



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

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

December 12, 2003

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 Annual National Trade Estimate Report on Foreign Trade Barriers, 68 Fed. Reg. 62159 (10/31/03)

To Whom It May Concern:

The Consumer Healthcare Products Association (CHPA) wishes to draw attention to the restrictive environment on where nonprescription medicines can be sold in Japan as a barrier to market entry for such products. CHPA is the 122-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 Blistex, Bayer aspirin, Tylenol, Claritin, and store brands, among many others. Japan's OTC medicines market is roughly \$8 billion, using market research firm IMS Health and Japan Self-Medication Industry estimates – approximately one fifth of the \$50 billion global OTC market.

In both the U.S. and Japan, there are two classes of medicines: prescription medicines, which require a prescription from a licensed healthcare practitioner and are dispensed by pharmacists; and nonprescription medicines, which have been judged safe and effective by the drug regulatory authority for consumer use on the basis of their labeling without the need for a prescription from a healthcare practitioner. In the U.S., nonprescription medicines are available in any and all retail outlets – supermarkets, mass merchandisers, or others, as well as pharmacies. In Japan, nonprescription medicines are restricted to pharmacies or drug stores.

When combined with the ban on comparative advertising in Japan (i.e., no X is “faster,” “stronger,” “easier to take,” etc., than Y claims), the advertising restrictions and channel restrictions make the long-term building of manufacturer-pharmacy trade relationships a cornerstone of business reality in Japan. This in turn reinforces a strong bias toward the status quo in the Japanese market and dramatically reduces the odds of success for American firms seeking to introduce their proven safe and effective OTC medicines in Japan. These distribution requirements are an indirect barrier to market entry in Japan.

We see two approaches to break this log jam. First, the ban on comparative advertising could be addressed. Unfortunately, there appears to be little, if any, support for this concept in Japan.

Second, there could be at least a partial relaxation or deregulation of distribution restrictions for OTC medicines in Japan, allowing more OTC medicines to be sold in a wider range of retail outlets. This would increase competitive options and contribute to a more level playing field among older and newer entrants in the OTC marketplace. Over the past year, Japan's government has considered such a move as part of their cabinet-level regulatory reform agenda. Japan's advisory Council on Regulatory Reform has similarly supported the concept. Despite these positive signals, there remains considerable resistance to the concept.

It is important to note that this isn't a question of relaxing standards for the approval of OTC medicines. Nor is it a question of permissible claims. To assure that these products are safe and effective for consumer use on the basis of their labeling, OTC medicines must meet rigorous approval standards in Japan, just as they do in the U.S.

We urge the Office of the U.S. Trade Representative to draw attention to OTC medicine distribution restrictions in the National Trade Estimate Report on Foreign Trade Barriers, and to encourage moves in Japan to address this indirect barrier to market entry. We would welcome the opportunity to discuss this further with USTR.

Sincerely,

/s/

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