

American Dental Association Statement: Food and Drug Administration Action on Dental Amalgam

WASHINGTON, July 28, 2009—The American Dental Association (ADA) agrees with the U.S. Food and Drug Administration's (FDA) decision not to place any restriction on the use of dental amalgam, a commonly used cavity filling material.

The FDA ruling issued today categorizes encapsulated dental amalgam as a class II medical device, placing it in the same class as gold and tooth-colored composite fillings. The ADA has supported a class II designation for dental amalgam since 2002 when first proposed by the FDA.

"The FDA has left the decision about dental treatment right where it needs to be—between the dentist and the patient," states ADA President Dr. John Findley. "This decision underscores what the ADA has long supported—a discussion between dentists and patients about the full range of treatment options to help patients make educated decisions regarding their dental care."

Dental amalgam is a cavity-filling material made by combining mercury with other metals such as silver, copper and tin. Numerous scientific studies conducted over the past several decades, including two large clinical trials published in the April 2006 *Journal of the American Medical Association*, indicate dental amalgam is a safe, effective cavity-filling material for children and others. And, in its 2009 review of the scientific literature on amalgam safety, the ADA's Council on Scientific Affairs reaffirmed that the scientific evidence continues to support amalgam as a valuable, viable and safe choice for dental patients.

"Dentists are doctors specializing in oral health care," Dr. Findley states. "We encourage people to talk with their dentists if they have any questions about their oral health."

Additional information about dental amalgam and other cavity-filling materials may be found on the ADA's web site at: www.ada.org.

About the American Dental Association

Celebrating its 150th anniversary, the not-for-profit ADA is the nation's largest dental association, representing more than 157,000 dentist members. The premier source of oral health information, the ADA has advocated for the public's health and promoted the art and science of dentistry since 1859. The ADA's state-of-the-art research facilities develop and test dental products and materials that have advanced the practice of dentistry and made the patient experience more positive. The ADA Seal of Acceptance long has been a valuable and respected guide to consumer dental care products. The monthly *Journal of the American Dental Association (JADA)* is the best-read scientific journal in dentistry. For more information about the ADA, visit the Association's Web site at www.ada.org