



**Academy of General Dentistry's Comments on FDA's Proposed Rule and Special Control Guidance on Dental Amalgam Products
[Docket No. 01N-0067]**

The Academy of General Dentistry submits these comments in support of the Food and Drug Administration's proposed rule on dental amalgam products and draft guidance document entitled "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Draft Guidance for Industry and FDA.

The Academy of General Dentistry [AGD] is a not-for-profit organization representing approximately 37,000 general dentists. The AGD is the second largest dental organization in the world.

In general, the AGD supports the comments submitted by the American Dental Association to FDA on the proposed rule. In particular, the AGD would like to emphasize the importance to promulgate a uniform national standard. Academy members practice their profession in all fifty U.S. states. Allowing the various states to preempt a national standard would wreck havoc on the practice of dentistry.

It should also be noted that dental amalgam is the most studied material that has been ever placed in a human body for health treatment purposes. As medical professionals, dentists rely strongly on sound scientific proof. The AGD notes that all sound, peer reviewed scientific studies support the efficacy of dental amalgam in the treatment of carious lesions except in certain patients whom can be readily identified by dentists. Finally, the AGD supports the FDA's efforts to create a uniform classification of dental amalgam.

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211 East Chicago Avenue, Suite 900
Chicago, Illinois 60611-1999

888-AGD-DENT
312-440-4300

312-440-0559 fax
www.agd.org



**Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20057**

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