DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

**Memorandum**

**Date:** July 28, 2009

**From:** Michael E. Adjodha, Chemical Engineer, DAGID/ODE/CDRH

**Subject:** Review of the Agency's Analysis of its NEPA obligations for the Classification of Dental Amalgam, Reclassification of Dental Mercury, Designation of Special Controls for Dental Amalgam, Mercury, and Amalgam Alloy

**Sponsor:** Agency Initiated Action

**To:** The Administrative Record

**Approved by:** Susan Runner, D.D.S., Acting Director, Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGID), Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration: _____

## I. The Final Rule

Dental amalgam[1] is a device that consists of a combination of elemental mercury[2], supplied as a liquid in bulk, sachet, or predosed capsule form, and amalgam alloy composed primarily of silver, tin, and copper, supplied as a powder in bulk, tablet, or predosed capsule form, for the direct filling of carious lesions or structural defects in teeth. This device also includes the individual component devices, mercury and amalgam alloy, when intended to be combined with each other to form dental amalgam.

This memorandum contains the Agency's analysis of its NEPA obligations for the final rule classifying dental amalgam into Class II, reclassifying mercury from Class I to Class II, and designating special controls to support the Class II classifications of dental amalgam, mercury, and amalgam alloy (currently classified as Class II). The three devices are now classified in a single regulation. The special control for these devices is the guidance document entitled, "Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy."

The special controls guidance identifies the risks to health of dental amalgam devices and recommends mitigation measures to address those risks. The risks to health of dental amalgam devices identified in the special controls guidance are: 1) exposure to mercury; 2) allergic

[1] Dental amalgam, as it is referred to in this final rule, is a device that is a combination of two component devices, mercury and amalgam alloy.

[2] FDA is no longer using the term "dental mercury," but instead is using "mercury," to more accurately reflect that the mercury used in dental amalgam is elemental mercury.

response including adverse tissue reaction; 3) mechanical failure; 4) corrosion; 5) contamination; and 6) improper use. To mitigate these risks, the special controls guidance document recommends that 1) exposure to mercury be addressed by label warning ("WARNING--CONTAINS MERCURY"), a warning about potential harm if vapors are inhaled, precautions regarding the need for adequate ventilation, performance data regarding mercury vapor release, and an information for use statement; 2) allergic response including adverse tissue reaction be addressed through biocompatibility testing as well as labeling contraindicating against use in persons with a known mercury allergy; 3) mechanical failure be addressed through composition and performance data with recommendations for certain physical property labeling; 4) corrosion be addressed through corrosion testing and labeling recommendations regarding intraoral contact with other metals; 4) contamination be addressed by quality control tests for mercury and 5) improper use be addressed by specific labeling precautions.

Specific labeling recommendations included in the special controls guidance are:

- Disclosure of mercury content on the label
- Disclosure of certain information on the physical properties
- Warning regarding mercury content and harm if vapors are inhaled
- Contraindications against use in persons with a known mercury allergy or sensitivity,
- Certain precautions on use; e.g., single use, use with adequate ventilation, and no direct contact with other types of metals, and
- Information for use stating the following:
  "Dental amalgam has been demonstrated to be an effective restorative material that has benefits in terms of strength, marginal integrity, suitability for large occlusal surfaces, and durability.[3] Dental amalgam also releases low levels of mercury vapor, a chemical that at high exposure levels is well-documented to cause neurological and renal adverse health effects.[4] Mercury vapor concentrations are highest immediately after placement and removal of dental amalgam but decline thereafter.

  Clinical studies have not established a causal link between dental amalgam and adverse health effects in adults and children age six and older. In addition, two clinical trials in children aged six and older did not find neurological or renal injury associated with amalgam use.[5]

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[3] 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.

[4] Liu, J. et al., "Toxic effects of metals," Casarett & Doull's Toxicology: The Basic Science of Poisons, Chapter 23, pp. 931-979, McGraw-Hill Medical, New York, New York, 2008.
Clarkson, T.W. et al., "The Toxicology of Mercury and Its Chemical Compounds," Critical Reviews in Toxicology, Vol. 36, pp. 609-662, 2006.

