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 Guidance Document "A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures." Docket No. 01D-0281 [66 Federal Register 38714-38716].

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 "Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures," (July 25, 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 Association appreciates the opportunity to review and comment on the draft FDA pilot program, which seeks to examine the best way to harmonize the various regulatory requirements for premarket device submissions in different countries. We understand that the agency is establishing its pilot program (guidance) to evaluate the recommendations it has received from the Global Harmonization Task Force (GHTF) in the task force's document, "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)."

ADA Comments

The ADA agrees with the FDA's effort to harmonize the content and format for premarket submissions and to establish guidance in this area. However, the Association is concerned that the agency has chosen dental endosseous implants as a candidate device for the pilot premarket program.

Currently, premarket submissions for dental endosseous implants must already follow an existing FDA guidance document. The current guidance requires specific information

and testing results to be submitted as part of the premarket approval application. Necessary information includes such items as mechanical testing, corrosion testing, biocompatibility testing, animal studies and sterilization information. The Association is concerned that these items are not addressed within the FDA's pilot program.

The ADA believes that dental endosseous implants are not an appropriate candidate for the FDA's pilot program as it is currently planned. We are concerned that applying the harmonized process to these implants through the pilot program will not provide the agency with necessary information on the safety and efficacy of these medical devices. The FDA's pilot program should ensure there are standards in place that are at least equivalent to the standards outlined in its current guidance document.

Conclusion

The ADA wants to ensure that the FDA does not consider premarket approvals for dental endosseous implants with less information on safety and efficacy than is currently required. We ask the agency to consider our comments, and to contact Dr. Daniel M. Meyer in the ADA Division of Scientific Affairs at 312-440-2543 for additional information or 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