



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

## CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

December 17, 2001

NTE Comments  
Office of Trade and Economic Analysis  
Room H-2815  
U.S. Department of Commerce  
Washington, D.C. 20230

Re: Comments with Respect to the National Trade Estimate Report on Foreign Trade  
Barriers, 66 Fed. Reg. 60237 (12/3/01)

To Whom It May Concern:

The Consumer Healthcare Products Association (CHPA) wishes to draw attention to varying restrictions on how nonprescription medicines can be displayed or accessed among European Union Member States as a barrier to market entry for such products. CHPA is the 120-year-old trade association representing manufacturers of nonprescription, or over-the-counter (OTC) medicines and dietary supplement products in the U.S. Our members make well known brands such as Tylenol, Advil, Lamisil AT, Centrum vitamins, and store brands, among many others. The U.S. market made up roughly 30% of the \$49 billion global nonprescription medicine market in 1999, and Europe made up 27% of the market, according to market research firm IMS Health.

As in the United States, within the EU there are two classes of medicines: prescription medicines, which require a prescription from a licensed health practitioner and are dispensed by pharmacists; and nonprescription medicines, which are available directly to consumers with necessary product labeling without the need for a doctor's prescription. While some EU Member States subdivide these categories, that is not the focus of these comments, nor does it meaningfully alter the basic prescription-nonprescription system.

Within the EU, individual Member States control where and under what conditions nonprescription medicines are sold. In a majority of EU Member States, nonprescription medicines may not be displayed or directly accessed by consumers in pharmacies. Instead, these products are behind the pharmacy counter out of the consumer's sight, just as prescription-only products are out of reach and sight. In contrast, nonprescription medicines are available to consumers in plain view on store shelves in the United States.

In the highly competitive nonprescription medicine market, the ability of consumers to see and choose among proven safe and effective products is vital to market entry and to communicating product attributes to consumers. Maintaining nonprescription products out of

sight and reach of consumers gives them little chance to examine and compare different products available. These restrictions raise the cost of introducing new products from the U.S. into EU Member States and lessen the impact of advertising and promotion expenditures, thus raising a practical barrier to market entry.

This issue has been raised on various occasions on the national level in Europe. Indeed, a few European countries, such as Finland and Sweden, have had positive experiences in allowing nonprescription medicines to be displayed and accessed directly by consumers in pharmacies. But no Europe-wide policy has been in place. Finding ways to eliminate the current restrictions throughout the EU would make it easier to introduce nonprescription medicines in Europe, ultimately broadening consumer choices and self-care opportunities.

We hope that the Office of the U.S. Trade Representative will draw attention to these restrictions in the 2002 National Trade Estimate Report on Foreign Trade Barriers. We would welcome the opportunity to discuss this further with USTR.

Sincerely,

A handwritten signature in black ink, appearing to read "David Spangler", with a stylized flourish at the end.

David C. Spangler  
Vice President – International &  
Assistant General Counsel

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