Dear Sir/Madam,

I wish to supply the following comment relevant to: SCCP Preliminary Opinion on Hydrogen Peroxide in Tooth Whitening Products 08 December 2004

Regarding 3.3.13.1 Effects of concern "particular care should be taken in administering bleaching agents to patients with gingivitis (or) periodontal disease"

* The primary etiological factor in gingivitis and periodontitis is microbial dental plaque: hydrogen peroxide has potential to provide benefit in these conditions through its well-established antimicrobial effect.
* Numerous studies have shown that hydrogen peroxide at levels of 1.5-3% in oral hygiene products has beneficial effects in reducing plaque and gingivitis, with no adverse soft tissue changes, even in prolonged use (up to 6 years, as reviewed by Walsh LJ; 2000, Aust Dent J, 45:257-269).

* 1% hydrogen peroxide has also been used as adjunctive treatment for periodontitis, applied subgingivally as irrigation. While systematic review of the evidence shows no additional benefit of this treatment over mechanical debridement alone, there is no indication that use of exogenous hydrogen peroxide at this concentration exacerbates periodontal destruction (Hallmon and Rees 2003, Ann Periodontol 8(1): 99-114) and case reports supporting longterm use are still being published (Kawamura et al. 2004, Aust Dent J 49(1): 40-44).

* While higher concentrations of hydrogen peroxide might constitute a potential hazard to periodontal tissue, the risk would appear to be low, considering that:

* product design and instructions aim to avoid direct application to gingiva

 \ast tooth whitening products are generally recommended for short-term use over a period of 1-4 weeks

* supragingival dental plaque control where the product is applied would probably be improved, reducing the primary etiological factor for inflammation

peroxide degrades rapidly in the mouth by action of salivary peroxidase
 if peroxide penetrates gingival epithelium it would degrade by action of
 tissue catalase and glutathione peroxidase

* there is low risk of direct access to any active periodontal lesion via the subgingival crevicular route, given the opposing flow of gingival crevicular fluid and its high catalase concentration derived from blood

A little about me and why I feel justified in making this statement.

Dr. Denis Kinane received his Bachelor of Dental Science degree from the University of Edinburgh in 1980, and his Ph.D. from the Department of Microbiology, University of Edinburgh Medical School in 1983. Since that time, he has served as a Lecturer in Periodontology at Dundee Dental Hospital and School, as a Senior Lecturer at the University of Glasgow Dental Hospital and School, and has been a Professor in Periodontology and Oral Immunology since 1994. He became Associate Dean for Research and Enterprise at the University of Glasgow in 1998. He chairs and is a member of multiple international committees and has directed and organized many international meetings and symposia over the last ten years. He has served as President of the Periodontal Research Group of the IADR and is on the organizing committee of the European Academy of Periodontology.

Dr. Kinane has published over 150 articles in peer-reviewed scientific journals, has received significant grant funding, is on numerous editorial boards and scientific committees and organizations both in the United States and Europe. Denis Kinane's work focuses on periodontal immune and inflammatory processes, mainly explaining the causes, development and susceptibility markers of periodontal disease. He is an international authority on the relationship of oral condition and systemic disease.

If you wish any additional information please contact me. I am making this comment as I am concerned about depriving Europeans of a product, widely used in the US for many years without serious problems or litigation, which apart from making teeth more asethetic, motivates the user to good oral health practices and a pride in their appearance and oral condition. I also think there are some very wooly comments included re these whitening products and oral cancer, smoking and alcohol but these are clearly unscientific and should not need serious rebuttal.

Yours sincerely,

Denis Kinane

Dr. Denis Kinane Associate Dean for Research School of Dentistry University of Louisville Louisville, Kentucky 40202, USA Tel:+1 502 852 3175 This paper represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.