

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 872

[Docket No. 01N-0067]

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

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing three actions that will provide consistent regulation of dental mercury and dental amalgam products. FDA is proposing to issue a separate classification regulation for encapsulated amalgam alloy and dental mercury, a preamendments device, intended to be mixed in a single-use capsule to form filling material for the treatment of dental caries as class II (special controls); to amend the classification for amalgam alloy, a class II preamendments device, by adding special controls; and to reclassify from class I (general controls) to class II the preamendments device dental mercury intended for use as a component of amalgam alloy in the restoration of a dental cavity or broken tooth. These actions are being taken because the agency believes that there is sufficient information to establish special controls that will provide reasonable assurance of the safety and effectiveness of these devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability for comment of a draft guidance document that is proposed as a special control.

**DATES:** Submit written or electronic comments by May 21, 2002. See section XI of this document for the proposed effective date of a final rule based on this document.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20057. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Susan Runner, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283.

#### SUPPLEMENTARY INFORMATION:

#### I. Highlights of the Proposed Regulation

In light of the information described below, FDA has reconsidered its regulatory approach to dental amalgam products. FDA is proposing to regulate amalgam products in a uniform manner, and apply class II special controls to these products to provide a reasonable assurance of safety and effectiveness. Specifically, FDA is proposing to:

1. Issue a separate classification regulation for encapsulated amalgam alloy and dental mercury. This product would be class II with special controls consisting of conformance to voluntary industry standard specifications in the following: (1) International Standards Organization “(ISO) 1559:1995 Dental Materials—Alloys for Dental Amalgam,” and (2) American National Standards Institute/American Dental Association (ANSI/ADA) “Specification No. 6-1987 for Dental Mercury” and FDA’s guidance document entitled “Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling.”

2. Reclassify dental mercury from class I to class II with special controls consisting of conformance to voluntary industry standard specifications in ANSI/ADA’s “Specification No. 6-1987 for Dental Mercury” and FDA’s guidance document entitled “Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling.”

3. Amend the class II classification regulation of amalgam alloy to provide for special controls consisting of conformance to voluntary industry standard specifications in “ISO 1559:1995 Dental Materials—Alloys for Dental Amalgam” and FDA’s guidance document entitled “Special Control Guidance Document on Encapsulated

Amalgam, Amalgam Alloy, and Dental Mercury Labeling.”

#### II. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101-629), and the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under the 1976 amendments, class II devices were defined as those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but there is sufficient information to establish performance standards to provide such assurance. The SMDA broadened the definition of class II devices to mean those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance. Special controls may include performance standards; postmarket surveillance; patient registries; and the development, and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device.

FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon "new information." The reclassification can be initiated by FDA or by the petition of an interested person. The term "new information," as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos v. United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn v. Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell v. Goddard* 366 F.2d 177 (7th Cir. 1966).) Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of changes in "medical science." (See *Upjohn v. Finch*, supra, 422 F.2d at 951.) However, regardless of whether data before the agency are past or new data, the "new information" on which any reclassification is based is required to consist of "valid scientific evidence," as defined in section 513(a)(3) of the act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). FDA relies upon "valid scientific

evidence" in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C.360j(c)).)

### III. Regulatory History of the Devices

Dental amalgam is a dental restorative material that is used as filling material in the treatment of dental caries. Dental amalgam is a mixture of approximately equal parts of elemental mercury (43 to 54 percent) and an amalgam alloy containing other metals, predominantly silver, but also tin and copper, with smaller amounts of zinc, palladium, or indium sometimes present. The mercury and amalgam alloy components are mixed in the dentist's office to form dental amalgam. FDA has regulated dental mercury and amalgam alloy separately, with dental mercury § 872.3700 (21 CFR 872.3700) being regulated as a class I device and amalgam alloy § 872.3050 (21 CFR 872.3050) as a class II device.

In the **Federal Register** of December 30, 1980 (45 FR 85962), FDA published a proposed rule to classify dental mercury (§ 872.3700) into class II, based on the recommendation of the panel. Subsequently, in the **Federal Register** of August 12, 1987 (52 FR 30082 at 30089), FDA issued a final rule classifying dental mercury into class I instead of into class II, as proposed. FDA stated that it believed that, at that time, there was no valid scientific evidence of systematic poisoning to patients from amalgam containing mercury to justify classifying the device into class II (see 52 FR 30082 at 30089).

Although the agency acknowledged the risks presented by dental mercury (i.e., mercury poisoning and adverse tissue reaction), the agency believed that general controls, including labeling for the device bearing adequate directions for use and warnings under section 502 of the act (21 U.S.C. 352), would warn dentists about the rare risks of allergic reactions among patients and the risk of toxicity to dental health professionals. The agency concluded that the establishment of performance standards for these devices would not reduce these risks. Accordingly, FDA found that general controls alone were sufficient to provide reasonable assurance of the safety and effectiveness of the device. In the same issue of the **Federal Register**, FDA classified amalgam alloy into class II because of

the potential risks to safety and effectiveness that could result from variations in chemical formulation related to percent composition and types of materials.

In the **Federal Register** of August 12, 1987 (52 FR 30082) and November 20, 1990 (55 FR 48436), FDA classified a total of 124 preamendments generic types of dental devices, including dental mercury (§ 872.3700) and amalgam alloy (§ 872.3050). Due to an inadvertent error, the preamendments device encapsulated amalgam alloy and dental mercury, was not separately classified. Encapsulated amalgam alloy and dental mercury is a device that consists of measured proportions of amalgam alloy and dental mercury, both separately sealed, but within the same single-use capsule, ready to be triturated to form an amalgam alloy filling material for use in the restoration of a dental cavity. Encapsulated amalgam alloy and dental mercury are now regulated as class II devices under the amalgam alloy classification (§ 872.3050).

### IV. Scientific Review Related to Dental Mercury and Amalgam

#### *A. Comprehensive Assessment of Dental Amalgam by the United States Public Health Service*

In 1991 to 1992, under the auspices of the Committee to Coordinate Environmental Health and Related Programs (CCEHRP), the U.S. Public Health Service (PHS), a component of the Department of Health and Human Services (HHS), performed a comprehensive risk assessment of dental amalgam.

The PHS performed this comprehensive risk assessment because of heightened public concern about the safety of this product as a result of anecdotal reports of mercury toxicity from amalgam fillings and the alleviation of chronic disease conditions when the fillings were removed. These reports and the public's reaction to them prompted senior PHS officials to order a fresh look at all relevant data to determine if such safety concerns had any basis in fact. In 1993, a CCEHRP Subcommittee on Risk Management issued a report on its findings (Ref. 1) (hereinafter referred to as the PHS report).

In preparing this assessment, the CCEHRP relied upon a number of scientific review groups that included clinicians, scientists, and public health experts from the PHS, the Environmental Protection Agency, and the health care and academic sectors (Ref. 1). One group referred to as the Ad Hoc Subcommittee on the Benefits of

Dental Amalgam (hereinafter referred to as the Benefits Assessment Subcommittee), assessed the benefits of dental amalgam. A separate group, the Subcommittee on Risk Assessment (hereinafter referred to as the Risk Assessment Subcommittee), examined the potential health risks associated with dental amalgam restorations.

The Risk Assessment Subcommittee, comprised of 34 senior level experts from the fields of health promotion and disease prevention, dentistry, dental materials, toxicology, and biostatistics, reviewed the existing body of scientific literature (Ref. 1). It examined nearly 120 publications that reported the results of studies on levels of exposure to mercury and its salts. In conducting its review, the Risk Assessment Subcommittee paid close attention to the amount of mercury absorbed by study subjects and the consequences, if any, of lifetime exposure among people with dental amalgam restorations (Ref. 1).

The Risk Assessment Subcommittee found that historic experience with dental amalgams did not offer persuasive evidence of adverse health effects related to amalgam treatments other than a few reported cases of hypersensitivity (Ref. 1). In terms of evidence concerning adverse effects of low level, long-term mercury exposure, the Risk Assessment Subcommittee reviewed studies that reported neurological and psychological changes resulting from long-term, low-level mercury exposure. The Risk Assessment Subcommittee could not draw unambiguous conclusions or develop a risk assessment based on these endpoints because these studies were judged to have serious methodological flaws (Ref. 1).

Given the shortcomings of the occupational studies, the Risk Assessment Subcommittee also decided against using occupational exposure data as the basis for establishing an acceptable level of exposure to long-term, low-level mercury vapor: in other words, the Risk Assessment Subcommittee recommended against a "no observed adverse effect level" (Ref. 1).

Based on its review, the Risk Assessment Subcommittee arrived at four general conclusions:

1. In low-level occupational exposure, the subclinical effects detected have occurred in groups with mean tissue mercury levels that are only tenfold higher than those of the general population. However, the relationship between the observed effects and the tissue levels is unclear, as is the

relationship between subclinical effects and a hazard to health.

2. Available data are not sufficient to indicate that health hazards can be identified in nonoccupationally exposed persons. Because there are no scientifically acceptable studies with sensitive, standardized measurements for physiological and behavioral changes in nonoccupationally exposed persons, it is not possible to determine whether those changes observed in persons with low-level occupational exposure to mercury might also occur as a result of exposure to mercury from dental amalgams. Adverse health consequences, however, cannot be totally dismissed.

3. The margin of safety may be lower in some individuals because of previously developed sensitivity to mercury or because body burdens of mercury are already high as a result of past exposure to other sources. It is possible, therefore, that some persons may respond adversely to the incremental exposure derived from dental amalgam restorations.

4. At the mercury doses produced by amalgam fillings, the evidence is not persuasive that the wide variety of nonspecific symptoms attributable to fillings and "improvement" after their removal are ascribable to mercury from the fillings. Conversely, the evidence is not persuasive that the potential for toxicity at the levels attributable to dental amalgams should be totally disregarded. The potential for effects at levels of exposure produced by dental amalgam restorations has not been fully explored (Ref. 1).

In addition to examining the risks of dental amalgam, a companion PHS subcommittee reviewed the benefits of this product (PHS report Ref. 1). It concluded that dental amalgam, which has been used successfully to treat millions of individuals for over 100 years, is an effective restorative material that offers many advantages over other materials. These advantages include wide potential applications, ease of manipulation, reasonable clinical serviceability, and relatively low cost. These findings, which are discussed in greater detail later in this document, were subjected to external review and found to be highly credible (Ref. 1).

On the basis of the assessment of available science on the risks and benefits of amalgam products, the PHS report recommended that FDA, the National Institute of Health, Centers for Disease Control and Prevention, Office of the Assistant Secretary for Health, and the National Institute of Dental Research implement a comprehensive strategy to address concerns about

amalgam products. Specifically, the PHS report recommended the development of a research agenda, a method to monitor research, and a public and professional educational campaign. The PHS report also recommended that FDA carry out the following regulatory initiatives: (1) Combine elemental mercury and dental alloy, which are presently regulated separately, into a single product for regulatory purposes; (2) require manufacturers of all dental restorative materials, including dental amalgam, to label their products with the ingredients to help dentists identify patients who may exhibit allergic hypersensitivity to these substances; and (3) encourage dentists and patients to report to FDA adverse effects from all restorative materials. (Ref. 1).

The HHS Environmental Health Policy Committee, the successor to the CCEHRP, met in mid-1995 and reaffirmed the findings and policy approaches outlined in the 1993 PHS report (Ref. 2).

#### *B. Citizen Petitions*

In 1993, several individuals filed citizen petitions related to the regulation of dental amalgam and dental mercury (Ref. 3). These petitions requested that FDA take numerous actions with respect to dental amalgam and mercury, including banning dental mercury, reclassifying dental mercury into class III, imposing restrictions on amalgam, conducting environmental assessments and issuing environmental policy statements, issuing policy statements addressing patients and health care workers, and convening a special panel to review the merits of these requests.

The petitioners submitted numerous scientific publications they believed supported the conclusion that dental mercury and amalgam were unsafe. FDA convened a group of experts to assess these additional studies. After reviewing the additional studies cited in the petitions, the group of experts did not find that any of the studies supported claims that individuals with dental amalgam fillings will experience adverse effects including neurologic, renal, or developmental effects. Their conclusions concerning the risks of amalgam were consistent with the conclusions in the 1993 and 1995 PHS reports. (Ref. 4).

After review of the existing information about the safety of dental amalgam and mercury, including additional information cited by petitioners, FDA responded that it intended to propose to place amalgam products into class II, not class III. FDA

further responded that it did not intend to ban mercury or impose restrictions on the use of amalgam products by certain subpopulations (Ref. 5).

#### C. U.S. Government Research

The U.S. Government has funded several studies related to dental amalgam. Since 1982, a large-scale epidemiological study, commonly referred to as the "Ranch Hand Study," has been continuing to assess the possible links between exposure of the U.S. military personnel to the herbicide Agent Orange, used during the Vietnam War, and reported health effects. The extensive medical and oral health database developed in support of this study, drawn from approximately 1,200 study participants, made it possible for persons with different research interests to use selected data in the pursuit of their own studies. Oral health information, dental records from military archives, and measures of mercury levels in blood and urine samples enabled the National Institute of Dental and Craniofacial Research to initiate a two-pronged study. One aspect of the study entailed the establishment of mercury levels from amalgam fillings and the occurrence of various reported health symptoms. The other aspect involved a longitudinal cohort assessment in which the number of amalgam restorations were determined retrospectively and comparisons made of reported health effects between groups with high and low exposure levels and those with no exposure. To date, no discernible causal or correlational connection has been observed between study subjects with amalgam fillings and adverse health effects. The period of observation is continuing. The government has sponsored several other continuing studies that relate to amalgam fillings with results anticipated in 2003.

#### D. International Reviews on Safety of Amalgam Fillings

There have been a number of major reviews by international authorities of the nature and magnitude of health risks associated with dental amalgam restorations. The majority of these assessments are based upon extensive reviews of the available body of relevant scientific literature and consensus among leading researchers and renowned experts from the fields of oral health, toxicology, medicine, and other related disciplines. The following overview identifies these individual reviews and provides the overall conclusions of each.

In 1994, an expert group convened by Sweden's National Board of Health and

Welfare took the position that: "Scrutiny of the results of recent research \* \* \* has not shown that mercury from amalgam has an adverse effect on health, with the exception of isolated cases of allergic reactions" (Ref. 6).

At the request of senior U.S. health officials, in 1994, a delegation of PHS scientists and regulators organized a nine-country information exchange forum in Berlin, Germany for the purpose of determining the scientific bases for national policies governing the use of dental amalgam. In 1998, a report memorializing the conclusions of this group was published. The report concluded that: (1) No systemic dose-dependent toxic effects have been shown to be related to amalgam; (2) local reactions to dental amalgam fillings do occur but are relatively rare; (3) the benefits of restoring teeth with dental amalgam outweigh significantly the documented risks; and (4) there is no indication that clinically satisfactory dental amalgam fillings should be removed (Ref. 7).

In 1995, Canadian health authorities released a report on amalgam safety (Ref. 8), which concluded:

Dental amalgam contributes detectable amounts of mercury to the [human] body, and is the largest source of mercury exposure for average Canadians. However, this exposure is not causing illness in the general population. Current evidence does not indicate that mercury contributes to Alzheimer's disease, amyotrophic lateral sclerosis, multiple sclerosis or Parkinson's disease.

In 1996, the University of Otago's Wellington School of Medicine in New Zealand, which serves as the World Health Organization (WHO) Collaborating Centre in Oral Health, enlisted four prominent researchers to conduct a review of available scientific reports on amalgam safety. In a draft report, three of the researchers concluded: "\* \* \* the assumption of a cause-and-effect relationship between amalgam and cases of ill health is evidence of an overreaction and unwise, considering the endemic prevalence of amalgam in the population" (Ref. 9).

In 1997, the Canadian province of Quebec undertook its own evaluation of the state of the science relating to amalgam safety. Taking a somewhat equivocal stance, Quebec authorities stated:

The mainstream scientific view holds that mercury exposure, even at very low levels attributable to dental amalgam, might be affecting people adversely, but the evidence currently available is inadequate to determine if this is the case. Existing evidence is weak, but the information base is inadequate to conclude that dental amalgam

has no effects that might be of concern (Ref. 10).

In early 1997, WHO convened a "consultation meeting" at its headquarters in Geneva, Switzerland to re-visit WHO's policy on dental amalgam use with the current science. In attendance were government officials, scientists, and representatives from the dental profession and dental trade industry from 10 of the world's major industrialized nations and 2 of WHO's regional offices. At the end of this meeting, the participants issued the following consensus statement:

Dental amalgam restorations are considered safe, but components of amalgam and other dental restorative materials may, in rare instances, cause local side effects or allergic reactions. The small amount of mercury released from amalgam restorations, especially during placement and removal, has not been shown to cause any other adverse health effects. (Ref 11).

In 1997, the Oral Health section of WHO's Division of Non-Communicable Diseases issued a publication based upon the working papers and presentations by participants at the 1997 WHO conference noted above. The publication included and gave WHO sanction to the consensus statement adopted by the participants at the 1997 WHO consultation meeting and provided supporting technical and scientific evidence on a wide range of discrete issues relating to dental amalgam (Ref. 11).

For example, in a section entitled "Direct Restorative Dental Materials in Oral Health Care Amalgam, Composites and Glass Ionomers," the document states:

Expert groups, convened by the Swedish National Board of Health and Welfare and the Swedish Medical Research Council (SOS, 1987) and the Department of Health and Human Services, USA (1993), have studied possible health effects of the use of mercury-containing amalgam. These study groups concluded that while it is well documented that individuals with amalgam fillings have higher concentrations of mercury in all tissues studied than those who have no amalgam fillings, there is no direct evidence of an adverse effect of mercury from amalgam tooth fillings on general health (Ref. 11).

In the section titled "Toxic and Allergic Risks Due to Dental Biomaterials", the document states:

Mercury from dental amalgam has been accused of being a toxic agent causing serious consequences to health, including various sclerosis, Alzheimer's disease, myalgic encephalitis, epilepsy, etc. without any proof having ever been presented. On the other hand, we know that certain allergies to mercury are involved in the appearance of lichenoid reactions, even if they are not the only responsible cause. The very rare epidemiological estimation of risk of allergy gives us percentages that go from 0.04% to

0.00001%. In this respect, the present data concerning mercury are perfectly characteristic of the risks of chronic intoxication and of allergies caused by dental therapies, i.e., extremely low (Ref. 11).

A third paper presented in the WHO publication entitled "Mercury Exposure From Dental Amalgam Fillings: Absorbed Dose and the Potential for Adverse Health Effects" stated: "It is concluded that no signs of renal toxicity could be found in conjunction with mercury released from amalgam fillings." Additionally, the paper recited the findings of a number of researchers who conducted studies on human subjects with symptoms allegedly caused by amalgam fillings. One study found that: "No symptom group had a higher estimated daily uptake of inhaled mercury vapor, or any higher mercury concentrations in blood and urine than the control group." Another study reported:

No significant differences regarding release of mercury vapor [sic] from the amalgam fillings before and after gum-chewing between the test subjects and the matched controls in a few spot measurements were found. Furthermore, no significant differences were found regarding urinary mercury levels and total excretion of proteins in urine. No damage in renal function was noted.

Yet another study cited in the WHO document found "no correlation between the total number of amalgam surfaces and fatigue, a symptom described as a mercury toxicity symptom" (Ref. 11).

December 1998 marked the culmination of a 2-year long study by an ad hoc working group constituted by the European Commission (the Commission) on amalgam safety and regulatory policies among the Commission's 15 member states. Comprised of leading dental professionals, researchers, and academics from western Europe, and with oversight by the Commission's medical devices expert group, the ad hoc working group issued a comprehensive assessment containing a number of conclusions, as follows:

In recent years, toxicological and biocompatibility aspects of dental amalgam have been reviewed extensively, both nationally and internationally, and risk analyses carried out. Currently available data indicate that mercury from dental amalgam will not cause an unacceptable health risk to the general population. \*\*\* levels of mercury found in tissues, blood and urine and associated with dental amalgam fillings are considerably below the levels at which systemic dependent toxic effects have been shown to occur \*\*\*. The hypothesis that there is a significant toxicological risk from dental amalgam fillings cannot be substantiated by the available evidence \*\*\*. Local reactions to dental amalgam fillings

and other dental restorative materials do occur but are relatively rare \*\*\*. There is no scientific evidence that the use of dental amalgam is related to adverse effects on pre- and post-natal health or fertility. Although there is not complete unanimity within the world community on either the potential health consequences arising from the use of dental amalgam or the appropriate posture that national health authorities should take with respect to regulating its use, there is overwhelming agreement among major health authorities that have assessed these risks that there is no evidence of a serious threat to the general population whose dental caries are treated with amalgam (Ref. 11).

Notwithstanding general international consensus about the level of risk, some Nordic countries, such as Denmark, Finland, Norway, and Sweden, have placed legal restrictions on dental amalgam for environmental concerns (Refs. 7 and 11). In addition, several European countries have taken very conservative approaches.

#### **V. 1993 and 1994 Panel Meeting Concerning Encapsulated Amalgam Alloy and Dental Mercury**

The Dental Products Panel (hereinafter referred to as the Panel) met on December 1, 2, and 3, 1993, and June 29, 1994, to discuss amalgam products. In addition to testimony from FDA staff, the Panel heard testimony from representatives of ADA, the American Dental Trade Association, and PHS. The Panel also reviewed the 1993 PHS report and an updated literature review. FDA requested that the Panel make a classification recommendation only on the encapsulated dental amalgam alloy and mercury.

After considering this testimony and information, the Panel unanimously recommended to classify encapsulated amalgam alloy and mercury for the restoration of teeth into class II. Specifically, the Panel recommended voluntary performance standards that could be issued by a group such as the Association for the Advancement of Medical Instrumentation (AAMI), voluntary testing guidelines, education, that the product be used only upon the written or oral authorization of a practitioner licensed by law to administer or use the device, and that the device be used only by persons with training or expertise in its use (Ref. 12).

##### *A. Identification*

The Panel identified encapsulated amalgam alloy and mercury as a device composed of elemental mercury and amalgam alloy separated by a septum,

which when placed in a dental amalgamator produces dental amalgam that is intended for the restoration of teeth. This product is hereinafter referred to in this document as encapsulated alloy/mercury.

##### *B. Classification Recommendation of Encapsulated Alloy/Mercury*

Class II (special controls): The Panel recommended that the establishment of special controls be a medium priority.

##### *C. Summary of the Reasons for the Panel's Recommendation for Encapsulated Alloy/Mercury*

The Panel, after considering the persons for whom the generic device is intended, and the proposed conditions for use for the generic device, gave the following reasons in support of its recommendation to classify the encapsulated alloy/mercury into class II.

1. General controls by themselves are insufficient to provide a reasonable assurance of the safety and effectiveness of the device.

2. There is sufficient information to establish special controls to provide reasonable assurance of safety and effectiveness.

3. Special controls will provide a reasonable assurance of safety and effectiveness.

##### *D. Summary of Data on Which the Panel's Recommendation Is Based*

The Panel based its recommendation on the review of the PHS report, other published literature, on expert testimony presented to the Panel, and on the Panel member's personal knowledge of, and experience with, the devices. The PHS report has been summarized under section IV.A of this document.

The Panel also reviewed a wide range of literature during its deliberation on the classification of encapsulated alloy/mercury in addition to the data described in the PHS report. The majority of the literature reviewed states that there is no compelling reason to change the current usage patterns of dental amalgam. There is, however, acknowledgement that continued research in the area is prudent. The following paragraphs describe specific information detailing the literature.

One of the articles reviewed indicated that mercury vapor is released from amalgam restorations. This article stated that there is release of mercury vapor from restorations during chewing, tooth brushing, and other oral activities. The author, however, indicated that there is insufficient knowledge about the metabolism of mercury vapor in the human to predict the health significance

of chronic exposure to this source of mercury (Ref. 13).

Another article reviewed by the panel demonstrated that mercury vapor can be analyzed in the oral cavity, especially following removal of amalgams, and during the setting and polishing of the amalgam. This study also demonstrated a significant direct correlation between the size of the amalgam restoration and the amount of vapor released. The study, however, concludes that mercury vapor exposure is of short duration and infrequent and is well below the exposure limits that are considered harmful (Ref. 14).

Another article indicated that although there is evidence of mercury vapor released from amalgam restorations there is no proof of a causal link of this specific source of the heavy metal to any major human health problem (Ref. 15).

One article indicated that Dental Amalgam remains one of the most versatile restorative materials in use (Ref. 16). The article further stated that certain measures should be instituted to assure patient and health care professional safety. These include the potential for chemical sensitivity to any of the elements and compounds found in dental amalgam. Similar concerns were also raised in the PHS report. The article reported that the chemical sensitivity response to specific compounds and elements in a dental amalgam are no different than other sensitivity reactions (Ref. 16). It further stated that evidence suggests that sensitivities to chemicals can occur within a small portion of the population.

Several articles addressed the benefits versus the risks of dental amalgam, and these articles agreed that, although dental amalgam can release minute amounts of elemental mercury, occupational studies indicate that the severity of response to this heavy metal follows a dose response pattern (Refs. 16 and 17). A dose response effect has not been demonstrated at a level of exposure associated with dental amalgams (Refs. 16 and 18). It also is noted that mercury is absorbed from many sources, including food and air, and there has been no demonstration that most people experience any clinical effects from this small additional body burden of mercury from amalgams (Ref. 16). The articles also stated that if there are adverse health effects from mercury in dental amalgam they may be so subtle and nonspecific that they would be difficult to detect, and noted that true allergies to dental amalgam rarely have been reported but do exist (Refs. 16 and 19).

One article directly examined the claims of mercury poisoning from dental amalgam (Ref. 19). This article and others concluded that although it is not possible to completely rule out adverse effects in a minority of susceptible patients, there is insufficient evidence to justify claims that mercury from dental amalgam restorations has an adverse effect on health on the vast majority of patients (Refs. 16 and 19). Other articles indicated that, although mercury vapor in high concentrations can have deleterious effects on organ systems, there is no evidence of risk at the levels generated by chewing with amalgam restorations (Refs. 13 and 15). The regulatory issues related to amalgam were addressed in one article. This article emphasized the need for continued surveillance and the need for practitioner input to report problems in performance with dental devices (Ref. 20).

#### *E. Risks to Health*

The Panel stated that there were no major risks associated with encapsulated amalgam alloy/mercury when used as directed, but recognized there was a small population of patients that may demonstrate allergic reactions to the materials in amalgam. The Panel noted that improper usage of the product also presented risks associated with mercury toxicity. The Panel specifically identified improper storage, trituration, and handling as contributing to this risk.

#### **VI. The Proposed Rule**

FDA is proposing classification actions in this document for dental mercury and dental amalgam products. FDA believes that the uniform regulation of all these products as class II devices, and the application of certain uniform special controls is appropriate, given the same risks are presented by the potential toxicity of mercury in each of these devices. This approach is consistent with the recommendation in the PHS report to regulate these products in a uniform manner. FDA believes that sufficient information exists to develop special controls, which will provide reasonable assurance of the safety and effectiveness of these devices.

With respect to encapsulated alloy/mercury, FDA agrees with the Panel's recommendation and is proposing that this product be classified into class II (special controls). Specifically, FDA is following the Panel's recommendation and proposing that labeling guidance and relevant recognized voluntary consensus standards be applied as special controls to these products.

FDA is also proposing to reclassify dental mercury as identified in § 872.3700 from class I to class II with labeling guidance and a relevant recognized voluntary consensus standard as special controls.

Lastly, FDA is proposing to add labeling guidance and a relevant voluntary consensus standard as special controls for the existing class II device, amalgam alloy, as identified in § 872.3050. Currently, no performance standard or other special controls are designated for amalgam alloy.

#### *A. Information FDA Reviewed Before Issuing This Proposal*

Before making this proposal, FDA carefully examined extensive information about the safety and effectiveness of dental restorative materials that contain mercury. As stated previously, public concern about the safety of dental amalgam engendered several national and international comprehensive reviews of scientific information about the risks and benefits of these products. FDA examined the 1993 and 1995 PHS reports, information presented to the Panel and the Panel's recommendations, information submitted in support of citizen petition's requests, and numerous reports of international health organizations and foreign countries that conducted comprehensive risk assessments of dental products that contain mercury.

In preparing the 1993 and 1995 PHS reports described in section IV.A of this document, the experts convened by the PHS conducted a comprehensive review of the scientific literature to assess the benefits and risks posed by dental restorative materials containing mercury (Ref. 1). In assessing the benefits of these products, the Benefits Assessment Subcommittee performed a literature search using the Medline system (Ref. 1). The scientific material reviewed for this report included well-qualified, prospective studies using objective assessment methods; cross-sectional studies reporting data for a given point or points in time; retrospective studies reporting the longevity of dental restorations; and articles published in peer-reviewed scientific journals (Ref. 1).

In assessing the risks associated with dental restorative materials containing mercury, the Risk Assessment Subcommittee viewed the body of significant literature that described the evidence for possible health effects produced from exposure to mercury from dental amalgam (Ref. 1). The Risk Assessment Subcommittee reviewed an extensive number of studies relating to

possible risks presented by amalgam, including studies relating to: Mercury forms, intake, uptake, metabolism and excretion; human exposure to mercury from dental amalgam; factors affecting estimates of daily intake of mercury vapor from dental amalgam; intraoral mercury vapor production and estimation of daily intake; mercury levels in body fluid; human and animal uptake of mercury from dental amalgam; hazard identification; human exposure and response; occupational hazards presented by dental amalgam exposure; hypersensitivity; psychological outcomes associated with mercury levels in body fluids; and mercury residues in neurological patients (Ref. 1). The PHS updated its review of scientific literature on risks and benefits and issued a new report in 1995 that confirmed its initial findings (Ref. 2).

FDA also examined the information reviewed by its expert Panel in 1994, and the Panel's recommendation. In making its recommendation, the Panel reviewed the 1993 PHS report, testimony from several professional and health organizations, and additional scientific literature as described in section V.D of this document.

FDA also carefully examined numerous studies, as described in section IV.B of this document, submitted by petitioners as evidence that amalgam fillings cause detrimental physiological and psychological effects.

Lastly, FDA reviewed the comprehensive reports of several international health organizations and foreign countries on the risks associated with these products, described in section IV.D of this document. In preparing these reports, these countries and organizations conducted extensive reviews and assessments of existing literature and scientific information.

### B. Weighing Benefits and Risks

For purposes of classification, FDA is to determine the safety and effectiveness of a device, in part, by weighing the probable benefits to health from use of the device against any probable risks of injury or illness from such use (section 513(a)(2) of the act).

#### 1. Benefits

Over the past 100 years, amalgam fillings have provided great benefit by restoring the structure of teeth of millions of individuals. Products used to make amalgam fillings are used today in the following situations (Ref. 1):

- Individuals of all ages;
- Stress-bearing areas and in small to moderate sized cavities in the posterior teeth;

- Teeth with severe destruction of structure;
- For cast-metal, metal-ceramic, and ceramic restorations as a foundation;
- When a patient's commitment to oral hygiene is poor; and
- When moisture control is problematic with patients.

These products provide substantial benefits over other dental restorative materials because amalgam fillings offer a broad range of applicability in clinical situations, durability, ease of use and relative insensitivity to variations in handling technique and oral conditions (Ref. 1).

#### 2. Risks

Dental amalgam can release minute amounts of elemental mercury, a metal whose toxicity at high exposure levels is well established. Estimates of human uptake of mercury from amalgam fillings have ranged between 1.24 and 27 micrograms ( $\mu\text{g}$ ) per day, a factor of more than twentyfold. However, the widely varying experimental conditions and assumptions in calculations undoubtedly contribute to the wide range of results. Non-physiologic-based models resulted in estimates likely being several times too high. Recalculations correcting for these factors produced estimates of less than 5  $\mu\text{g}$  per day. Studies have demonstrated higher blood and urine levels of mercury in individuals with amalgam fillings. However, estimates of mean daily mercury exposure from all sources vary (Ref. 1).

There is also evidence that mercury levels in body fluids spike during placement and removal of amalgam fillings and then decline over time, but no controlled clinical studies of health consequences of this phenomenon have been conducted. Occupational studies indicate that subclinical effects may occur at exposure levels tenfold higher than those typically experienced by the general population. Severity of response generally follows a dose-response pattern. There is no valid scientific evidence demonstrating specific adverse responses or a dose effect in humans at levels of mercury exposure associated with dental amalgam (Ref. 1).

Mercury is absorbed from many sources, including food and air. Because of the variability of exposures to mercury from all sources in the population, the margin of safety for some persons may be lowered when mercury from amalgam fillings is added. There is no valid scientific evidence that the general population treated with dental amalgam experiences any adverse clinical effects from this

additional body burden of mercury arising from amalgam use (Ref. 1).

As stated previously, public concern has been expressed over the toxic effects of mercury from amalgam fillings and certain persons have attributed a variety of detrimental physiological and psychological effects to mercury toxicity from amalgam fillings. In response to these concerns, numerous national and international reviews have examined reports of adverse effects from amalgam fillings, and FDA has reviewed substantial information about amalgam risks, as described in sections IV and V of this document.

After review of the scientific evidence and review of numerous studies submitted in support of banning or upclassifying dental restorative products containing mercury, FDA does not find any persuasive evidence that the physiological and psychological symptoms attributed to amalgam fillings are caused by amalgam fillings. Furthermore, FDA does not find any persuasive evidence that there is any improvement of these symptoms after removal of amalgam fillings. Although there are studies purporting to support the view that amalgam products pose risks to persons beyond the small subpopulation of hypersensitive individuals, conclusions cannot be drawn from these studies because they are methodologically flawed.

This position concerning the evidence of risks posed by amalgam fillings is supported by the findings of the PHS reports (Ref. 1), international health organizations, foreign governments, and the recommendations of FDA's expert advisory Panel as described in sections IV and V of this document. FDA does believe that there are some risks associated with dental products used in amalgam fillings from mercury toxicity that are associated with improper storage, trituration, and handling of the product. However, FDA does not believe that there are any major risks associated with toxicity of mercury when these products are used as directed. FDA believes there are also risks of allergic reaction to these products in a small subpopulation of individuals.

