- The Blue Cross petition is deficient in its content for a switch application. The success of switch over the years has been the rigorous development of the in-use aspects of consumer selection of switch candidates.

For these reasons, CHPA does not believe that the citizen petition by Blue Cross is an appropriate approach to be taken by the Agency.

I look forward to you reply concerning our requested time allotment. Our members clearly have an interest in ensuring that their concerns are expressed at the meeting. Michael D. Maves, M.D., MBA, President, CHPA, will be presenting on our behalf.

Sincerely yours,

R. William Soller, Ph.D./jkq

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

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