DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

NORRIS ALDERSON, Ph.D.
DIRECTOR, OFFICE OF SCIENCE AND HEALTH COORDINATION

FOOD AND DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

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SUBCOMMITTEE ON DOMESTIC POLICY
HOUSE OF REPRESENTATIVES

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Introduction

Mr. Chairman and Members of the Subcommittee, I am Dr. Norris Alderson, Director, Office of Science and Health Coordination at the Food and Drug Administration (FDA or the Agency). I appreciate your invitation and the opportunity to discuss the issue of dental amalgams and FDA's implementation of the National Environmental Policy Act of 1969.

In my testimony today, I will first briefly describe dental amalgam and how FDA regulates these medical devices. Then, I will describe Federal government activities related to dental amalgam. I will also describe FDA's implementation of the National Environmental Policy Act of 1969 with respect to dental amalgam.

Background

Dental amalgam is a restorative material that is used for direct filling of carious lesions or structural defects in teeth. It is made onsite in a dentist's office by mixing elemental (liquid) mercury and a powdered (amalgam) alloy composed primarily of silver, tin, and copper (the mixture is also called "encapsulated amalgam alloy and dental mercury" or simply "encapsulated amalgam").

Let me begin with a brief overview of our regulatory authorities regarding medical devices and how we exercise them in the case of dental amalgam. As defined by Federal law, the term "medical device" encompasses several thousand health products, from simple articles

such as tongue depressors and heating pads, to cutting-edge and complex devices such as pacemakers, lasers and imaging technologies. Dental amalgam, as well as its components – dental mercury and the alloy with which the mercury is combined – are medical devices. The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) gave FDA specific authority to regulate the safety and effectiveness of medical devices. The FD&C Act prescribes a variety of mechanisms to achieve this goal. These include classification of medical devices, establishment registration, Quality Systems Requirements for manufacturing, and controls over the market introduction of medical devices.

Classification and Reclassification of Medical Devices

Devices that were in commercial distribution before the enactment of the Medical Device Amendments of 1976 (May 28, 1976), are commonly referred to as "preamendments devices" and were assigned to one of three "classes" consistent with the procedures described in the statute. Under section 513 of the Act, FDA classifies preamendments devices according to the following steps: (1) FDA receives a recommendation from a device classification panel (an FDA advisory committee); (2) FDA publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) FDA publishes a final regulation. The Act also has a specific procedure for effecting a change to the classification of a preamendments device, which includes issuing a regulation (section 513(e) of the Act) and, if the Agency believes appropriate, obtaining a recommendation from the panel that provided the original classification recommendation. Devices that were first introduced into

commercial distribution after enactment of the Medical Device Amendments Act of 1976, are known as “postamendments devices.”

Let me describe the statutory criteria FDA used when classifying medical devices. Devices posing the lowest risk, such as elastic bandages, were placed in Class I. Class I devices are subject to the “general controls” applicable to all devices. Class II devices, which pose incrementally greater risk and for which general controls are not sufficient to provide reasonable assurance of safety and effectiveness, are subject to “special controls” in addition to general controls. Special controls may include labeling requirements, performance standards, post-market surveillance studies to conformance with mandatory performance standards, or other controls the Agency deems necessary to provide reasonable assurance of the safety and effectiveness of the device. The riskiest devices, such as some implants and life-supporting or life-sustaining devices, are placed in Class III and may be marketed only after approval of a premarket approval application, which includes clinical studies and other information establishing the safety and effectiveness of the device. Preamendments devices classified into Class III are not subject to the requirement of premarket approval until the Agency issues a regulation requiring the submission of applications.

Dental mercury and amalgam alloy are preamendments devices that FDA classified in accordance with the procedure described above. In a Final Rule published on August 12, 1987, FDA placed dental mercury into Class I (Title 21, *Code of Federal Regulations*, section 872.3700) and amalgam alloy into Class II (Title 21, *Code of Federal Regulations*, section 872.3050). This action was taken because comments submitted to the Agency acknowledged

that the risks to health presented to dentists and other dental workers are inherent in the device and would not be reduced through establishment of performance standards for the device. The comments also stated that manufacturers have voluntarily accomplished actions to protect dentists and others from the inherent risks presented by the device such as packaging the device in leak proof containers and placing cautionary statements in the labeling of the device. FDA agreed with the comments urging that dental mercury be classified into Class I. The encapsulated form of amalgam, which consists of measured proportions of amalgam alloy and dental mercury that are separately sealed and sold as a single-use capsule, was not separately classified during the original classification process. However, like other products that are a combination of more than one device, FDA has regulated the encapsulated amalgam in accordance with the requirements applicable to the component with the higher classification. Accordingly, the encapsulated form of amalgam (which includes amalgam alloy and dental mercury) is regulated as a Class II device.

