



American Dental Association
www.ada.org

March 6, 2008

Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
Parklawn Building
5600 Fishers lane
Rockville, MD 20857

Dear Commissioner von Eschenbach:

The recent report of lead in a dental prosthesis produced in an overseas dental laboratory is of great concern to the 155,000 members of the American Dental Association (ADA). It is the ADA's understanding that there are no Food and Drug Administration (FDA)-approved materials that contain any lead beyond so-called trace amounts, and we are urging our members to seek assurances from their dental laboratory suppliers that only FDA-approved materials are used in dental lab work. Based on the information presented in the media thus far, it does not appear that this is a widespread problem. However, the health and safety of our patients is the primary concern of all dentists, and we are eager to get complete information on the extent of any problems with materials used in dental labs—foreign or domestic—as quickly as possible, and to share that information with the public as soon as it becomes available.

Staff members from the ADA divisions of Science and Government and Public Affairs already have been in contact with the Food and Drug Administration's Center for Devices and Radiological Health Dental Devices Branch. We are undertaking our own efforts to study the problem, including random, objective testing of prosthetics from both overseas and domestic labs and will be happy to share that information with the FDA. Of course, any such testing by the ADA is no substitute for the FDA and other government agencies performing their mandated functions to protect the health and safety of the public. Although we are not aware of any risk to health based on the small amount of information available, we and our patients are looking to the FDA to affirm that this is true or, if it is not, to take appropriate steps to protect the public. Accordingly, we request that the FDA keep the ADA informed of its efforts to identify the sources of potential contamination and of its plans for action. We believe working together we can enhance the public safety and confidence.

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If you have any questions, please feel free to contact Dr. Frank Kyle in our Government Relations Office in Washington, DC at 202-789-5175 or e-mail kylef@ada.org or Dr. John Kuehne in the ADA's Division of Science at 312-440-2505 or kuehnej@ada.org.

Sincerely,

Handwritten signature of Mark J. Feldman, D.M.D. in black ink.

Mark J. Feldman, D.M.D.
President

Handwritten signature of James B. Bramson, D.D.S. in black ink.

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

MJF:JBB:fk

cc: Dr. Daniel G. Schultz