



celebrating 125 years

September 11, 2006

LT Darrell Lyons
Center for Drug Evaluation and Research
Advisors and Consultants Staff
Food and Drug Administration, HFD-21
5600 Fishers Lane
Rockville, Maryland 20857

Dear Lieutenant Lyons:

The Consumer Healthcare Products Association (CHPA) requests time on September 25, 2006, to address the Nonprescription Drugs Advisory Committee (NDAC). Our comments will provide industry perspectives on evaluating consumer behavior in the use of nonprescription drug products.

CHPA, founded in 1881, is the national organization representing the manufacturers and distributors of nonprescription medicines and dietary supplements. By sales, CHPA member companies account for more than 90 percent of nonprescription drugs marketed in the United States. Many CHPA member companies hold approved new drug applications (NDAs) for products that have been switched from prescription (Rx) to nonprescription, over-the-counter (OTC) status and are working on new switch candidates. Those companies and others who belong to the association are keenly interested in helping to shape future approval decisions about appropriate products for Rx-to-OTC switch.

Douglas Ws. Bierer, Ph.D., of Douglas Bierer Consulting, LLC, will represent CHPA at the September 25th meeting. We anticipate needing 30 minutes to cover our points.

We ask that you provide the attached documents to the NDAC members and other special government employees (SGEs) who may sit with the committee on September 25. They are important background for the planned deliberation.

Thank you for assisting us in the arrangements for the NDAC meeting.

Sincerely yours,

A handwritten signature in cursive script that reads "Lorna C. Totman".

Lorna C. Totman, Ph.D., DABT
Senior Director, Scientific Affairs
and Toxicology

Attachments:

Letter to NDAC members, September 11, 2005

“Outcomes from the CHPA-FDA Consumer Behavior Roundtable”