[5] De Rouen, T. et al., "Neurobehavioral Effects of Dental Amalgam in Children, A Randomized Clinical Trial," Journal of the American Medical Association, Vol. 295, 1784-1792,No. 15, April, 19, 2006.
Bellinger, D.C. et al., "Neuropsychological and Renal Effects of Dental Amalgam in Children: A Randomized Clinical Trial," Journal of the American Medical Association, Vol. 295, No. 15, April 19, 2006, 1775-1783, 2006.
Barregard, L. et al., "Renal Effects of Dental Amalgam in Children: The New England Children's Amalgam Trial," Environmental Health Perspectives, Volume 116, 394-399,,No. 3, March 2008.
Woods, J.S. et al., "Biomarkers of Kidney Integrity in Children and Adolescents with Dental Amalgam Mercury Exposure: Findings from the Casa Pia Children's Amalgam Trial," Environmental Research, Vol. 108, pp. 393-399, 2008.

The developing neurological systems in fetuses and young children may be more sensitive to the neurotoxic effects of mercury vapor. Very limited to no clinical information is available regarding long-term health outcomes in pregnant women and their developing fetuses, and children under the age of six, including infants who are breastfed.

The Agency for Toxic Substances and Disease Registry's (ATSDR) and the Environmental Protection Agency (EPA) have established levels of exposure for mercury vapor that are intended to be highly protective against adverse health effects, including for sensitive subpopulations such as pregnant women and their developing fetuses, breastfed infants, and children under age six.[6] Exceeding these levels does not necessarily mean that any adverse effects will occur.

FDA has found that scientific studies using the most reliable methods have shown that dental amalgam exposes adults to amounts of elemental mercury vapor below or approximately equivalent to the protective levels of exposure identified by ATSDR and EPA. Based on these findings and the clinical data, FDA has concluded that exposures to mercury vapor from dental amalgam do not put individuals age six and older at risk for mercury-associated adverse health effects.

Taking into account factors such as the number and size of teeth and respiratory volumes and rates, FDA estimates that the estimated daily dose of mercury in children under age six with dental amalgams is lower than the estimated daily adult dose. The exposures to children would therefore be lower than the protective levels of exposure identified by ATSDR and EPA.

In addition, the estimated concentration of mercury in breast milk attributable to dental amalgam is an order of magnitude below the EPA protective reference dose for oral exposure to inorganic mercury. FDA has concluded that the existing data support a finding that infants are not at risk for adverse health effects from the breast milk of women exposed to mercury vapors from dental amalgam.""

Performance specifications for dental amalgam and its individual components, mercury and amalgam alloy, are provided in ISO 24234; 2004(E), Dentistry – Mercury and Alloys for Dental Amalgam, the recognized consensus standard indentified in the special controls guidance. The standard includes specifications for the composition of amalgam alloy and the purity of mercury as well as protocols for measuring the following physical properties of dental amalgam:

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Lauterbach, M. et al., "Neurological Outcomes in Children with and Without Amalgam-Related Mercury Exposure: Seven Years of Longitudinal Observations in a Randomized Trial," Journal of the American Dental Association, Vol. 139, 138-145, February 2008.

[6] Agency for Toxic Substances and Disease Registry (ATSDR) and Research Triangle Institute, Toxicological profile for mercury, U.S. Dept. of Health and Human Services, Public Health Service, Atlanta, Georgia, 1999. United States Environmental Protection Agency (EPA), "Integrated Risk Information System (IRIS) Screening-Level literature Review" – Mercury, elemental, 2002.

- compressive strength
- maximum creep
- dimensional change
- corrosion products, including ions and mercury vapor released.

In addition, the special controls guidance document recommends submission of the following specifications for dental amalgam and amalgam alloy:

- particle size distribution and shape
- trituration time
- working time.

The final rule establishes a special control for dental amalgam and its components, mercury and amalgam alloy.

