

OHIO DENTAL ASSOCIATION  
*Informing – Representing – Serving*

June 26, 2003

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

Dear Sir/Madam:

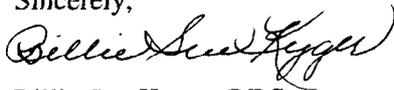
On May 9, the FDA published an announcement in the Federal Register that it will establish a panel to perform a literature review on dental amalgam. The stated purpose of this review is to determine whether any studies published in the peer-reviewed, scientific literature provide new evidence related to the health effects of dental amalgam in humans. The announcement indicates that the review will begin in the latter part of 2003.

On behalf of the Ohio Dental Association's (ODA), which represents 5,400 Ohio dentists we would like to express that it is essential that the FDA receive input from the dental community on this issue. It appears as though the FDA has confined its scientific studies search period to between January 1, 1996 and June 1, 2003, however many studies of significant value predate this timeframe and should be considered.

We also respectfully request that the FDA include qualified dental experts on the review panel to ensure these individuals are familiar with dental amalgam and its use in clinical dentistry. Additionally, the FDA should publish qualifications and selection methods for those who will be conducting the review. We applaud the FDA's intent to select reviewers who have no potential bias or conflict of interest is applauded, however, to exclude individuals solely because they have been involved in prior reviews could unnecessarily deny the agency the expertise of those who are most qualified to contribute.

Thank you for your time and consideration of these recommendations. If you should have any questions, please feel free to contact Keith Kerns, ODA Director of Legal and Legislative Services at 1-800-282-1526.

Sincerely,



Billie Sue Kyger, DDS.  
President



David J. Owsiany, J.D.  
Executive Director

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