



E. Edward Kavanaugh
President

27 January 2005

To: European Commission, DG Sanco, SCCP Secretariat

The following comments are submitted by the Cosmetic, Toiletry, and Fragrance Association¹ (CTFA) and the Consumer Healthcare Products Association² (CHPA) on behalf of our members that manufacture and market tooth whitening products in the United States and worldwide. Based on the U.S. experience with the consumer marketing of whitening products, the members of CTFA and CHPA endorse the proposal in Europe to allow marketing of cosmetic tooth whitening products containing up to 6% hydrogen peroxide directly to consumers. From our experience these products are safe for consumer use in a retail setting.

In the U.S. tooth whitening products are regulated as cosmetics. Cosmetic tooth whitening products have been marketed in the United States since 1997. Many of the products currently marketed in the U.S. contain hydrogen peroxide or hydrogen peroxide releasers in concentrations up to 6.5% (as hydrogen peroxide) and are labeled to use for 14 days. We are aware that there are some consumer tooth whitening products that contain up to 10% that have been safely marketed in the U.S., however these comments address the proposed level of 6% for sale in the EU.

¹ The Cosmetic, Toiletry, and Fragrance Association (CTFA) is a national trade association that represents the personal care products industry. It has an active membership of more than 300 companies that manufacture and distribute the vast majority of finished personal care products marketed in the United States, as well as a large number of OTC drug products that are both drugs and cosmetics. CTFA also represents approximately 300 associate member companies from related industries, including testing laboratories and manufacturers of raw materials, ingredients (both active and inactive) and packaging materials.

² The Consumer Healthcare Products Association is a national trade association representing manufacturers and distributors of nonprescription or over-the-counter (OTC) medications. Members of CHPA are responsible for over 90 percent of the retail sales of OTC drugs in the United States. In addition, CHPA members manufacture or distribute many cosmetic products and some products that are both drugs and cosmetics.

To date over 42 million units of product have been sold directly to the consumer through a variety of retail outlets, including supermarkets, drug stores, convenience stores, bulk purchasing outlets, as well as through dental offices. Tooth whitening products are sold in a variety of delivery forms including whitening toothpastes, strips, paint-on applicators, and trays. These products have been marketed directly to consumers in the U.S. and have a long history of safe use.

U.S. tooth whitening products are labeled to advise consumers about potential adverse effects that may be associated with their use, such as exacerbation of a pre-existing tooth sensitivity. Information that accompanies the product also describes what consumers should do if tooth sensitivity or soft tissue irritation occurs.

Manufacturers provide a toll-free 1-800 telephone number on the packages for consumers to contact the company if they experience any adverse event associated with the product's use. This facilitates the company collecting information about the safety of its products and allows a timely and accurate response to the consumer's concerns. Adverse effects may also be reported by healthcare providers, including dentists.

The adverse event profile of tooth whitening products confirms their safety for purchase and use by consumers. No serious adverse events as defined by U.S. FDA regulations have been associated with the use of these products since they were initially marketed in 1997. The majority of consumer-reported adverse events have been for mild oral soft tissue irritation and tooth sensitivity, all of which are mild and self-limiting. Furthermore, follow-up with consumers who have reported these complaints has confirmed that they have been transient in nature and self-resolve shortly after discontinuing product use.


A professional tooth whitening product containing 6.5% hydrogen peroxide for use over a 21-day period has also been marketed exclusively to dentists since 2001. The adverse events associated with the use of this product have also been limited to mild, transient oral soft tissue irritation and tooth sensitivity. These effects are similar in type and nature to those reported by consumers from products available through retail distribution. No other types of adverse events have been reported by dental professionals who are qualified to identify potential adverse effects of these products. When viewed in totality the adverse events associated with tooth whitening products are easily recognized by the consumer and do not differ from those seen and reported by professionals.

In summary, given the millions of units of tooth whitening products used by U.S. consumers and the remarkable safety profile of these products, we believe the U.S. data supports the Colipa recommendation for the marketing of cosmetic tooth whitening products, containing up to 6% hydrogen peroxide and with appropriate labeling, in all retail outlets.

Sincerely,

Elizabeth H. Anderson

Elizabeth H. Anderson
Associate General Counsel
The Cosmetic, Toiletry, and Fragrance Association

A handwritten signature in black ink, appearing to read "Doug Bierer", with a long horizontal line extending to the right.

Doug Bierer, Ph.D.
Vice President - Regulatory & Scientific Affairs
Consumer Healthcare Products Association