



Consumer Healthcare  
Products Association

15 July 2005

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket No. 2005D-0240: Draft Guidance for Industry on Gingivitis:  
Development and Evaluation of Drugs for Treatment or Prevention; Availability.  
70 Fed. Reg. 37102-37103 (28 June 2005)

Dear Sir or Madam:

On behalf of member companies who manufacture and distribute over-the-counter oral healthcare drug products, the Consumer Healthcare Products Association (CHPA) and the Cosmetic, Toiletry, and Fragrance Association (CTFA)<sup>1</sup> request a 60-day extension of the comment period on the Draft Guidance for Industry on Gingivitis: Development and Evaluation of Drugs for the Treatment and Prevention.

This is the first time the Food and Drug Administration has published a draft guidance on the development and evaluation of drugs for the treatment and prevention of gingivitis. This draft guidance addresses a variety of clinical design elements, such as the appropriate inclusion/exclusion criteria, selection of relevant endpoints for assessing gingivitis, determining the clinical significance of the effect, enrollment of special populations, and the collection of meaningful safety data, as well as other substantive issues such as prevention versus treatment claims, OTC versus prescription status, and the nonclinical testing of products intended for oral cavity administration for the treatment or prevention of gingivitis. The agency requested comments by 29 August 2005 (60-day comment period).

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<sup>1</sup> CHPA, founded in 1881, is the national trade association representing manufacturers and distributors of OTC drugs and nutritional supplements. CHPA members account for more than 90 percent of retail sales of OTC drugs in the United States. Based in Washington, D.C., CTFA is the trade association representing the cosmetic, toiletry, and fragrance industry in the United States and globally. Founded in 1894, CTFA has a membership of nearly 600 companies including manufacturers, distributors, and suppliers for the vast majority of finished personal care products marketed in the United States.

With its wide breadth, this guidance will have a substantial impact on CHPA and CTFA member companies who develop and market oral care products for gingivitis. Therefore, CHPA and CTFA have formed a committee of industry representatives to consider this proposed draft guidance. We need additional time to coordinate an industry response and to provide the agency with meaningful and substantive comments. Thus, we request a 60-day extension with comments on the Draft Guidance for Industry on Gingivitis being accepted up to 28 October 2005, rather than the current due date of 29 August 2005.

The CHPA and CTFA joint committee appreciates FDA's consideration of our request for adequate additional time to provide constructive comments and useful perspective on this draft guidance document.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Bierer", with a stylized flourish extending to the left.

Douglas Ws. Bierer, Ph.D.  
Vice President, Regulatory and Scientific Affairs  
Consumer Healthcare Products Association

A handwritten signature in blue ink, appearing to read "Elizabeth H. Anderson", written in a cursive style.

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

cc: Frederick Hyman, D.D.S., M.P.H. (HFS-540)