



*Advancing Quality Healthcare
Through Over-the-Counter Medicines
and Nutritional Supplements*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

March 26, 2003

The Honorable Tommy G. Thompson
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Ave. S.W.
Washington, D.C. 20201

Mark McClellan, M.D., Ph.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
5600 Fishers Lane (HF-1)
Rockville, MD 20857

Re: FDA adoption of a forced switch policy

Dear Secretary Thompson and Commissioner McClellan:

We understand that FDA is considering a switch of a second generation antihistamine, from prescription to OTC status, over the objections of the company.

The Consumer Healthcare Products Association (CHPA) opposes a policy to force switch over the objections of the drug sponsor.* The holder of the approved new drug application (NDA)—the company that developed the drug for prescription use—knows the most about the drug and is in the best position to determine whether and under what circumstances it would be appropriate to request a switch. FDA certainly can and should consult with the NDA holder about whether the switch process should be initiated, but switches pursued over the NDA holder's objection run the risk of prematurely or inappropriately removing prescription safeguards. In the only case in which FDA did switch a drug without the prior support of the sponsor (metaproterenol), extensive adverse comment ensued, and the agency moved quickly to rescind its decision.

Since 1974 there have been over 70 successful switches of prescription drugs to OTC status, each one the result of cooperation between the agency and the sponsor applicant of the

* CHPA, founded in 1881, is the national association representing manufacturers and distributors of over-the-counter (OTC) medicines and nutritional supplements. CHPA members account for over 90 percent of the retail sales volume of OTC medicines in the United States. CHPA previously submitted comments to FDA in opposition to forced switch on August 25, 2000 (Docket No. 00N-1256) and on May 4, 2001 (Docket No. 98P-0610).

Secretary Thompson
Commissioner McClellan
Page Two

drug. Attempting to force a switch would be a misallocation of FDA's very limited and finite resources available for OTC activities. By diverting OTC resources to try to force a switch where the sponsor is opposed, FDA loses the opportunity to make important gains in OTC monographs and other OTC areas not supported by user fees. Further, FDA has a significant backlog of switch applications filed by sponsors who are prepared with data and resources to work with FDA to achieve OTC status. We recommend that FDA work with the sponsors to address these potential switches, and not force switches without the support of the drug innovators.

Thank you for your consideration of our views. We would be happy to discuss these issues with you further at your convenience.

Sincerely,

Linda A. Suydam
President

cc: Daniel E. Troy
Chief Counsel
U.S. Food and Drug Administration