

## News & Events

### FDA NEWS RELEASE

**For Immediate Release:** July 28, 2009

**Media Inquiries:** Peper Long, 301-796-4671, mary.long@fda.hhs.gov

**Consumer Inquiries:** 888-INFO-FDA

#### FDA Issues Final Regulation on Dental Amalgam

The U.S. Food and Drug Administration today issued a final regulation classifying dental amalgam and its component parts – elemental mercury and a powder alloy—used in dental fillings. While elemental mercury has been associated with adverse health effects at high exposures, the levels released by dental amalgam fillings are not high enough to cause harm in patients.

The regulation classifies dental amalgam into Class II (moderate risk). By classifying a device into Class II, the FDA can impose special controls (in addition to general controls such as good manufacturing practices that apply to all medical devices regardless of risk) to provide reasonable assurance of the safety and effectiveness of the device.

The special controls that the FDA is imposing on dental amalgam are contained in a guidance document that contains, among other things, recommendations on performance testing, device composition, and labeling statements.

Specifically, the FDA recommended that the product labeling include:

- A warning against the use of dental amalgam in patients with mercury allergy;
- A warning that dental professionals use adequate ventilation when handling dental amalgam;
- A statement discussing the scientific evidence on the benefits and risk of dental amalgam, including the risks of inhaled mercury vapor. The statement will help dentists and patients make informed decisions about the use of dental amalgam.

Dental amalgam is a “pre-amendment device,” which means that it was in use prior to May 28, 1976, when the FDA was given broad authority to regulate medical devices. That law required the FDA to issue regulations classifying pre-amendment devices according to their risk into class I, II, or III. Although the FDA previously had classified the two separate parts of amalgam – elemental mercury and the metal powder alloy – it had not issued a separate regulation classifying the combination of the two, dental amalgam. During this time, however, dental amalgam has been subject to all applicable provisions of the law.

Today’s regulation also reclassifies the mercury component of dental amalgam from Class I (low risk) to Class II (moderate risk).

Over the past six years, the FDA has taken several steps to assure that the classification of dental amalgam is supported by strong science.

In 2002, the agency issued a proposed rule to classify dental amalgam and identify any special controls necessary for its safe and effective use.

Due to a high number of comments on that rule, the agency held an advisory committee meeting in 2006, inviting dental and neurology experts to review existing scientific data on dental amalgam, especially with regard to its toxicity in pregnant women and children.

The agency drafted a review of recent and relevant peer-reviewed scientific literature on exposure to dental amalgam mercury. The advisory committee asked that the agency conduct an even deeper review of the scientific literature on this topic. In all, the agency considered some 20 scientific studies.

On April 28, 2008, the FDA reopened the comment period on the 2002 proposed classification in order to elicit the most up-to-date comments and information related to classification of dental amalgam. Today’s rule reflects the years of agency review on this topic.

FDA’s Web site on dental amalgam:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/default.htm><sup>1</sup>

#

[RSS Feed for FDA News Releases](#)<sup>2</sup> [[what is RSS?](#)<sup>3</sup>]

---

#### Links on this page:

1. <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/default.htm>
2. <http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/PressReleases/rss.xml>
3. <http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/ucm144575.htm>