(*see* § 404.430), after your benefits may have been reduced because of the following:

(a) The family maximum (*see* §§ 404.403 and 404.404), which applies to entitled beneficiaries remaining after exclusion of beneficiaries deemed not entitled under § 404.436 (due to a deduction for engaging in non-covered remunerative activity outside the United States or failure to have a child in one's care);

(b) Your entitlement to benefits (*see* § 404.410) for months before you reach full retirement age FRA (*see* § 404.409) (this applies only to old-age, wife's, widow's, widower's or husband's benefits);

(c) Your receipt of benefits on your own earnings record, which reduces (*see* § 404.407), your entitlement (or deemed entitlement; *see* § 404.420) to benefits on another individual's earnings record; and

(d) Your entitlement to benefits payable (or deemed payable) to you based on the earnings record of an individual entitled to a disability insurance benefit because of that individual's entitlement to worker's compensation (*see* § 404.408).

12. Section 404.452 is revised to read as follows:

§ 404.452 Reports to Social Security Administration of earnings: wages; net earnings from self-employment.

(a) *Reporting requirements and conditions under which a report of earnings, that is, wages and/or net earnings from self-employment, is required.* (1) If you have not reached full retirement age (*see* § 404.409) and you are entitled to a monthly benefit, other than only a disability insurance benefit, you are required to report to us the total amount of your earnings (as defined in § 404.429) for each taxable year. This report will enable SSA to pay you accurate benefits and avoid both overpayments and underpayments.

(2) If your wages and/or net earnings from self-employment in any month(s) of the year are below the allowable amount (*see* §§ 404.446 and 404.447), your report should include this information in order to establish your grace year (*see* § 404.435) and possible eligibility for benefits for those months.

(3) Your report to us for a taxable year should be filed on or before the 15th day of the fourth month following the close of the taxable year; for example, April 15 when the beneficiary's taxable year is a calendar year. An income tax return or form W–2, filed timely with the Internal Revenue Service, may serve as the report required to be filed under the provisions of this section, where the income tax return or form W–2 shows the same wages and/or net earnings from self-employment that must be reported to us. Although we may accept W–2 information and special payment information from employers, you still have primary responsibility for making sure that the earnings we use for deduction purposes are correct. If there is a valid reason for a delay, we may grant you an extension of up to four (4) months to file this report.

(4) You are not required to report to us if:

(i) You reached full retirement age before the first month of your entitlement to benefits; or

(ii) Your benefit payments were suspended under the provisions described in § 404.456 for all months of a taxable year before the year of full retirement age, or for all months prior to your full retirement age in the full retirement age year, unless you are entitled to benefits as an auxiliary or survivor and your benefits are reduced for any month in the taxable year because of earnings and there is another person entitled to auxiliary or survivor's benefits on the same record, but living in a different household.

(b) *Report required by person receiving benefits on behalf of another.* When you receive benefits as a representative payee on behalf of a beneficiary (*see* subpart U of this part), it is your duty to report any earnings of the beneficiary to us.

(c) *Information required.* If you are the beneficiary, your report should show your name, address, Social Security number, the taxable year for which the report is made, and the total amount of your wages and/or net earnings from self employment during the taxable year. If you are a representative payee, your report should show the name, address, and Social Security number of the beneficiary, the taxable year for which the report is made, and the total earnings of the beneficiary, as well as your name, address, and Social Security number.

(d) *Requirement to furnish requested information.* You, the beneficiary (or the person reporting on his/her behalf) are required to furnish any other information about earnings and services that we request for the purpose of determining the correct amount of benefits payable for a taxable year (*see* § 404.455).

(e) *Extension of time for filing report.* (1) *Request for extension to file report.* Your request for an extension of time, or the request of your authorized agent, must be in writing and must be filed at a Social Security Administration office before your report is due. Your request must include the date, your name, the Social Security number of the beneficiary, the name and Social Security number of the person filing the request if other than the beneficiary, the year for which your report is due, the amount of additional time requested, the reason why you require this extension (*see* § 404.454), and your signature.

(2) *Evidence that extension of time has been granted.* If you do not receive written approval of an extension of time for making your report of earnings, it will be presumed that no extension of time was granted. In such case, if you do not file on time, you will need to establish that you had good cause (§ 404.454) for filing your report after the normal due date.

[FR Doc. 03–21613 Filed 8–22–03; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 356

[Docket No. 81N–033P]

RIN 0910–AA01

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.

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. 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, 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: August 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–21669 Filed 8–22–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 4

[USCG–2001–8773]

RIN 1625–AA27 (formerly 2115–AG07)

Marine Casualties and Investigations; Chemical Testing Following Serious Marine Incidents

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking; notice of public meeting; reopening of comment period.

SUMMARY: The Coast Guard is reopening the comment period on the notice of proposed rulemaking for Marine Casualties and Investigations; Chemical Testing Following Serious Marine Incidents published in the **Federal Register** on February 28, 2003. In response to requests for a public meeting that were submitted to the public docket, the Coast Guard will hold a public meeting in Washington, DC. The purpose of the meeting is to obtain information from the public in addition to the comments already submitted to the docket.

DATES: The meeting will be held Friday, September 19, 2003, from 9 a.m. to 5 p.m. in Washington, DC. This meeting may close early if all business is finished. Comments must reach the docket on or before September 30, 2003.

ADDRESSES: The meeting location is: United States Coast Guard Headquarters, Transpoint Building, 2100 Second Street, SW., Room 2415, Washington, DC 20593. You may submit comments identified by Coast Guard docket number USCG–2001–8773 to the Docket Management Facility at the U.S. Department of Transportation (DOT). To avoid duplication, please use only one of the following methods:

(1) Web Site: *http://dms.dot.gov.*

(2) Federal eRulemaking Portal: *http://www.regulations.gov.*

(3) Mail: Docket Management Facility, DOT, 400 Seventh Street SW., Washington, DC 20590–0001.

(4) Fax: 202–493–2251.

(5) Delivery: Room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC,