



*Producers of Quality  
Nonprescription Medicines and  
Dietary Supplements for Self-Care*

## CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

*Formerly Nonprescription Drug Manufacturers Association*

September 18, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Rockville, MD 20852

Re: Docket Nos. 98N-0337, 96N-0420,  
95N-0259, and 90P-0201  
Over-the-Counter Human Drugs;  
Labeling Requirements; Partial  
Extension of Compliance Dates  
65 FR 38191, June 20, 2000

These comments are provided in response to the publication of the above document on behalf of the Consumer Healthcare Products Association (CHPA). CHPA is the 119-year-old national trade association representing manufacturers and distributors of nonprescription or over-the-counter (OTC) drug products and dietary supplements. Members of CHPA account for 90-95% of the volume of OTC drug products sold in the United States. CHPA members are vitally interested in regulations affecting OTC drug products.

The Food and Drug Administration published the above document as "providing a partial extension of the compliance dates for its final rule that appeared in the *Federal Register* of March 17, 1999."

While CHPA welcomes the additional time, it may not be enough due to a lack of clear direction in several areas:

- The continuing delays in addressing small package issues and convenience sizes means that industry has been unable to effectively move on package redesign, and more time will likely be needed. The industry, through CHPA, has made suggestions and offered solutions to the problem of small packages.
- The agency has not yet finalized the guidance on the use of columns, even though it has been seven months since the close of the comment period for the proposed guidance. Columns are well known to increase the level of readability of printed matter, and allowing columns within the Drug Facts box is an obvious step forward.
- The promised guidance on exemption petitions has not yet even been issued in draft form. Individual exemption requests by companies have not been promptly addressed,

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even though prompt feedback is essential to the exemption process. For example, it took the agency seven months to respond to one member company's exemption petition.

- An additional hindrance has been added, which will slow down the progress of implementation of the labeling rule. FDA's confidentiality assurances given at the November 1999 feedback meeting have not been adhered to in at least one circumstance of which we are aware. Companies cannot effectively submit complete information in exemption requests if they cannot rely upon the agency to maintain confidentiality of proprietary information.

In summary, CHPA supports the partial extension of compliance dates as published in the *Federal Register* of March 17, 1999. But we note that further extensions may be needed to compensate for agency inaction on several important issues related to the Otc labeling rule.

These comments are offered in a spirit of cooperation, and we hope they are helpful as the agency continues its work.

Sincerely,



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



Eve E. Bachrach  
Senior Vice President and Secretary

WS/EB/WB/b