The Dental Products Panel of the Medical Devices Advisory Committee met in 1993 and 1994 to discuss the classification, reclassification and safety of dental amalgam devices. After considering testimony and other information, the Panel unanimously recommended to classify dental mercury and amalgam alloy intended for the restoration of teeth into Class II. The Panel also recommended that the device be subject to voluntary performance standards, voluntary testing guidelines, and requirements that the device be used only on the written or oral authorization of a licensed practitioner, and only by persons with training or expertise in its use. The Panel stated that there were no major risks associated with encapsulated amalgam when used as directed, but recognized there was a small population of patients who

may experience allergic reactions to the materials in the device. The Panel also noted that improper use of the device by practitioners presented risks associated with mercury toxicity.

As mentioned earlier, the FD&C Act authorizes the Agency to "reclassify" a medical device into a different regulatory class as more knowledge emerges regarding product risk gained from actual use. In most cases, devices are down-classified. Occasionally, however, devices are reclassified into a higher class.

2002 Proposed Rule Reclassifying Amalgam Products

In February 2002, FDA proposed a rule to bring all amalgam products into Class II and increase the Agency's regulatory oversight over these devices by requiring ingredient labeling and proposing conformance to international standards. By requiring disclosure of amalgam ingredients, the Agency believed the rule would help dental providers to quickly diagnose and treat rare allergic reactions arising from exposure to amalgam components. Given the high level of interest in this proposed rule, FDA twice reopened the comment period and received more than 750 comments submitted to the docket.

FDA received significant adverse public comments on the 2002 proposed rule. The majority of the comments stated that the Agency was not proposing enough restrictions on the marketing and use of dental amalgam and that the proposed special controls did not adequately address the potential health risks of the device.

Dental Amalgam Literature Reviews

In January 1993, the United States Public Health Service (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 FDA have continued to study the issue. The National Institute of Dental & Craniofacial Research at NIH has also provided grants to study the safety of dental amalgam and to develop non-mercury alternatives. This effort included research and clinical studies of dental amalgam use in children. In addition, 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.

2006 Joint Meeting of the Dental Products Panel and the Peripheral and Central Nervous System Drugs Advisory Committee

In 2006, FDA held a joint meeting of the Dental Products Panel and the Peripheral and Central Nervous System Drugs Advisory Committee. The joint committee deliberated on a series of questions FDA had posed on its most recent draft review of the dental amalgam literature, and provided recommendations to the Agency related to those questions. The Committee asked FDA to expand its literature review to include additional data bases and searches for information on special populations. The 2006 joint committee generally agreed,

however, that there is no evidence that dental amalgam cause health problems in the vast majority of the population. The 2006 joint committee also agreed that the most recent well-controlled clinical studies showed no evidence of neurological harm from dental amalgam. While the committee did not take consensus votes on these issues, non consensus opinions included a panelist recommendation that FDA consider labeling requirements related to the use of dental amalgam in pregnant women and small children, as well as patient information to ensure that consumers understand that these devices contain mercury.

The National Environmental Policy Act (NEPA)

The National Environmental Policy Act of 1969 (NEPA) requires that Federal agencies evaluate whether major actions they take will significantly affect the quality of the human environment. FDA's regulations implementing NEPA are contained in 21 CFR Part 25, "Environmental Impact Considerations." This regulation describes Agency actions that require preparation of an Environmental Assessment (EA), that require preparation of an Environmental Impact Statement (EIS), and those Agency actions that are categorically excluded, generally, from the requirement to prepare and EA or an EIS absent extraordinary circumstances. Actions are categorically excluded from the requirement to prepare an EA or an EIS where the Agency has made a finding that the category of action does not individually or cumulatively have a significant effect on the human environment. If the Agency finds that a particular action, that would otherwise be categorically excluded, may significantly affect the quality of the human environment (referred to as an "extraordinary circumstance"), the Agency would prepare either an EA or an EIS. It should be clarified that the analysis is

determined by the action taken by the Agency, and not the product in question. FDA has no reason to think that changing the classification of mercury, by itself, will affect its level of use, e.g., either increase or decrease, in a way that would have a significant effect on the environment.

In the case of a classification of dental amalgam, reclassifying dental mercury from Class I to Class II does not necessarily affect the amount of mercury introduced into the environment. If it is not reasonably foreseeable that there would be any increase in the amount of mercury introduced into the environment that would constitute an extraordinary circumstance, FDA would appropriately rely on its existing categorical exclusion for such an action. The 2002 Proposed Rule noted above cited the categorical exclusion contained in Title 21, *Code of Federal Regulations* section 25.34(b), which categorically excluded the classification or reclassification of a device from the requirement to prepare an EA.

Next Steps/Options

We will continue to evaluate the available information to determine appropriate next steps to fulfill FDA's mission to protect and promote public health.

Mr. Chairman, thank you again for the opportunity to address this important topic. I will be happy to answer any questions.