#### 3. Benefits Versus Risks

FDA believes that valid scientific evidence, as defined in § 860.7(c)(2), exists to determine the safety and effectiveness of dental amalgam: Namely, certain studies described in the PHS report; the studies and reports upon which the Panel based its recommendation; studies and reports reviewed by international health organizations and foreign governments; and most notably the significant human

experience with amalgam for over 100 years.

Although the degree of risk is not known to a certainty, FDA must make an assessment to weigh the probable benefits with the probable risks associated with the use of the device, in accordance with the criteria for a reasonable assurance of safety under § 860.7(d)(1). The statute states that FDA's classification decisions are to be predicated on a "reasonable assurance of safety and effectiveness," not an absolute assurance of safety and effectiveness (section 513(a)(1) of the act). Moreover, the statute directs FDA, in determining what is a "reasonable assurance" of safety and effectiveness, to assess "probable risk," not absolute risk (section 513(a)(2) of the act). FDA believes that the benefits and risks of encapsulated alloy/mercury and amalgam alloy are sufficiently characterized to make a determination that these products should be classified into class II with special controls. FDA notes that there is more significant human experience with dental amalgam than any other restorative material, and that, accordingly, more is known about the risks of dental amalgam than any other restorative material (Ref. 1).

Given the known risks of untreated caries, the longstanding history of successful use of dental amalgam restorations, the benefits of products used in amalgam fillings over other alternative materials, and the overall lack of valid scientific evidence that persons whose carious teeth are treated with dental amalgam experience any adverse health effects, other than a very small number of people who are hypersensitive to mercury, FDA believes that the probable benefits of restorative dental products containing mercury outweigh the probable risks of using these products.

The agency acknowledges that a small subpopulation of persons that already have high body burdens of mercury or suffer from allergies may respond adversely to the additional mercury exposure from amalgam fillings. For these subpopulations, the agency believes the risks can be addressed by labeling and by using alternative filling materials.

FDA believes that special controls, such as those described below by the Panel, will address those risks presented by dental amalgam products, both to hypersensitive individuals and health care workers, and that class II with special controls will provide a reasonable assurance of the safety and effectiveness of dental amalgam products.

#### 4. Proposed Special Controls to Address Risks Associated With the Use of Dental Restorative Materials Containing Mercury

FDA is proposing a labeling guidance and relevant recognized voluntary consensus standards as special controls for dental mercury and dental amalgam products. These special controls are consistent with the Panel's recommendations for special controls for encapsulated amalgam alloy and dental mercury, and FDA believes they address the risks related to toxicity associated with improper handling of dental mercury and dental amalgam products, and the risks for the small subpopulation of individuals who are allergic to ingredients in these products.

FDA's proposed guidance recommends that dental amalgam and dental mercury labeling lists all ingredients. By doing so, the clinician would be made aware of all materials he/she is placing in a patient's mouth, and would be able to avoid use of the product if the patient had known hypersensitivities to ingredients in amalgam products. This guidance also addresses risks to hypersensitive patients by recommending labeling instructing the practitioner not to use these products in hypersensitive persons, and of steps to take if allergic reactions do occur. FDA believes the guidance also controls the risks related to toxicity from improper storage, trituration, and handling by recommending instructions for storage, handling, and use. Finally, the guidance describes the prescription labeling requirements. FDA is including labeling aspects of the current edition of "ISO 1559:1995" and ANSI/ADA's "Specification No. 6-1987," described below, into its labeling guidance.

The agency has adopted good guidance practices (GGPs) regulation, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of this draft guidance document for comment in accordance with GGPs.

FDA is also proposing "ISO 1559:1995 Dental Materials—Alloys for Dental Amalgam" as a special control for both encapsulated alloy/mercury and amalgam alloy. This standard was developed by international governmental and nongovernmental committees in liaison with ISO, a worldwide federation of national standards bodies. The standard describes appropriate specifications and test methods for alloys composed

mainly of silver, tin, and copper used in amalgam. The alloy may be in either powder or tablet form, or in capsules with portions of alloy and mercury. It describes the minimum silver content and the maximum content of tin, copper, indium, palladium, platinum, zinc, and mercury. It also describes the recommended physical properties of the alloy, specifically, maximum percent creep, percent dimensional change, and compressive strength after 1 hour and after 24 hours. This standard also describes the test methods for determining physical properties. This standard addresses consistency of chemical composition and the important physical properties of the restorative material. This aspect of the special control allows the practitioner to know what substances are contained in the product, which will allow the practitioner to provide better counsel to patients who are allergic.

The standard also addresses the risks identified by the panel related to improper storage, tituration, and handling by providing recommendations, specifications, and instructions for proper handling, storage, and tituration.

This standard also has packaging and labeling instructions including a recommendation to list elements present in the alloy that are in concentrations greater than 0.1 percent, (see ISO 1559: 1995 section 7.2.1(f)). These packaging and labeling recommendations are consistent with the FDA labeling guidance discussed previously in all respects except one: The recommendation concerning the listing of ingredients. The specification in ISO 1559:1995 section 7.2.1(f) suggests listing only those elements present in the alloy in concentrations greater than 0.1 percent mass/mass (m/m), whereas the FDA labeling guidance recommends listing all ingredients in the product labeling. FDA is not incorporating this aspect of section 7.2.1 of ISO 1559:1995 as a special control because it believes all ingredients, even in concentrations smaller than 0.1 percent(m/m) could cause allergic reactions in some subset of persons. Therefore, FDA believes that practitioners should be informed of all ingredients. If practitioners are informed of the ingredients they will be able to counsel patients on appropriate treatment options.

This standard may be obtained from the International Organization for Standardization, Case Postale, Geneva, Switzerland, CH-1121. ISO also maintains a site on the Internet at <http://www.iso.org>.



FDA is also proposing to adopt ANSI/ADA's "Specification No. 6-1987 for Dental Mercury" as a special control for dental mercury (§ 872.3700) and encapsulated alloy/mercury (§ 872.3070). This standard specifies the specifications and test methods for mercury suitable for the preparation of dental amalgam and provides recommendations for packaging and marketing. It recommends packaging in air tight containers, and providing hazard warnings regarding mercury hygiene. This standard will allow the dentist to be aware of the physical properties of the mercury that will be used for restorations that will enable the dentist to better counsel allergic patients and will alert the dentist to mercury hygiene procedures. The risks identified by the Panel, including toxicity resulting from improper handling and storage that may result in systemic absorption of liquid mercury through the skin, local chemical sensitivity reaction, and inhalation of minute amounts of mercury vapor, are addressed in the standard by detailed recommendations for mercury manipulation and its packaging information, transport and handling procedures. This standard may be obtained from ANSI/AAMI, 11 West 42d St., New York, NY 10036. ANSI also maintains a site on the Internet at <http://www.ansi.org>.

### VII. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### VIII. Paperwork Reduction Act of 1995

FDA has tentatively determined that this proposed rule does not contain any new information collection requirements and, therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not necessary.

### IX. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104-121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12366 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is

necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the classification actions are not significant regulatory actions as defined by the Executive order. If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities.