The final rule does the following:

- removes 21 CFR 872.3050, Amalgam Alloy, Class II
- removes 21 CFR 872.3700, Dental Mercury, Class I
- adds 21 CFR 872.3070, Dental Amalgam, Mercury, and Amalgam Alloy, Class II Special Controls, which reads as follows:

§ 872.3070 Dental Amalgam, Mercury, and Amalgam Alloy
(a) Identification. Dental amalgam is a device that consists of a combination of elemental mercury, supplied as a liquid in bulk, sachet, or predosed capsule form, and amalgam alloy composed primarily of silver, tin, and copper, supplied as a powder in bulk, tablet, or predosed capsule form, for the direct filling of carious lesions or structural defects in teeth. This device also includes the individual component devices, mercury and amalgam alloy, when intended to be combined with each other to form dental amalgam.

(b) *Classification*. Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy." See § 872.1(e) for the availability of this guidance document.

The new classification regulation, 872.3070, includes dental amalgam as well as its individual components, dental mercury and amalgam alloy. Firms intending to market mercury or amalgam alloy separately will need to address the relevant portions of the special controls guidance.

## II. Environmental Impact Considerations and NEPA

Under the National Environmental Policy Act of 1969 (NEPA), all federal agencies must assess the environmental impact of any "major federal action" they take (42 U.S.C. 4332(C)). The Council on Environmental Quality (CEQ) is responsible for overseeing federal efforts to comply with NEPA and issued regulations on procedural requirements of NEPA (40 CFR Parts

1500-1508). CEQ directs federal agencies to adopt procedures, as necessary, to supplement the CEQ regulations (40 CFR 1507.3). FDA promulgated its supplemental NEPA regulations in 21 CFR Part 25.

For major federal actions "significantly affecting the quality of the human environment," an agency must prepare an Environmental Impact Statement (EIS) (*see id.*; 40 CFR 1501.4; 21 CFR 25.22). If the action "may" have such a significant environmental effect, an agency must prepare an Environmental Assessment (EA) to provide sufficient evidence and analysis for the agency to determine whether to prepare an EIS or a finding of no significant impact (FONSI) (40 CFR 1501.3; 21 CFR 25.20). Agencies can establish categorical exclusions for categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an EA nor an EIS is required (*see* 40 CFR 1508.4). However, agency procedures must "provide for extraordinary circumstances in which a normally excluded action may have a significant environmental effect" (40 CFR 1508.4; *see also* 21 CFR 25.21).

FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that "the specific proposed action may significantly affect the quality of the human environment" (*see* 21 CFR 25.21; 40 CFR 1508.4). Agency regulations provide two examples of extraordinary circumstances: "(a) actions for which, at the expected level of exposure, there is the potential for serious harm to the environment; and (b) actions that adversely affect an endangered, threatened, or otherwise specially protected species" (21 CFR 25.21).

A regulation to classify or reclassify a device constitutes a major federal action under NEPA (*see* 40 CFR 1508.18). Under FDA regulations, however, the classification or reclassification of a device under 21 CFR Part 860, including the establishment of special controls, is categorically excluded, provided that the action will not result in 1) increases in the existing levels of use of the device or 2) changes in the intended use of the device or its substitutes (21 CFR 25.34(b)). As a result of our review of the final rule, we have determined that the action qualifies for categorical exclusion under 21 CFR 25.34(b) and, therefore, neither an EA nor an EIS is required. Below is a discussion of our decision that the cited exclusion is warranted because 1) the action meets the criteria of the exclusion, i.e., there are no increases in existing levels of use or changes in intended use, and 2) there are no extraordinary circumstances.

## III. Application of the Categorical Exclusion (§ 25.34(b)) to the Final Rule

### A. No increases in the existing levels of use

Below is a discussion of how the final rule does not result in increases in existing levels of use of dental amalgam or its individual components, mercury and amalgam alloy.

1. Dental Amalgam

Dental amalgam is currently an unclassified, preamendments device. The final rule changes the classification of dental amalgam from unclassified (preamendments) to Class II (Special Controls) and a establishes special control. The change in classification alone does not result in the introduction of any substance into the environment, does not increase the

existing levels of use, and does not change the intended use of this device or its substitutes. The special control is the guidance document entitled," Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy," which includes recommendations for testing and labeling based on the consensus standard ISO 24234 Dentistry—Mercury and Alloys for Dental Amalgam.

