



**American Association of Dental Editors**

735 North Water Street, Suite 617  
Milwaukee, Wisconsin 53202 USA  
Telephone: 414.272.2759  
Telefax: 414.272.2754

5404 102 FEB 22 1996

August 18, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20057

RE: Docket Number 01N-0067

Dear Sirs:

The American Association of Dental Editors (AADE) has resolved to support the Food and Drug Administration's proposed modification to its regulation of encapsulated dental amalgam, dental mercury and amalgam alloy to a uniform class II classification with special controls. Thus, the AADE supports the American Dental Association's (ADA) position that it "... agrees with the Agency's determination that, upon review of the scientific evidence, there are no major health risks associated with the use of encapsulated amalgams, amalgam alloy, and dental mercury. ADA also agrees that the proposed special controls will adequately address the risks associated with improper handling of dental amalgam products and the risks to the small subpopulation of individuals who are allergic to the ingredients of these products."

We believe the FDA proposal for this classification is reasonable and the need for further hearings is superfluous for the following reasons:

1. It is our understanding that the FDA has spent many years reviewing the scientific literature prior to proposing this new classification.
2. We are not aware of any credible scientific evidence showing dental amalgam to be the cause of any adverse medical problem.
3. The special controls proposed by the FDA address the risks to allergic individuals and health care workers.

01N-0067

C42

RE: Docket Number 01N-0067

Page 2

4. The significant public health benefits far outweigh the possibility of adverse reaction.

Thank you for allowing us to contribute to this process.

Sincerely,

A handwritten signature in cursive script that reads "Richard J. Galeone".

Richard J. Galeone DDS

President

cc. Detlef Moore: American Association of Dental Editors  
Jonathon B McLeod: American Dental Association



**American Association of Dental Editors**

735 North Water Street, Suite 617  
Milwaukee, Wisconsin 53202 USA



Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20057

20857+0001 A POSTNET barcode consisting of a series of vertical bars of varying heights, used for automated mail sorting.