U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Appendix I : Summary of Changes to the Classification of Dental Amalgam and Mercury

On July 28, 2009, FDA issued a final rule that: (1) reclassified mercury from a class I (least risk) device to class II (more risk) device; (2) classified dental amalgam as a class II device; and (3) designated a special controls guidance document for dental amalgam.

The special controls guidance document identifies the risks to health of dental amalgam and recommends mitigation measures to address those risks. The potential risks to health of dental amalgam identified in the guidance document are: (1) exposure to mercury; (2) toxicity and adverse tissue reaction; (3) corrosion and mechanical failure; (4) contamination; and (5) improper use. The guidance document recommends measures to mitigate these risks, including certain labeling recommendations

The guidance document recommends the following specific labeling:

- Warning regarding the presence of mercury in the device and the possibility of harm if vapors are inhaled
- Disclosure of mercury content
- Contraindication for use in persons with a known mercury allergy or sensitivity
- Disclosure of certain information about the physical properties of the device
- Certain precautions with respect to use; e.g., the device is intended for single use only, it should be used with adequate ventilation, and it should not directly contact other types of metals
- Information for use including the following, or an equivalent, statement:

  "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.[1] 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.[2] 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.[3]

  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.[4] 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."

The guidance document also recommends that the device and its individual components, mercury and amalgam alloy, meet the performance specifications contained in ISO 24234; 2004(E), Dentistry – Mercury and Alloys for Dental Amalgam, the recognized consensus standard identified in the guidance document.

---

[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] 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.

[3] 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.
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.

[4] 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.