The labeling recommendations for dental amalgam in the special controls guidance are as follows:

- WARNING – CONTAINS MERCURY
- contains [ ]% mercury by weight
- may be harmful if vapors are inhaled
- compressive strength (MPa) @ 24 hrs
- dimensional change during hardening (%)
- trituration time (s)
- working time (min)
- contraindication: do not use in persons with a known mercury allergy
- do not place the device in direct contact with other types of metals
- use with adequate ventilation
- single-use only
- a recommended information for use statement.

The labeling recommendations of the special controls guidance do not require, nor are they expected to result in, an increase in existing levels of use of dental amalgam by either manufacturers or users (dental practitioners and their patients) of the device. To conform to the special control, manufacturers of dental amalgam will have to revise the labeling of these devices by adding information for the dentist, precautions, and physical property data consistent with guidance. While additional cost may be incurred by label modification, making a modification to labeling does not require the use of additional dental amalgam material and, therefore, would not increase the existing levels of use of dental amalgam by manufacturers or users, nor would such a modification be expected to increase such levels of use. The recommendations will further highlight the potential risks, benefits, and key properties of dental amalgam for users. After examination of the label, some users may decide to use alternative treatment; for others, it will have no effect. We have no basis to suggest or expect that the additional precautions and information recommended by the labeling may result in a net increase in existing levels of use of dental amalgam by manufacturers or users.

The testing recommendations for dental amalgam in the special controls guidance are as follows:

- chemical composition
- biocompatibility
- compressive strength (MPa) @ 1 hr
- compressive strength (MPa) @ 24 hrs
- maximum creep (%)
- dimensional change during hardening (%)
- particle size distribution (μ) and shape.

- corrosion products[7] identifying the ions leached ($\mu g/cm^2$) and mercury vapor released during corrosion ($ng/cm^2$ in 4 hrs)
- trituration time (s)
- working time (min).

These testing recommendations do not require, nor are they expected to result in an increase in existing levels of use of dental amalgam by manufacturers or users of the device. The testing recommendations are directed at manufacturers. FDA will review the performance data in a 510(k) submission for the dental amalgam device.

For manufacturers, the testing recommendations include tests that are routinely performed (based on the data provided in 510(k) submissions) by such manufacturers, except for the following:

- particle size distribution ($\mu$) and shape
- corrosion products[8] identifying the ions leached ($\mu g/cm^2$) and mercury vapor released during corrosion ($ng/cm^2$ in 4 hrs).

Particle size is a specification determined by the manufacturer of amalgam alloy powder. It is determined by microscopy. No additional dental amalgam specimens are needed to determine particle size. Corrosion product testing requires four test specimens. However, according to our calculations (see Appendix I) these specimens can be obtained from a previous non-destructive test such as dimensional change during hardening or from the 100 g inventory of dental amalgam specified in ISO 24234 as needed for all testing, in which case no additional dental amalgam material is needed. Thus, the testing recommendations do not require any additional dental amalgam material for test sampling, and therefore, would not increase, or be expected to increase, the existing levels of use of dental amalgam by manufacturers.

Theoretically, manufacturers could decide to procure additional dental amalgam for specimens that are needed to conduct corrosion testing; however, it is not known to what extent a manufacturer may elect to do so. If a manufacturer decided to procure additional dental amalgam for corrosion testing, the amount needed per product[9] is estimated to be 4.4 g of dental amalgam. If 4.4 grams is multiplied by 50, the approximate number of dental amalgam products currently on the market in the U.S., the maximum result is 220 g of dental amalgam, assuming all products will undergo testing. Note that manufacturers of these devices for use in the United States are located worldwide[10]. Even if manufacturers opt to procure additional dental amalgam for test specimens, the total amount needed is minimal, especially when compared to the 37.6 tons[11] (34 million grams) of dental amalgam used in

[7] See Annex A, Determination of Immersion Corrosion for Dental Amalgam, of ISO 24234:2004(E)
[8] See Annex A, Determination of Immersion Corrosion for Dental Amalgam, of ISO 24234:2004(E)
[9] This testing is not periodic but is performed at least once in a product's lifecycle to determine its chemical and mechanical properties and after changes to the formulation are made.
[10] Companies currently registered with FDA to market dental amalgam in the United States are located in Sweden, United Kingdom, Switzerland, Germany, Liechtenstein, France, Australia, Israel, Costa Rica, and United States (Delaware, New Jersey, New York, Michigan, and Nevada).
[11] See Appendix I for this calculation.

the United States. Further diminishing the effect of this testing is the fact that the testing will be distributed worldwide and is not concentrated at any one location.

2. Mercury

Mercury is currently a Class I, non-exempt device (i.e., mercury is subject to premarket notification requirements). As a Class I device, mercury is subject to general controls including establishment registration, device listing, quality system regulations, labeling regulations, and the submission of a premarket notification (510(k)). The final rule changes the classification of mercury from Class I to Class II (Special Controls) and establishes special controls. The change in classification alone does not result in the introduction of any substance into the environment, does not increase the existing levels of use, and does not change the intended use of these devices or their substitutes. The special control is the guidance document entitled, "Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy," which includes recommendations for testing and labeling based on the consensus standard ISO 24234 Dentistry—Mercury and Alloys for Dental Amalgam.

The labeling recommendations of the special control guidance apply to mercury when intended to be combined with amalgam alloy to form dental amalgam.

The labeling recommendations for mercury in the special controls guidance are as follows:

- WARNING – CONTAINS MERCURY
- contains [ ]% mercury by weight
- may be harmful if vapors are inhaled
- contraindication: do not use in persons with a known mercury allergy
- use with adequate ventilation
- single-use only
- information for use regarding the risks, benefits, and properties of dental amalgam.

These labeling recommendations do not require, nor are they expected to result in, an increase in existing levels of use of mercury by either manufacturers or users of the device. The labeling recommendations are directed at users and should have no effect on the levels of mercury used by manufacturers. The labeling recommendations will further highlight the potential risks, benefits, and key properties of mercury for users. We have no basis to suggest or expect that the additional precautions recommended by the labeling may result in a net increase in the existing levels of use of mercury by manufacturers or users.

The testing recommendations for mercury in the special controls guidance are as follows:

- the device should be free of contamination by oil, water, and foreign material
- the device should pour freely and completely without tailing.

These testing recommendations do not require, nor are they expected to result in, an increase in existing levels of use of mercury by either manufacturers or users of the device. The testing recommendations are directed at manufacturers. The recommendations are visual

quality control checks that do not require any additional specimens (inventory) of mercury for the test itself. Manufacturers of mercury are to visually inspect the device for impurities. Contaminated mercury is not discarded but is purified or returned to the supplier before it can be marketed. No new specimens are needed for this testing. It is highly unlikely that any manufacturer would procure additional mercury solely for a test that is a visual inspection, where no additional material is needed to conduct the test itself. FDA will review the results for the visual quality control checks in a 510(k) submission for the mercury device.

3. Amalgam Alloy

Amalgam alloy is currently a Class II device and, as such, it is subject to general controls including establishment registration, device listing, quality system regulations, labeling regulations, the submission of a premarket notification (510(k)) and special controls (not specified). The final rule changes the classification of amalgam alloy from Class II to Class II (Special Controls) and establishes a special control.[12] The special control is the guidance document entitled," Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy," which includes recommendations for testing and labeling based on the consensus standard ISO 24234 Dentistry—Mercury and Alloys for Dental Amalgam.

The labeling recommendations of the special control guidance apply to amalgam alloy when intended to be combined with mercury to form dental amalgam.

The labeling recommendations for amalgam alloy in the special controls guidance are as follows:

- compressive strength (MPa) @ 24 hrs
- dimensional change during hardening (%)
- trituration time (s)
- working time (min)
- contraindication: do not use in persons with a known mercury allergy
- do not place the device in direct contact with other types of metals
- use with adequate ventilation
- single-use only
- a recommended information for use statement.

These labeling recommendations do not require, nor are they expected to result in, an increase in existing levels of use of amalgam alloy by either manufacturers or users of the device. The discussion here parallels that of dental amalgam because amalgam alloy becomes dental amalgam, as a finished form, once mercury is added. Therefore, except for warnings concerning mercury content, the labeling of amalgam alloy is exactly the same as that for dental amalgam.

[12] The Safe Medical Devices Act of 1990 (SMDA) (Public Law 101-629) broadened the definition of class II devices to mean those devices for which the "general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, . . . recommendations, and any other appropriate actions the Secretary deems necessary to provide such assurance." Section 513(a)(1)(B) of the Act (21 U.S.C. 360c(a)(1)(B)).

