1. Highly malignant tumors, such as medulloblastoma or other primitive neuroectodermal tumors (PNETs) with documented metastases, grades III and IV astrocytomas, glioblastoma multiforme, ependymoblastoma, diffuse intrinsic brain stem gliomas, or primary sarcomas.

2. Progressive or recurrent following initial antineoplastic therapy.

* * * * *

13.14 *Lungs.*

* * * * *

OR

C. Carcinoma of the superior sulcus (including Pancoast tumors) with multimodal antineoplastic therapy. Consider under a disability until at least 18 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

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13.23 *Cancers of the female genital tract*—carcinoma or sarcoma.

* * * * *

E. Ovaries, as described in 1 or 2:

1. All tumors except germ cell tumors, with at least one of the following:

a. Tumor extension beyond the pelvis; for example, tumor implants on peritoneal, omental, or bowel surfaces.

b. Metastases to or beyond the regional lymph nodes.

c. Recurrent following initial antineoplastic therapy.

* * * * *

13.24 *Prostate gland*—carcinoma.

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B. With visceral metastases (metastases to internal organs).

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13.27 *Primary site unknown after appropriate search for primary*—metastatic carcinoma or sarcoma, except for squamous cell carcinoma confined to the neck nodes.

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Part B

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113.00 MALIGNANT NEOPLASTIC DISEASES

* * * * *

I. *What do these terms in the listings mean?*

1. *Metastases:* The spread of tumor cells by blood, lymph, or other body fluid. This term does not include the spread of tumor cells by direct extension of the tumor to other tissue or organs.

2. *Persistent:* Failure to achieve a complete remission.

3. *Progressive:* The malignancy became more extensive after treatment.

4. *Recurrent, relapse:* A malignancy that had been in complete remission or entirely removed by surgery has returned.

* * * * *

K. *How do we evaluate specific malignant neoplastic diseases?*

1. *Lymphoma.*

a. We provide criteria for evaluating aggressive lymphomas that have not responded to antineoplastic therapy in 113.05. Indolent lymphomas are rare in children. We will evaluate indolent lymphomas in children under 13.05 in part A.

* * * * *

2. *Leukemia.*

a. *Acute leukemia.* * * * Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination, or by testicular biopsy. * * *

* * * * *

4. *Thyroid tumors.* We use the criteria in 113.09 to evaluate anaplastic carcinoma and carcinoma treated with radioactive iodine. Medullary carcinoma of the thyroid gland, which is not treated with radioactive iodine, is rare in children. We evaluate medullary carcinoma in children under 13.09C in part A.

5. *Brain tumors.* We use the criteria in 113.13 to evaluate malignant brain tumors. We consider a brain tumor to be malignant if it is classified as grade II or higher under the World Health Organization's classification of tumors of the central nervous system (*WHO Classification of Tumours of the Central Nervous System,* 2007). We evaluate any complications of malignant brain tumors, such as resultant neurological or psychological impairments, under the criteria for the affected body system. We evaluate benign brain tumors under 111.05.

* * * * *

113.01 Category of Impairments, Malignant Neoplastic Diseases

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113.13 *Brain tumors.* (See 113.00K5.) Highly malignant tumors, such as medulloblastoma or other primitive neuroectodermal tumors (PNETs) with documented metastases, grades III and IV astrocytomas, glioblastoma multiforme, ependymoblastoma, diffuse intrinsic brain stem gliomas, or primary sarcomas.

* * * * *

[FR Doc. E8–9170 Filed 4–25–08; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA–2008–N–0163] (formerly Docket No. 2001N–0067)

Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 90 days, the comment period for the proposed rule, published in the **Federal Register** of February 20, 2002 (67 FR 7620), on the classification of encapsulated amalgam alloy and dental mercury, the reclassification of dental mercury, and the issuance of special controls for amalgam alloy. In the **Federal Register** of July 17, 2002 (67 FR 46941), the initial comment period was reopened for 60 days. The agency is taking this action to provide the public with an additional opportunity to comment and to request data and information that may have become available since publication of the proposed rule.

