



U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Consumer Update: Dental Amalgams

FDA and other organizations of the U.S. Public Health Service (USPHS) continue to investigate the safety of amalgams used in dental restorations (fillings). However, no valid scientific evidence has shown that amalgams cause harm to patients with dental restorations, except in the rare case of allergy.

The safety of dental amalgams has been reviewed extensively over the past ten years, both nationally and internationally. In 1994, an international conference of health officials concluded there is no scientific evidence that dental amalgam presents a significant health hazard to the general population, although a small number of patients had mild, temporary allergic reactions. The World Health Organization (WHO), in its Consensus Statement on Dental Amalgam reached a similar conclusion. They wrote: "Amalgam restorations are safe and cost-effective...Components in dental restorative materials, including amalgam, may, in rare instances, result in local side-effects or allergic reactions. The risk of adverse side-effects is very low for all types of restorative materials, including amalgam and all resin-based materials." Similar conclusions were reached by the USPHS, the European Commission, the National Board of Health and Welfare in Sweden, the New Zealand Ministry of Health, Health Canada and the province of Quebec.

In January 1993, the USPHS published a broad scientific report about the safety and use of dental amalgam and other materials commonly used to fill dental cavities. USPHS reaffirmed these conclusions in 1995 and 1997. Since then, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) have continued to study the issue. The National Institute of Dental & Craniofacial Research at NIH has also provided money to study the safety of dental amalgams and to develop non-mercury alternatives. This effort includes research and clinical studies of dental amalgam use in children. These studies are ongoing and will require several years of follow-up in order to detect any subtle and long-range health effects.

Also, USPHS scientists analyzed approximately 175 peer-reviewed studies submitted in support of three citizen petitions received by FDA after the 1993 report. The USPHS concluded that data in these studies did not support claims that individuals with dental amalgam restorations will experience problems, including neurologic, renal or developmental effects, except for rare allergic or hypersensitivity reactions.

Although there is international agreement that the scientific data do not confirm the presence of a significant health hazard, several countries restrict the use of dental amalgams or have recommended limitations on their use. For example, Health Canada recommended that dental amalgam be avoided in people allergic to mercury or with impaired kidney function; if possible, to avoid its placement or removal in the teeth of pregnant women; and to consider the use of alternatives in the primary

teeth of children. Some manufacturers now include these "contraindications" (against using) in their labeling of dental amalgams sold in those countries. If a manufacturer wishes to make a similar labeling change in its dental amalgam sold in the United States, FDA will require the manufacturer to submit a new marketing application with data supporting the change.

FDA is examining its regulation of dental amalgam alloy, and pre-encapsulated dental amalgam. To reduce possible allergic reactions from restorative materials, FDA is proposing in labeling guidance that the product's labeling list the ingredients in descending order of weight by percentage and include lot numbers, appropriate warnings and precautions, handling instructions and expiration dating. The labeling guidance will be most useful with new restorative materials.

While research, regulatory changes, and educational efforts are underway, the use of dental amalgams in the U.S. is declining. Pediatric dentists, in particular, are using resin (plastic) FDA cleared tooth-colored materials that are bonded to the tooth. They may release fluoride and are mercury-free. Other reasons for the decline in amalgam use include increasing use of sealants and community fluoridation, an expanding selection of fluoride-containing dental products, improved oral hygiene practices, and greater access to dental care. With the improvement of alternative restorative materials over the past few years, dentists increased their use of these products.

The USPHS will continue to gather data about possible risks of dental amalgams and other restorative products and to pursue new methods of dental treatment and oral health. As an important part of this plan, USPHS will continue working with the dental profession to bring about changes in the delivery of oral healthcare based on valid scientific research.

Updated 12/31/2002