To conform to the special control, manufacturers of amalgam alloy will have to revise the labeling of this device by adding information for the dentist, precautions, and physical property data consistent with the special controls guidance. While additional cost may be incurred by label modification, making a modification to labeling does not require the use of additional amalgam alloy material and, therefore, would not increase the existing levels of use of amalgam alloy by manufacturers or users. Nor would such a modification be expected to increase such levels of use. The labeling recommendations will further highlight the potential risks, benefits, and key properties of amalgam alloy (as it pertains to its finished form, dental amalgam) for users. After examination of the label, some users may decide to use alternative treatment; for others, it will have no effect. We have no basis to suggest or expect that the additional precautions and information recommended by the labeling may result in a net increase in existing levels of use of amalgam alloy by manufacturers or users.

The testing recommendations for amalgam alloy in the special controls guidance are as follows:

- chemical composition
- biocompatibility
- compressive strength (MPa) @ 1 hr
- compressive strength (MPa) @ 24 hrs
- maximum creep (%)
- dimensional change during hardening (%)
- particle size distribution (μ) and shape
- corrosion products[13] identifying the ions leached ($\mu g/cm^2$) and mercury vapor released during corrosion ($ng/cm^2$ in 4 hrs)
- trituration time (s)
- working time (min).

The discussion here again parallels that of dental amalgam because amalgam alloy becomes dental amalgam in its finished form once mercury, in a 1:1 ratio by mass is added. Therefore, testing of amalgam alloy is exactly the same as that for dental amalgam[14]. The testing recommendations do not require, nor are they expected to result in, an increase in existing levels of use of amalgam alloy by manufacturers or users. The testing recommendations are directed at manufacturers. FDA will review the performance data in a 510(k) submission for the amalgam alloy device.

For manufacturers, the testing recommendations include tests that are routinely performed (based on the data provided in 510(k) submissions) by such manufacturers, except for the following:

- particle size distribution (μ) and shape

[13] See Annex A, Determination of Immersion Corrosion for Dental Amalgam, of ISO 24234:2004(E)

[14] Other than chemical composition and particle size distribution, both manufacturing specifications, there are no separate performance tests for amalgam alloy. The performance test results for amalgam alloy are to be determined from its finished form -- dental amalgam.

- corrosion products[15] identifying the ions leached ($\mu g/cm^2$) and mercury vapor released during corrosion ($ng/cm^2$ in 4 hrs).

Particle size is a specification determined during the manufacture of amalgam alloy powder. It is determined by microscopy. No additional amalgam alloy specimens are needed to determine particle size. Corrosion product testing requires four test specimens. However, according to our calculations (see Appendix I), these specimens can be obtained from a previous non-destructive test such as dimensional change during hardening or from the 50 g inventory of amalgam alloy specified in ISO 24234 as needed for all testing, in which case no additional amalgam alloy material is needed. Thus, the testing recommendations do not require any additional amalgam alloy material for test sampling, and therefore, would not increase, or be expected to increase, the existing levels of use of amalgam alloy by manufacturers.

Theoretically, manufacturers could decide to procure additional amalgam alloy for specimens that are needed to conduct corrosion testing; however, it is not known to what extent a manufacturer may elect to do so. If a manufacturer decided to procure additional amalgam alloy for corrosion testing, the amount needed per product[16] is estimated to be half of the mass needed for dental amalgam or 2.2 g of amalgam alloy.
If 2.2 grams is multiplied by 50, the approximate number of amalgam alloy products currently on the market in the U.S., the maximum result is 110 g of amalgam alloy, assuming all products will undergo testing. Note that manufacturers of these devices for use in the United States are located worldwide[17]. Even if manufacturers opt to procure additional amalgam alloy for test specimens, the total amount needed is minimal, especially when compared to the 18.8 tons[18] (17 million grams) of amalgam alloy used in the United States. Further diminishing the effect of this testing is the fact that the testing will be distributed worldwide and is not concentrated at any one location.

**B. No Changes in the intended use of the device or its substitutes**

Below is a discussion of how the final rule is not expected to change the intended use of dental amalgam, its individual components, amalgam alloy and mercury, or its substitutes.

