DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

April 14, 2008

Mark J. Feldman, D.M.D.
President
American Dental Association
1111 14th St., NW., Suite 1100
Washington, DC 20005

Dear Dr. Feldman:

Thank you for your March 6 and March 19 letters regarding the American Dental Association's (ADA's) concern over the recent report of lead in a dental prosthesis produced in an overseas dental facility.

The Food and Drug Administration (FDA) is taking this report very seriously. FDA's Center for Devices and Radiological Health (CDRH) is also working to obtain additional information on the presence of lead in dental prosthetics. This information will guide our regulatory strategy and help determine our next steps in the handling of this issue.

We appreciate and welcome your offer to share any new information that you gather during your independent research into this problem and agree that combined efforts will further enhance the agency's understanding of any potential problems that come to light in those investigations. When you have completed your random testing or if you become aware of any adverse events associated with the dental devices you are studying, please contact Susan Runner, D.D.S., M.A., Branch Chief Dental Devices, CDRH, at 240-276-3776.

At this time, FDA will not be issuing a Consumer Update; however, the agency will consider further actions after careful evaluation of the scientific evidence. Again, thank you for bringing this to our attention. A similar letter has been sent to Dr. Bramson.

Sincerely,

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs