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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 356

[Docket No. 81N-033P]

RIN 0910-AA01

Display Date 8-22-03  
Publication Date 8-25-03  
Certifier J. COOKE

**Oral Health Care Drug Products for Over-the-Counter Human Use;  
Antigingivitis/Antiplaque Drug Products; Establishment of a Monograph;  
Extension of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Advance notice of proposed rulemaking; extension of comment period.

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**SUMMARY:** The Food and Drug Administration (FDA) is extending to November 25, 2003, the comment period for an advance notice of proposed rulemaking (ANPR) for over-the-counter (OTC) antigingivitis/antiplaque drug products. The ANPR was published in the **Federal Register** of May 29, 2003 (68 FR 32232). FDA is taking this action in response to a request for extension of the comment period to allow interested persons additional time to submit comments and information on the conditions under which OTC antigingivitis/antiplaque drug products are generally recognized as safe and effective and not misbranded. FDA is also extending the reply comment period to February 23, 2004.

**DATES:** Submit written or electronic comments by November 25, 2003. Submit reply comments by February 23, 2004.

**ADDRESSES:** Submit written and reply comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, cd03141

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rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Robert L. Sherman, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of May 29, 2003 (68 FR 32232), FDA published an ANPR based on the recommendations of the Dental Plaque Subcommittee (the Subcommittee) of the Nonprescription Drugs Advisory Committee (NDAC). FDA issued this notice to establish conditions under which OTC drug products for the reduction or prevention of dental plaque and gingivitis are generally recognized as safe and effective and not misbranded.

**II. Request for Extension of Time**

On July 15, 2003, the Consumer Healthcare Products Association (CHPA), a trade association of manufacturers of nonprescription drugs and dietary supplements, and the Cosmetic, Toiletry, and Fragrance Association (CTFA), a trade association of manufacturers of personal care products, requested a 90-day extension in which to file comments and new information (Ref. 1). CHPA/CTFA also requested that FDA accept reply comments up to 180 days after the closing date for the comment period. The request stated that the closing date for the original comment period would not allow CHPA/CTFA time to adequately assess the implications of the Subcommittee's proposed rulemaking. The request noted that, because this is the first time FDA published the Subcommittee's recommendations, industry needs sufficient time to provide additional data and perspectives on inclusion of several of the

Subcommittee's proposed Category III (insufficient data) active ingredients in a tentative final monograph, and to support a Category I (safe and effective) status for these ingredients. In addition, CHPA/CTFA stated that because FDA specifically requested information on testing protocols, statistical methods, and effectiveness criteria, industry needs sufficient time to develop a set of common elements and basic criteria for performance testing.

CHPA/CTFA stated that individual companies are likely to submit relevant data on antigingivitis/antiplaque active ingredients and on drug products in which antigingivitis/antiplaque active ingredients are combined with other oral health care active ingredients. Further, these companies are considering additional clinical studies that would involve time for FDA's review of submitted protocols and likely require 12 to 18 months to complete.