DATES: Submit written or electronic comments by July 28, 2008.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–N–0163 (formerly Docket No. 2001N–0067), by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''How to Submit Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts

and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael E. Adjodha, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3688.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 20, 2002 (67 FR 7620), FDA published a proposed rule entitled ''Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy.'' In that document, FDA proposed the following actions: (1) Issue a separate classification regulation for encapsulated amalgam alloy and dental mercury; (2) amend the classification for amalgam alloy by adding special controls; and (3) reclassify dental mercury from class I (general controls) to class II. FDA proposed that all three products would have the same labeling guidance as a special control. In addition, FDA proposed that dental mercury would have a voluntary American National Standards Institute (ANSI) standard as a special control; encapsulated amalgam alloy and dental mercury would have voluntary ANSI and International Standards Organization (ISO) standards as special controls; and the amalgam alloy products would have a voluntary ISO standard as a special control. Since that time, a 2006 joint meeting of the Dental Products Panel and the Peripheral and Central Nervous System Drugs Advisory Committee raised the need for FDA to further consider scientific issues that are potentially relevant to this classification and we seek additional comments on the proposed classification.

In an effort to provide an update on the latest scientific information concerning dental amalgam, a working group of the U.S. Department of Health and Human Services, known as the Trans-agency Working Group on the Health Effects of Dental Amalgam, commissioned a new review of the scientific literature in 2004 (the 2004 review). The 2004 review, funded by the National Institutes of Health in cooperation with FDA, the Centers for Disease Control and Prevention, and the Office of the Chief Dental Officer of the Public Health Service, was completed in 2004 by Life Sciences Research Office, Inc. (LSRO). LSRO engaged an independent panel of experts from academia with preeminent qualifications and experience in the appropriate scientific disciplines needed for the 2004 review. The 2004 review was a systematic and comprehensive evaluation of approximately 300 peer-reviewed studies of dental amalgam and mercury vapor published from 1996 through 2003, intended to determine whether these studies provided new evidence related to the health effects of dental amalgam in humans. The panel concluded that the studies contained insufficient evidence to support a correlation or causal relationship between exposure to dental amalgam and kidney or cognitive dysfunction; neurodegenerative disease (specifically Alzheimer's disease and Parkinson's disease); autoimmune disease (including multiple sclerosis); or adverse pregnancy outcomes (Refs. 1 and 2).

Dental amalgam was the subject of an advisory committee meeting in 2006. As announced in the **Federal Register** of April 3, 2006 (71 FR 16582), on September 6 and 7, 2006, FDA held a joint meeting of the Dental Products Panel and the Peripheral and Central Nervous System Drugs Advisory Committee (the 2006 joint committee). The 2006 joint meeting was held to discuss and make recommendations to FDA on a draft FDA White Paper (2006 draft White Paper) (Ref. 3) regarding the potential adverse health risks associated with exposure to mercury in dental amalgam. The goal of the 2006 draft White Paper was to provide an assessment and conclusions regarding significant new information and health risks from mercury in dental amalgam and to build on previous Public Health Service literature reviews and risk assessments (1993 and 1997) and reviews by other Federal agencies since 1997. The 2006 joint committee, comprised of 24 panelists, heard presentations from the following groups: (1) Scientists; (2) regulatory officials from Canada and Sweden, on the scientific basis for the regulation of dental amalgam in their respective countries; and (3) FDA, on how the United States has regulated and evaluated dental amalgam. Numerous public speakers also presented their views.

The 2006 joint committee then deliberated on a series of questions FDA had posed on its draft review of the dental amalgam literature and provided recommendations to the agency related to those questions (Ref. 4). By majority vote, the committee concluded that FDA's draft White Paper had significant limitations. Among its criticisms, the 2006 joint committee identified insufficient explanation about the following: (1) How the scientific references were chosen; (2) failure to identify the significant gaps in the scientific knowledge, particularly with respect to exposure limits; and (3) lack of attention to sensitive subpopulations. The majority of the 2006 joint committee voted that it could not find the conclusions of the draft White Paper to be ''reasonable.''

Despite the limitation on the draft White Paper, the 2006 joint committee generally agreed that there is no evidence that dental amalgams cause health problems. The 2006 joint committee also agreed that the most recent well-controlled clinical studies, including two prospective clinical studies in children (Refs. 5 and 6), showed no evidence of neurological harm from dental amalgams. In addition, a more recent article corroborated this evidence (Ref. 7). Panelists provided individual recommendations, including recommendations that FDA consider requirements related to the use of dental amalgam in pregnant women and small children, as well as patient information to ensure that consumers understand that these devices contain mercury.

II. Reopening of the Comment Period

FDA believes it is important for members of the public to have the opportunity to further comment on FDA's proposal. Accordingly, FDA is asking for comments concerning whether these devices should be classified into class II (special controls). We specifically request comments supported by empirical data and scientific evidence concerning this classification and these special controls. In addition, if class II (special controls) is the appropriate classification for these devices, FDA requests comment on whether the two types of special controls proposed by FDA in 2002 (materials and labeling) provide reasonable assurance of the safety and effectiveness of these devices and on whether the proposed special control guidance document should be revised in light of the recommendations and with respect to the discussions by the 2006 joint committee.

