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THE MISSION OF THE AMERICAN DENTAL EDUCATION ASSOCIATION is to lead individuals and institutions of the dental education community to address contemporary issues influencing education, research, and the delivery of oral health care for the improvement of the health of the public.

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July 26, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

TO WHOM THIS MAY CONCERN:

The American Dental Education Association (ADEA), representing 55 U.S. dental schools, U.S. dental research institutions, hospital and community-based advanced dental education programs, and allied dental schools and programs, supports written comments submitted by the American Dental Association (ADA) to the Food and Drug Administration (FDA) on the draft guidance entitled "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Draft Guidelines for Industry and FDA".

In summary ADEA concurs with the ADA's supports for the FDA's proposal to:

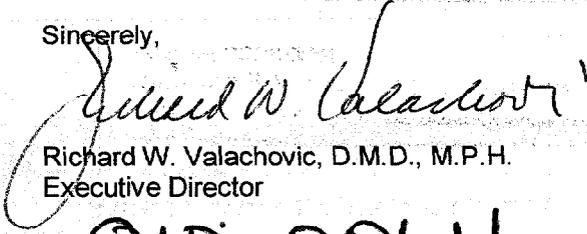
- Issue a separate classification regulation for encapsulated amalgam alloy and dental mercury, a preamendments device intended to be mixed in a single-use capsule to form filling material for the treatment of dental caries, as a class II device with special controls;
- Amend the existing classification for amalgam alloy, a class II preamendments device, by adding special controls; and
- Reclassify from class I (general controls) to class II with special controls dental mercury, a preamendments device intended for use as a component of amalgam alloy in the restoration of a dental cavity or broken tooth.

ADEA further supports ADA's recommendation that the proposed rule preempt conflicting state laws and regulations regarding dental amalgam products.

FDA's special controls aim to provide a practical assurance of the safety and usefulness of dental amalgam products. Amalgam has been used in tooth restorations worldwide for more than 100 years. No study has proven a link between amalgam restorations and any medical disorder. Fewer than 100 cases have been reported of allergic reactions to amalgam fillings; with patients exhibiting symptoms similar to a skin allergy. In these instances, mercury may trigger an allergic response. For patients who are allergic to amalgam another restorative material may be used.

If you require further assistance or information, please contact Gina G. Luke in the Center for Public Policy and Advocacy, at 202-667-9433, Ext. 128 or [LUKE@ADEA.org](mailto:LUKE@ADEA.org).

Sincerely,

  
Richard W. Valachovic, D.M.D., M.P.H.  
Executive Director

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