

News from the Missouri Dental Association

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From the ADA: FDA Reaffirms Amalgam Safety

After years of careful investigation and the review of some 200 scientific studies, the U.S. Food and Drug Administration today reaffirmed its view that **dental amalgam is a safe, effective material for use in dental restorations.**

The FDA ruling classifies encapsulated amalgam as a class II medical device, which places it in the same class as gold and composite fillings. The ADA has supported a class II designation for amalgam since the FDA first proposed it in 2002.

"The FDA has left the decision about dental treatment right where it needs to be-between the dentist and the patient," said Dr. John S. Findley, ADA president.

Speaking for the FDA today at a lunchtime news conference was Dr. Susan Runner, acting director of the agency's Division of Anesthesiology, General Hospital, Infection Control and Dental Devices, FDA's Center for Devices and Radiological Health.

"The best available scientific evidence supports the conclusion that patients with dental amalgam fillings are not at risk for mercury-associated adverse health effects," said Dr. Runner.

She went on to say that "long-term clinical studies in adults and children aged 6 and older with dental amalgam fillings have not established a causal link between dental amalgam and adverse health effects."

Dr. Runner noted, too, that the FDA explored potential health effects of dental amalgam in developing fetuses, breast-fed infants and children under age six. Although the research on these populations is more limited, she said, "the scientific evidence that is available suggests that these populations also are not at risk."

Some patients, she noted, have an allergy or sensitivity to the mercury or other metals in dental amalgam. Such patients may develop "contact reactions" within the oral cavity.

To address the needs of these patients, said Dr. Runner, the FDA is placing special controls on dental amalgam to help provide "reasonable assurance" of its safety and effectiveness. These special controls include recommended performance tests to ensure that essential information is provided to the FDA when devices are submitted for evaluation.

The special controls also instruct manufacturers to add language to their product labeling that:

- warns against the use of amalgam in patients with mercury allergies;
- advises dental professionals to use adequate ventilation when handling amalgam, and;

- reviews the benefits and risks of amalgam.

The ADA is in the process of revising its public information on dental amalgam to reflect the FDA's validation of amalgam as safe and effective.

To read the FDA's complete media statement on dental amalgam, please visit [fda.gov](https://www.fda.gov).

Other links:

- [News article from Reuters on FDA Ruling on Dental Amalgam](#)
- [News Release: "American Dental Association Statement: Food and Drug Administration Action on Dental Amalgam"](#)

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