The agency certifies that these proposed classification actions, if finalized, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

The proposed classification actions will affect the three separate devices: Dental mercury, amalgam alloy, and encapsulated dental amalgam. Professional dental groups have recommended the use of encapsulated dental amalgam over the other separate products. According to FDA data, encapsulated amalgam now accounts for over 99 percent of the amalgam market. Encapsulated dental amalgam is typically purchased and stored in packages of 80 capsules. These packages are kept at hand in dental clinics until needed. A typical restoration is expected to require two capsules of amalgam.

According to FDA records, there are 35 manufacturers of dental mercury, amalgam alloy, and encapsulated dental amalgam. In total, FDA expects that 40 distinct products will be affected by the proposed classification actions. Over 200 million dental restorations were performed during the last year for which FDA has data (1999), of which 64 million utilized dental amalgam (ADA, 1999). There are currently approximately 155,000 active dentists operating in 145,000 separate clinics (Bureau of Labor Statistics, 1998).

FDA is proposing to: (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 is proposing that all three products would have the same labeling guidance as a special control. In addition, FDA is proposing that dental mercury would have a voluntary ANSI standard as a special control, encapsulated alloy and dental mercury would have voluntary ANSI and ISO standards as special controls, and the amalgam alloy products would have a voluntary ISO standard as a special control.

FDA does not expect any change in costs related to the voluntary standard special controls. Manufacturers that export encapsulated amalgam are already responsible for meeting these voluntary standards, and other manufacturers currently follow equivalent standardized methods. Any change in performance test procedures is likely to result in little, if any, incremental change in production costs.

The special control labeling guidance, however, would entail some minimal costs to manufacturers. While some manufacturer's products currently include ingredient labeling, there is no consistent industry format. FDA is recommending a consistent label that will allow interested consumers of dental amalgam to easily obtain necessary information that may result in mercury exposure avoidance. Thus, FDA believes that manufacturers of these products will redesign their labeling or develop for the first time ingredient labeling as a result of these proposed classification actions.

FDA has developed estimates of the costs of enhanced labeling for dental amalgam. This estimate is based on costs developed by a consultant firm (Eastern Research Group (ERG)) for developing labeling for similar medical devices, specifically medical gloves (Ref. 21). These estimates include the costs of artwork, design, regulatory review, production, and application. Overall, the cost of developing a new label under these guidelines is estimated to be \$1,444 (or approximately \$1,500). FDA expects that 40 labels will be developed, 1 label for each product produced by the 35 manufacturers of the three devices. Thus, the total cost of designing and applying enhanced labels is expected to equal \$60,000 for 40 products. Over an estimated 5-year useful life (based on estimated cycle of labeling in the device industry), the average annualized cost to industry of this requirement (at 7 percent discount rate) is approximately \$15,000.

FDA does not expect the proposed classification actions to affect dental clinics.

FDA believes the costs of developing new labeling (approximately \$1,500) per product are not significant for a substantial number of small entities. The dental instrument and supplies industry, standard industrial code (SIC 3843) is typified by small establishments. Only about 35 of the approximately 650 establishments in the industry have more than 100 employees. (According to the Small Business Administration, any entity with fewer than 500 employees is considered small for this industry). These establishments are highly specialized (93 percent of their shipments are in this industry group) and concentrated (97 percent of dental sales were from these establishments). Total value of shipments was estimated at \$2.0 billion, or about \$125,000 per employee.

The Bureau of Census (Census) has estimated that 12 percent of all industry shipments come from dental establishments with fewer than five employees. Using the Census figures for dental manufacturers that have fewer than five employees, the average value of their shipments would equal \$1.25 million per year. The proposed classification actions would result in the design and application of enhanced labeling, at a cost of \$1,500 per product. There are 35 manufacturers producing 40 products. Assuming one manufacturer produces six products, the costs for the manufacturer producing six products would be \$9,000 and the cost for manufacturers producing one product would be \$1,500. The costs would only be approximately 0.1 percent to 0.7 percent (less than 1.0 percent) of the expected revenues for an extremely small entity. Thus, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), FDA certifies that the proposed regulations will not have a significant economic impact on a substantial number of small entities.

#### X. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this proposal by May 21, 2002. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m. Monday through Friday.

#### XI. Effective Dates

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

#### XII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Dental Amalgam: A Scientific Review and Recommended Public Health Service Strategy for Research, Education and Regulation; Public Health Service, U.S. Department of Health and Human Services, January 1993.
2. Update Statement by the U.S. Public Health Service on the Safety of Dental Amalgam, September 1, 1995.
3. Citizen petition Docket No. 93P-0424, citizen petition Docket No. 94P-0354/CP1, and citizen petition from Dr. Baylin et al.
4. Summary of the documented review of scientific studies referenced in the dental amalgam petitions, May 28, 1997.
5. Response to citizen petition Docket No. 93P-0424/CP1, letter to Robert E. Reeves, Esq., dated October 31, 1997; response to citizen petition Docket No. 94P-0354, letter to Robert E. Reeves, Esq., dated November 10, 1997; and response to citizen petition submitted to the National Institute for Environmental Health Sciences referred to FDA for reply, letter to Michael A. Baylin, D.D.S. dated October 31, 1997.
6. Swedish National Board of Health and Welfare, Possible Health Effects and Dental Amalgam, 1994.
7. Dental Amalgam—A Report with Reference to the Medical Devices Directive 93/42/EEC from an Ad Hoc Working Group Mandated by the European Commission, June 1998.
8. The Safety of Dental Amalgam, Health Canada, 1995.
9. Dental Amalgam and Human Health (A Current Consensus); WHO Collaborating Centre in Oral Health, Wellington School of Medicine, University of Otago, Wellington, New Zealand, June 1996.
10. The Safety of Dental Amalgam: A State of the Art Review, Conseil d'Evaluation des Technologies de la Sante' de Quebec, April 1997.
11. Consensus Statement on Dental Amalgam, World Health Organization Consultation on Assessing the Risks and Benefit to Oral Health, Oral Care and Environment Using Dental Amalgam and its Replacement, March 7, 1997, draft.
12. Transcript from 1993 meeting of the Food and Drug Administration Dental Products (Advisory) Panel, December 1 to 3, 1993, and transcript from 1994 meeting of the Food and Drug Administration's Dental Products (Advisory) Panel, June 29, 1994.
13. Enwonwu, C. O., "Potential Health Hazard of Use of Mercury in Dentistry: Critical Review of the Literature" *Environmental Research* 42:257-274, 1987.
14. Haikel, Y. et al. "Exposure to mercury vapor during setting, removing, and polishing amalgam restorations" *Journal of Biomedical Materials Research* 24:1551-1558, 1990.
15. Mandel, Irwin D., "Amalgam Hazards; An Assessment of Research" *Journal of the American Dental Association*, 122:62-65 August 1991.

16. Corbin, Stephen B., "The Benefits and Risks of Dental Amalgam: Current Findings Reviewed" *Journal of the American Dental Association*, 125:381-387, April 1994.

