

August 12, 2009

The Honorable Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: Dental Devices—Classification of Encapsulated Amalgam Alloy
[Docket No. FDA-2008-N-0163]

Dear Dr. Hamburg:

The American Dental Association (ADA) commends your agency for the sound rationale it applied in its recent decision classifying encapsulated dental amalgam as a Class II medical device. The agency relied upon the best available science in reaching its decision and presented its findings in a clear and comprehensible way.

The ADA is America's leading advocate for oral health. We believe public policy should be guided by reputable science, carefully analyzed and applied to the facts. By using this method, the Food and Drug Administration resisted public pressure some advocates sought to apply against it while still respectfully addressing the concerns and claims of all those who submitted comments.

After your careful investigation and the review of some 200 scientific studies, we thank you for your due diligence

Sincerely,

/s/

John S. Findley, D.D.S.
President

/s/

Kathleen T. O'Loughlin, D.D.S., M.P.H.
Executive Director

JSF:KTO:RJB:nh