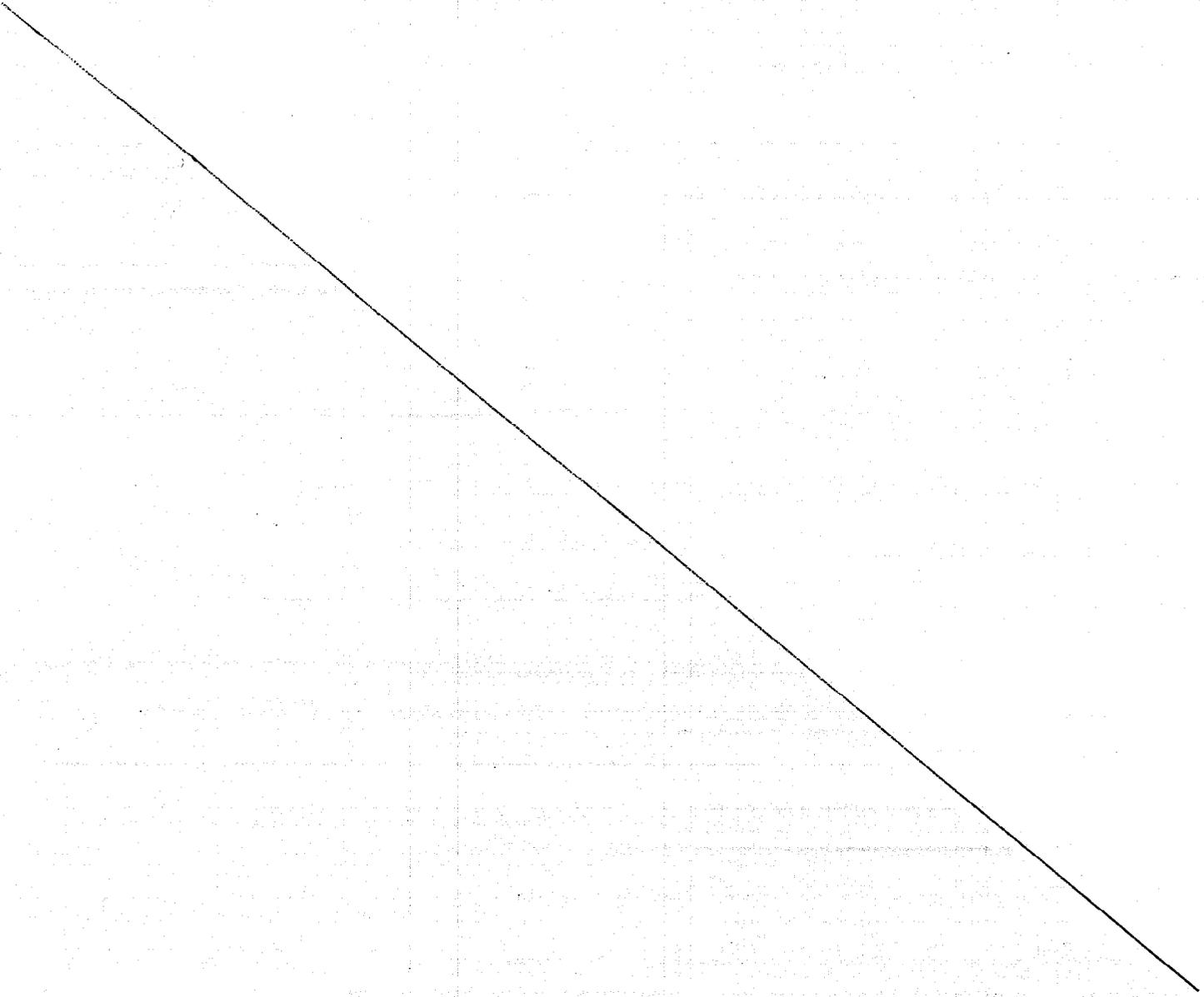
### **III. FDA's Decision**

FDA has carefully considered the request and acknowledges its request for information on effectiveness criteria for antigingivitis/antiplaque active ingredients, performance testing, and the statistical approaches used to evaluate these tests. Manufacturers and CTFA/CTFA may require additional time to develop and review information to fully respond to the agency's request. However, FDA believes that extension of the reply comment period from 60 to 90 days should be sufficient time for manufacturers to respond to comments submitted during the comment period. The reply comment period is not intended to remain open for new study results to be submitted.

Accordingly, the comment period is extended to November 25, 2003, and the reply comment period is extended to February 23, 2004. FDA considers an extension of time for comments in this case to be in the public interest.

#### IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the ANPR. Submit a single paper copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



**V. Reference**

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

- 1. Comment No. EXT7.

Dated: 8/19/03  
August 19, 2003.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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J. Coole

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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