1. Dental Amalgam

The intended use of dental amalgam is for the direct filling of carious lesions or structural defects in teeth. The final rule does not change the intended use of dental amalgam. It codifies its current usage in the classification regulation of Dental Amalgam, Mercury, and Amalgam Alloy, 872.3070.

2. Mercury

[15] See Annex A, Determination of Immersion Corrosion for Dental Amalgam, of ISO 24234:2004(E).
[16] This testing is not periodic but is performed at least once in a product's lifecycle to determine its chemical and mechanical properties.
[17]Companies currently registered with FDA to market dental amalgam/amalgam alloy in the United States are located in Sweden, United Kingdom, Switzerland, Germany, Liechtenstein, France, Australia, Israel, Costa Rica, and United States (Delaware, New Jersey, New York, Michigan, and Nevada).
[18] See Appendix I for this calculation.

The intended use of mercury is for combination with amalgam alloy to form dental amalgam. The final rule does not change the intended use of mercury. Its current usage is captured in the classification regulation of Dental Amalgam, Mercury, and Amalgam Alloy, 872.3070.

3. Amalgam Alloy

The intended use of amalgam alloy is for combination with mercury to form dental amalgam. The final rule does not change the intended use of amalgam alloy. Its current usage is captured in the classification regulation of Dental Amalgam, Mercury, and Amalgam Alloy, 872.3070.

4. Substitutes

The substitutes or alternatives to dental amalgam are composite resins, glass ionomer cements, and gold foil. Indirect (fabricated outside the mouth) alternatives to dental amalgam include crowns, bridges, inlays, and onlays, composed of noble metals, base metals, and/or ceramics. The final rule has no affect on the intended use of these alternative materials.

The final rule does not change the intended use of dental amalgam or its individual components, mercury and amalgam alloy, or substitutes for these devices.

**C. No Extraordinary Circumstances**

FDA's action to classify, reclassify, and establish special controls, does not lead to an increase in the level of use of these devices or a change in the intended use of these devices or their substitutes. Moreover, it is only speculative as to whether a particular manufacturer would use an additional sample of amalgam alloy or dental amalgam to conduct tests not already routinely performed. Even if a manufacturer opted to use additional material, the incremental increase in the amount of all components is not significant. Further, the tests for mercury only require visual inspection of material, and do not require any additional material. FDA has no basis to suggest that any manufacturer would use additional mercury for a test involving only visual inspection. Thus, there is no potential for serious harm to the environment resulting from the final rule that would otherwise constitute an extraordinary circumstance. *See* 21 CFR 25.21.

FDA is finalizing this rule to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices; any particular individual's use would be evaluated in future 510(k) submission for such use. Amalgam alloy, mercury, and dental amalgam that were legally marketed prior to the effective date of the final rule are expected to comply with the requirements of special controls and address the issues of safety and effectiveness identified in the special controls guidance, either by following the recommendations in the guidance or by some other means that provides equivalent assurances of safety and effectiveness, on or before the effective date of the final rule.

FDA concludes that this final rule does not significantly affect the quality of the human environment and that there are no extraordinary circumstances indicating that the final rule may significantly affect the quality of the human environment. For these reasons set forth above, FDA concludes that this final rule is appropriately categorically excluded under 21 CFR

25.34(b), and therefore, does not require an environmental assessment or an environmental impact statement.

**D. Environmental Decision**

The agency previously relied on the categorical exclusion in 21 CFR 25.34(b) in the proposed rule. No new information or comments have been received that would affect the agency's previous determination that, under 21 CFR 25.34(b), this action is of a type that does not individually or cumulatively have a significant effect on the human environment, and that therefore, neither an environmental assessment nor an environmental impact statement is required.

Prepared by: <signed>

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References

1. Beazoglu, T et al., Economic Impact of Regulating the Use of Amalgam Restorations, Public Health Reports, September-October 2007, Volume 122

Attachment: APPENDIX I: Calculation of Dental Amalgam Material Needed for Performance Testing.