17. Mackert, J. R., "Factors Affecting Estimation of Dental Amalgam Mercury Exposure from Measurements of Mercury Vapor Levels in Intra-oral Expired Air" *Journal of Dental Research*, 66 No. 12:1775-1780, December 1987.

18. Mackert J. Rodway, "Dental Amalgam and Mercury" *Journal of the American Dental Association*, 122:61, August 1991.

19. Reinhardt, John W., "Risk Assessment of Mercury Exposure from Dental Amalgams" *Journal of Public Health*, 48 No. 3, Summer 1988.

20. Jacobson, Elizabeth D., "Regulatory Issues in Dentistry: How Dentists Can Participate" *Journal of American Dental Associates*, 4:444-50, April 12, 1994.

21. Eastern Research Group; "Preliminary Estimates: Labeling and Related Testing Costs for Medical Glove Manufacturers," memorandum, January 18, 1999.

#### List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 872 be amended as follows:

#### PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 872.3050 is amended by revising paragraph (b) to read as follows:

#### § 872.3050 Amalgam alloy.

\* \* \* \* \*

(b) *Classification*. Class II (special controls). The special controls for this device are:

(1) International Standard "ISO 1559:1995 Dental Materials—Alloys for Dental Amalgam," and

(2) FDA's "Special Control Guidance for Industry on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling."

3. Section 872.3070 is added to read as follows:

#### § 872.3070 Encapsulated amalgam alloy and mercury.

(a) *Identification*. Encapsulated amalgam alloy and mercury is a device composed of elemental mercury and amalgam alloy, separated by a septum, which, when placed in a dental amalgamator, produces dental amalgam which is intended for the restoration of teeth.

(b) *Classification*. Class II (special controls). The special controls for this device are:

(1) "ISO 1559:1995 Dental Materials—Alloys for Dental Amalgam,"

(2) ANSI/ADA's "Specification No. 6-1987 for Dental Mercury," and

(3) FDA's "Special Control Guidance for Industry on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling."

4. Section 872.3700 is amended by revising paragraph (b) to read as follows:

**§ 872.3700 Dental mercury.**

\* \* \* \* \*

(b) *Classification*. Class II (Special Controls). The special controls for this device are:

(1) ANSI/ADA "Specification No. 6-1987 for Dental Mercury," and

(2) FDA's "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling."

Dated: February 7, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-4028 Filed 2-19-02; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[REG-209114-90]

RIN 1545-AH49

#### Golden Parachute Payments

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking and notice of public hearing.

**SUMMARY:** This document contains proposed regulations relating to golden parachute payments to provide guidance to taxpayers who must comply with section 280G. Proposed regulations under section 280G were previously published in the **Federal Register** on May 5, 1989 (the 1989 proposed regulations). These proposed regulations are proposed to apply to any payments that are contingent on a change in ownership or control occurring on or after January 1, 2004. Taxpayers may rely on these proposed regulations until the effective date of the final regulations. Alternatively, taxpayers may rely on the 1989 regulations for any payment contingent on a change in ownership or control that occurs prior to January 1, 2004.

**DATES:** Written or electronic comments must be received by June 5, 2002. Requests to speak and outlines of topics

to be discussed at the public hearing scheduled for June 26, 2002, must be received by June 5, 2002.

**ADDRESSES:** Send submissions to CC:ITA:RU (REG-209114-90), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:ITA:RU (REG-209114-90), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington, DC or sent electronically, via the IRS Internet site [www.irs.gov/regs](http://www.irs.gov/regs). The public hearing will be held in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Concerning the regulations, Erinn Madden at (202) 622-6030 (not a toll-free number). To be placed on the attendance list for the hearing, please contact LaNita M. Vandyke at (202) 622-7180.

**SUPPLEMENTARY INFORMATION:**

**Background**

This document contains proposed amendments to 26 CFR part 1 under section 280G of the Internal Revenue Code (Code). Sections 280G and 4999 of the Code were added to the Code by sec. 67 of the Deficit Reduction Act, Public Law 98-369 (98 Stat. 585). Section 280G was amended by sec. 1804(j) of the Tax Reform Act of 1986, Public Law 99-514 (100 Stat. 2807), sec. 1018(d) of the Technical and Miscellaneous Revenue Act of 1988, Public Law 100-647 (102 Stat. 3581) and sec. 1421 of the Small Business Job Protection Act of 1996, Public Law 104-188 (110 Stat. 1755).

Section 280G denies a deduction to a corporation for any excess parachute payment. Section 4999 imposes a 20-percent excise tax on the recipient of any excess parachute payment. Related provisions include section 275(a)(6), which denies the recipient a deduction for the section 4999 excise tax, and section 3121(v)(2)(A), which relates to Federal Insurance Contributions Act. Proposed regulations (PS-217-84) under section 280G were previously published in the **Federal Register** at 54 FR 19390 on May 5, 1989 (the 1989 proposed regulations).

**Explanation of Provisions**

*Overview*

Section 280G denies a deduction to a corporation for any excess parachute payment. Section 4999 imposes a 20-percent excise tax on the recipient of any excess parachute payment. The disallowance of the deduction under

section 280G is not contingent on the imposition of the excise tax under section 4999, and the imposition of the excise tax under section 4999 is not contingent on the disallowance of the deduction under section 280G. For example, an individual may be subject to the 20-percent excise tax under section 4999 even though the payor is a foreign corporation not subject to United States income tax.

Section 280G(b)(2)(A) defines a *parachute payment* as any payment that meets all of the following four conditions: (a) The payment is in the nature of compensation; (b) the payment is to, or for the benefit of, a disqualified individual; (c) the payment is contingent on a change in the ownership of a corporation, the effective control of a corporation, or the ownership of a substantial portion of the assets of a corporation (a change in ownership or control); and (d) the payment has (together with other payments described in (a), (b), and (c) of this paragraph with respect to the same individual) an aggregate present value of at least 3 times the individual's base amount. Section 280G(b)(2)(B) provides that the term parachute payment also includes any payment in the nature of compensation to, or for the benefit of, a disqualified individual if the payment is pursuant to an agreement that violates any generally enforced securities laws or regulations (securities violation parachute payment).

Section 280G(b)(1) defines the term excess parachute payment as an amount equal to the excess of any parachute payment over the portion of the disqualified individual's base amount that is allocated to such payment. For this purpose, the portion of the base amount allocated to a parachute payment is the amount that bears the same ratio to the base amount as the present value of the parachute payment bears to the aggregate present value of all such payments to the same disqualified individual.

Generally, excess parachute payments may be reduced by certain amounts of reasonable compensation. Section 280G(b)(4)(B) provides that, except in the case of securities violation parachute payments, the amount of an excess parachute payment is reduced by any portion of the payment that the taxpayer establishes by clear and convincing evidence is reasonable compensation for personal services actually rendered by the disqualified individual before the date of change in ownership or control. Such reasonable compensation is first offset against the portion of the base amount allocated to the payment.