



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

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

July 15, 2003

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

Re: [Docket No. 81N-033P] Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Drug Products; Establishment of a Monograph. 68 Fed. Reg. 32232-32287 (May 29, 2003)

Dear Sir or Madam:

On behalf of member companies who manufacture and distribute over-the-counter oral healthcare drug products, Consumer Healthcare Products Association (CHPA) and Cosmetic, Toiletry and Fragrance Association (CTFA)¹ request (a) a 90-day extension of the comment period on the Advance Notice of Proposed Rulemaking for Antigingivitis/Antiplaque Drug Products for Over-the-Counter Human Use and (b) a 90-day extension of the reply comment period on the Advance Notice of Proposed Rulemaking for Antigingivitis/Antiplaque Drug Products for Over-the-Counter Human Use.

I. Request for 90-Day Extension of Comment Period

CHPA and CTFA have formed a committee of industry representatives to consider the proposed rules for Antigingivitis/Antiplaque oral care drug products and to develop constructive comments.

Because this is the first time the Food and Drug Administration has published the recommendations of the Dental Plaque Subcommittee and the Agency has provided its perspectives and conclusions based on this report, we need additional time to adequately assess the implications of the proposed rulemaking. Specifically, the Agency has classified several active ingredients as Category III and industry needs

¹ CHPA, founded in 1881, is the national trade association representing manufacturers and distributors of OTC drugs and nutritional supplements. CHPA members account for over 90 percent of retail sales of OTC drugs in the United States. CTFA is the national trade association representing the cosmetic, toiletry and fragrance industry. Founded in 1894, CTFA has approximately 600 members involved in manufacturing and distributing personal care products throughout the United States. Between CHPA and CTFA, all major drug and cosmetic oral care products are represented.

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sufficient time to provide additional data and perspectives on inclusion of these active ingredients in a Tentative Final Monograph (TFM) and to support Category I status of these ingredients. Also, the Agency has requested information on testing protocols, effectiveness criteria, and statistical methods. Sufficient time is also needed to adequately document industry's perspectives in this area and to develop a set of common elements and basic criteria for performance tests, including statistical methods and efficacy criteria. Furthermore, information previously submitted to the docket and reviewed by the Dental Plaque Subcommittee was not placed on public display until 30 June 2003, thus leaving less than 60 days for review and comment on this information.

We, therefore, request that comments on the Advance Notice of Proposed Rulemaking for Antigingivitis/Antiplaque Drug Products be accepted up to 25 November 2003, rather than the current due date of 27 August 2003.

II. Request for 90-Day Extension of the Reply Comment Period

The current 90-day reply comment period should also be extended an additional 90 days to provide adequate time for industry to review the comments submitted to the docket and to determine whether additional expert perspective may be needed. Without knowledge of the data or comments submitted during the comment period, it is difficult to determine whether an adequate reply to the comments could be developed and additional data provided within the 90-day reply comment period. Given the number of issues presented in the Advance Notice of Proposed Rulemaking, it is almost certain that additional time will be needed at the reply stage.

We, therefore, request that reply comments on the Advance Notice of Proposed Rulemaking for Antigingivitis/Antiplaque Drug Products be accepted up to 180 days after the closing date of the comment period. If the Agency agrees to extend the comment period until 25 November 2003 as proposed above, we believe reply comments should be accepted until 25 May 2004.

III. Timing of the Tentative Final Monograph

Several member companies are likely to submit relevant data to the docket on Antigingivitis/Antiplaque Drug Products. In the Advance Notice of Proposed Rulemaking for Antigingivitis/Antiplaque Drug Products, the FDA dissented from the Category I recommendations of the Dental Plaque Subcommittee with respect to combination products. Specifically, these combination products included: (1) an antigingivitis/antiplaque active ingredient combined with an anticaries active ingredient, (2) an antigingivitis/antiplaque active ingredient combined with a tooth desensitizer active ingredient, and (3) an antigingivitis/antiplaque active ingredient combined with an anticaries active ingredient and a tooth desensitizer active ingredient. The Agency stated that data are needed to establish the safety and effectiveness of these combination products. Individual companies are considering additional clinical studies to obtain the data sought by the Agency and may wish to

submit protocols to the Agency for comment. In addition to the protocol review time, these types of clinical studies are likely to require 12-18 months to conduct. Therefore the data could not be submitted within the comment period of the Advance Notice of Proposed Rulemaking, although the docket remains open for 12 months after publication of the TFM. In addition, individual industry members may also conduct additional efficacy studies to support the reclassification of proposed Category III active ingredients to Category I. It should also be noted that, because the Agency has requested information on testing protocols, effectiveness criteria, and statistical methods in the Advance Notice of Proposed Rulemaking, there is no agreement on the basic criteria for performance tests, including the statistical methods. CHPA and CTFA believe it is appropriate for the Agency to consider the time needed for development of the criteria for performance tests and likely clinical studies, as well as submission of any resultant data prior to publication of the TFM in order to preserve the resources of the Agency.

Summary

CHPA and CTFA request the comment period for the Advance Notice of Proposed Rulemaking for Antigingivitis/Antiplaque Drug Products be extended an additional 90 days (until 25 November 2003) and that reply comments be accepted up to 180 days after the close of the comment period. Industry appreciates FDA's consideration of our request for adequate additional time for generation and submission of constructive comments and relevant data for this proposed monograph.

Sincerely,



Douglas Ws. Bierer, Ph.D.
Vice President, Regulatory & Scientific Affairs

cc: Charles J. Ganley, M.D. (HFD-560)
Robert L. Sherman (HFD-560)
Elizabeth Anderson, CTFA

DB/mm