APPENDIX I: Calculation of Dental Amalgam Material Needed for Performance Testing

Dental amalgam:

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|---|---|
| Density: | ~11 g/cm$^3$ |
| Composition: | ~50% mercury |

Test specimens[19] for Special Control:

| | |
|---|---|
| Dimensions: | cylinder, 4mm in diameter, 8 mm in height |
| Volume: | = 100.53 mm$^3$ = 0.10053 cm$^3$ |
| Amalgam Mass: | = 0.10053 cm$^3$ X 11 g/cm$^3$ = 1.1 g of amalgam |
| Mercury Mass: | = 0.5 X 1.1 = 0.55 g of mercury |

Reference Data:

To conduct the tests, ISO 24234 requests procurement of 50 g of mercury and 50 g of amalgam alloy (100 g of dental amalgam).

Number of dental amalgam/amalgam alloy firms registered with FDA: 16
Dental amalgam and alloy products listed by these firms: ~50
Number of mercury firms[20] registered with FDA: 0

Number of amalgam restorations placed in US (2005): 52.5 million[21]
Average mass of amalgam restoration: 0.65 g
Total mass of amalgam restorations in placed US: 34,100 kg or 37.6 tons
(17,000 kg or 18.8 tons of mercury or amalgam alloy)

[19] ISO 24234, Dentistry – Mercury and Alloys for Dental Amalgam, 2004.
[20] Dental amalgam manufacturers are obtaining elemental mercury from non-medical suppliers.
[21] Ref. 1

**Table 1: Itemized List of Tests/Specifications Recommended by Special Control**

| Performance Tests | Routinely Provided when Applicable for Premarket Notification? (Y/N) | Destructive[22] Test? (Y/N) |
|---|---|---|
| Composition[23] | Y | NA |
| Biocompatibility | Y | Y |
| Compressive Strength @ 1 hour | Y | Y |
| Compressive Strength @ 24 hrs | Y | Y |
| Maximum Creep | Y | Y |
| Dimensional Change | Y | N |
| Trituration Time (s) | Y | NA |
| Working Time (min) | Y | NA |
| Particle Morphology | N | NA |
| Corrosion Products – Ions and Mercury Vapor Released | N | Y |

**Table 1.1: Non-Routine Tests in Table 1**

| Performance Tests | Minimum Number of Specimens | Maximum Number of Specimens | Destructive Test? (Y/N) | Specimen Reusable? (Y/N) |
|---|---|---|---|---|
| Particle Morphology[24] | 0 | 0 | N | N |
| Corrosion Products – Ions and Mercury Vapor Released | 2 | 4 | Y | N |

The only test requiring additional specimens is corrosion products testing. The total number of specimens needed for this test is at most four.

Ideally, no new specimens are needed for corrosion products testing, which can be obtained from other non-destructive tests such as that for dimensional change. Not all specimens from other tests may be reused; e.g., specimens from compressive strength and creep tests may not be useful because of deformations and/or defects introduced in these specimens.

[22] By "destructive" it is meant that the specimen is rendered unusable for additional testing
[23] Composition is determined by manufacturing specifications
[24] Alloy particle size and shape is determined by manufacturing specifications

If new specimens are used the total mass of additional dental amalgam needed is :

4 specimens X 1.1 g of amalgam/specimen = 4.4 g of amalgam (2.2 g of mercury)

ISO 24234 recommends that 100 g of mercury be procured for all sample testing. It is assumed that the additional 4.4 g of dental amalgam will be obtained from the 100 g already procured for testing. If additional material is procured, the additional quantity is 4.4 g of amalgam per marketed product.

Multiplying this by the number of dental amalgam/amalgam alloy products currently on the U.S. market:

4.4g/ marketed product X 50 amalgam products = 220 g (110 g of mercury).

Thus, the special controls would, if at all, contribute to an increase in amalgam usage of 220 g, total, by all manufacturers of dental amalgam/amalgam alloy worldwide for use in the United States. Compared to available data on the levels of use of dental amalgam by users[25] in the United States, 37.6 tons (34,100 kg), this represents an insignificant increase in use by manufacturers worldwide to satisfy the performance recommendations of the special controls.

References

1. Beazoglu, T et al., Economic Impact of Regulating the Use of Amalgam Restorations, Public Health Reports, September-October 2007, Volume 122

[25] in 2005