- Controls on the Materials. For example, should the material controls proposed by FDA address conformance to recognized consensus standards that make recommendations for testing, compressive strength, and identifying the mercury vapor released by the device?
- Labeling Controls. For example, how should labeling controls, if any,

address the disclosure of composition, including mercury content, and precautions regarding use of the device in sensitive subpopulations composed of individuals who respond biologically at lower levels of exposure to mercury than the general population? If so, which subpopulations should be included (e.g., children under age 6, pregnant and lactating women, hypersensitive or immunocompromised individuals)? Should the labeling controls require more specific patient labeling (e.g., informing patients of identified sensitive subpopulations of the mercury content, the alternatives to the device and their relative costs, and health risks associated with the failure to obtain dental care)?

For the agency's future analysis of benefits and costs of the regulatory options for dental amalgams, FDA also requests comments, including available data, on the following questions:

(1) How many annual procedures use mercury amalgams? What are the trends?

(2) What are the differences in cost between amalgams and alternative materials (e.g., composite, other metals, ceramics, etc.)? Are there differences in replacement lives?

(3) What are reimbursement rates for dental amalgam and the alternative materials?

(4) How would labeling describing the risks of amalgam for certain subpopulations (e.g., children under age 6, pregnant and lactating women, hypersensitive or immunocompromised individuals) affect the demand for, and use of, mercury amalgam? How would the risks included in the labeling be communicated to those subpopulations?

(5) What is the current exposure to mercury for patients? For professionals? What would be the reduction in exposure associated with the alternatives described previously in this section of this document?

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.regulations.gov* 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Governmental-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. References

The following references have 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. Review and Analysis of the Literature on the Potential Adverse Health Effects of Dental Amalgam, LSRO, July 2004.

2. Brownawell, A.M., et al., ''The Potential Adverse Health Effects of Dental Amalgam,'' *Toxicological Reviews*, 24(1):1–10, 2006.

3. Draft FDA Update/Review of Potential Adverse Health Risks Associated With Exposure to Mercury in Dental Amalgam, National Center for Toxicological Research, FDA, August 2006.

4. Transcripts from the Joint Meeting of Dental Products Panel and Central Nervous System Drugs Advisory Committee, September 6 and 7, 2006.

5. Bellinger, D.C., et al., ''Neuropsychological and Renal Effects of Dental Amalgam in Children: A Randomized Trial,'' *Journal of the American Medical Association*, 295:1775–1783, 2006.

6. DeRouen, T.A., et al., ''Neurobehavioral Effects of Dental Amalgam in Children: A Randomized Clinical Trial,'' *Journal of the American Medical Association*, 295:1784–1792, 2006.

7. Dunn, Julie E., ''Scalp hair and urine mercury content of children in the Northeast United States: The New England Children's Amalgam Trial,'' *Environmental Research*, Vol. 107, Issue 1, pages 79 to 88, May 2008.

Dated: April 22, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. 08–1187 Filed 4–23–08; 10:15 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–208199–91]

RIN 1545–BC55

Suspension of Running of Period of Limitations During a Proceeding to Enforce or Quash a Designated or Related Summons

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and withdrawal of notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations regarding the use of designated summonses and related summonses and the effect on the period of limitations on assessment when a case is brought with respect to a designated or related summons. This document also withdraws the previous proposed regulations published in the **Federal Register** on July 31, 2003 (68 FR 44905). These proposed regulations reflect changes to section 6503 of the Internal Revenue Code of 1986 made by the Omnibus Budget Reconciliation Act of 1990 and the Small Business Job Protection Act of 1996. These regulations affect corporate taxpayers that are examined under the coordinated issue case (CIC) program and are served with designated or related summonses. These regulations also affect third parties that are served with designated or related summonses for information pertaining to the corporate examination.

DATES: Written or electronic comments and requests for a public hearing must be received by July 28, 2008.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–208199–91), room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Alternatively, submissions may be hand delivered between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–208199–91), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Comments may also be submitted electronically to the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–208199–91).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Elizabeth Rawlins, (202) 622–3630; concerning submissions of comments, Richard Hurst, (202) 622–7180 or *Richard.A.Hurst@IRSCounsel.Treas.Gov* (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed regulations amending the Procedure and Administration regulations (26 CFR part 301) under section 6503. Section 11311 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, 104 Stat. 1388) amended section 6503(k) to suspend the period of limitations on assessment when a case is brought with respect to a designated or related summons. Section 6503(k) was