



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

## **CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®**

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March 5, 2002

Ms. Christy Schmidt  
Executive Coordinator  
Regulatory Reform Initiative  
Office of the Assistant Secretary for  
Planning and Evaluation  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Ms. Schmidt:

The January 4 Federal Register included a request for comments on the Secretary's initiative and advisory committee on ways to reduce challenges that can inhibit the delivery of health care or the development of medical products. The Consumer Healthcare Products Association is the 121-year-old trade organization representing the manufacturers and distributors of nonprescription medicines and dietary supplements. CHPA has over 200 members across the manufacturing, distribution, supply, research, and advertising sectors of the self-care products industry. Our members manufacture well known brands such as Tylenol, Bayer Aspirin, and Centrum vitamins, among many others.

We have two general comments and three specific comments.

**1. OTC Medicines: Empowering American Consumers.** Consumers are extremely interested in taking an active role in their own healthcare. And self-care with OTC medicines and dietary supplements plays a part in that. Illustrations of both interest and activism abound:

- The four most commonly used medicines are all available over-the-counter, as are six of the top ten.<sup>1</sup>
- 59 percent of Americans say they are more likely to treat their own health conditions now than they were a year ago.<sup>2</sup>

Consumer access to self-medication options provides convenience, cost efficiencies, and time savings. Consumers turn to OTC medicines for 38 percent of the everyday health problems they experience, yet for this vast volume, OTCs take up less than two cents of every healthcare

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<sup>1</sup> See Kaufman, et al., "Recent Patterns of Medication Use in the Ambulatory Adult Population of the U.S." JAMA, January 16, 2002.

<sup>2</sup> Self-Care in the New Millennium, Roper Starch Worldwide for CHPA, March 2001.

dollar.<sup>3</sup> Further, resource savings to the healthcare system through responsible self-medication allow better allocation of limited healthcare resources to issues beyond the scope of self-care.

**2. Rx-to-OTC Switch: A Continuing Success Story.** The switch of prescription drugs to nonprescription status when proven by manufacturers to be safe and effective for consumer use has provided consumers with an even wider variety of self-medication options. Over 80 ingredients, dosage forms, and strengths have been switched from Rx-to-OTC status since 1972. The success of switch has stemmed from industry, consumers, and the Food and Drug Administration (FDA) working in partnership to evaluate the specific merits of a switch and to make a scientifically documented, data-driven decision. CHPA welcomes opportunities to continue to work with FDA in refining the switch process as we look toward the future of switch in new OTC categories and conditions.

**3. Dialogue Needed on Economic Consequences of Pending Regulations.** Regulations and guidances often have significant economic consequences to the regulated industries. For example, individual companies have estimated the cost of their compliance with the regulation on electronic records and signatures (see 21 CFR Part 11) to be as high as \$100 million for a regulation that was inadequately developed, did not utilize the significant expertise available in the private sector, and failed to consider the enormous cost implications of compliance. CHPA recommends that HHS initiate a dialogue between FDA and the regulated industries, so that a better mutual understanding can be developed on how to share credible economic consequence information on pending regulations and guidances. Understanding the potential enormity of the costs of a pending rule helps to place into perspective the purported benefits, thereby leading to leaner and more efficient regulations.

**4. Operation Risk Management Contrasted with GMPs.** Guidance on Good Manufacturing Practices (GMPs) for pharmaceutical and food products can be helpful to facilitate GMP compliance and thereby help prevent adulteration and labeling errors. Recently, the agency has suggested operational risk management (ORM) as a voluntary approach to responding to security concerns related to terrorism. ORM and GMPs can be compatible approaches to product security, but they are fundamentally different, in that a company must comply with all aspects of GMPs applicable to its products, while ORM is a flexible voluntary management approach that is company, site and product specific. ORM should therefore continue to be a voluntary approach intended to help facilitate company responses to heightened product security concerns and not be incorporated into formal GMP compliance either through regulation or guidances.

**5. Pressing Need for Dietary Supplement GMPs.** The dietary supplement industry has strongly supported GMPs specific to dietary supplements and submitted proposed GMPs to the Food and Drug Administration on November 20, 1995. The Dietary Supplement Health and Education Act (1994) amended the Food, Drug & Cosmetic Act by adding section 402(g) (21 U.S.C. 342(g)), which provides, in part, that the Secretary may prescribe GMPs for dietary

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<sup>3</sup> Self-Medication in the '90s: Practices and Perceptions, Heller Research Group for CHPA, March 1992; ACNielsen OTC sales estimates, 2000; and CMMS health expenditure estimates, 2001, respectively.

supplements. On January 9, 2002, the Center for Food Safety and Applied Nutrition (CFSAN) issued two guidances relating to facility and product security, which read very similarly to GMPs, but do not address many manufacturing issues relating to adulteration. If facility and product security guidance is necessary for the food industry and government to respond to the threats and acts of terrorism, then the industry/government response to the events of September 11 would be facilitated by the immediate issuance of GMPs regulations for dietary supplements, which would cover virtually all aspects of product adulteration. Dietary supplement GMPs are needed for general quality and specific security concerns.

We hope these comments are useful and welcome opportunities to discuss these matters in greater detail.

Sincerely,

R. William Soller, Ph.D.  
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Director of Science & Technology

David C. Spangler  
Vice President – International  
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