

American  
Dental  
Association



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

**RE: FDA Draft Guidance on the "Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings." Docket No. 01D-0297 [66 Federal Register 37483].**

Dear Sir or Madam:

The American Dental Association (ADA or Association) is pleased to provide comments to the Food and Drug Administration (FDA) on the agency's draft guidance document (July 18, 2001). The ADA represents over 70 percent of the dental profession in the United States and seeks to advance the art and science of dentistry and to promote high quality dental care and the oral health of the American public.

The ADA supports the FDA's effort to disclose to industry and the public information about medical devices that is addressed through the FDA's Center for Devices and Radiological Health (CDRH) advisory panel meetings. The Association believes that the agency's approach to provide such information is practical and fair. We understand that necessary scrutiny will be given before any information is released to ensure that trade secrets or other confidential information are exempt from public disclosure.

The Association agrees with the measures outlined to work with the sponsor(s) of dental devices and to ensure their input in determining what information is made available to the public. We support the agency's approach toward protecting information that is to be removed or obliterated upon agreement with the device sponsor(s).

The ADA is concerned, however, that the FDA intends to make information available to the public only "one business day" before an advisory panel meeting. For information to be useful, especially for organizations and industry that must reach a consensus opinion, a longer lead-time is necessary. The Association urges the FDA to reconsider this time frame and provide notice within at least five business days prior to an advisory meeting.

01D-0297

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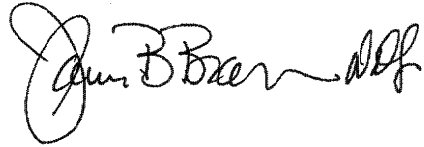
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The ADA appreciates the opportunity to comment on the draft guidance. We ask the agency to consider our comment, and to contact Dr. Daniel M. Meyer in the ADA Division of Scientific Affairs at 312-440-2543 with any questions.

Sincerely,



Robert M. Anderton, D.D.S., J.D., LL.M.  
President



James B. Bramson, D.D.S.  
Executive Director

RMA:JBB:JAS