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

Washington Office
1111 14th Street, NW, Suite 1100, Washington, DC 20005
p 202-898-2400 f 202-898-2437

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,

Mark J. Feldman, DMD

Mark J. Feldman, D.M.D
President

James B. Bramson, DDS

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

MJF:JBB:fk
cc: Dr. Daniel G. Schultz

American Dental Association
www.ada.org

March 18, 2008

Julie L. Gerberding, M.D., M.P.H
Director
Centers for Disease Control and Prevention
Building 21
1600 Clifton Road, N.E.
Atlanta, GA 30333

Dear Director Gerberding:

Since late February, when an Ohio media outlet first reported findings of lead in a dental prosthesis produced in an overseas dental laboratory, the American Dental Association (ADA) has taken steps to alert dentists and provide information to the public.

In spite of no new information on the possible extent of this problem, media reports on 'contaminated' dental materials produced in foreign dental laboratories have become more frequent. The reports have an increasingly alarming tone and a sense of urgency since we first wrote to you on March 6. As a result, dentists are fielding more inquiries from concerned patients and there are disquieting reports of patients declining recommended treatment because of unsubstantiated fears.

We are eager to understand the extent of any problems with dental materials, whether they are produced in foreign or domestic dental laboratories. In particular, we ask that you provide some context for claims of possible health impacts of lead in dental prosthesis in the amounts reported in the media. While recognizing that much remains to be learned about this issue, some general information from the CDC about the likelihood of harm would be of great interest to both dentists and patients and should come from the federal agency whose mission is to protect the public's health.

We also look to your agency to reassure patients that recommended dental treatment should not be ignored. The ADA is asking both the CDC and the Food and Drug Administration to consider providing a media update that will reassure the public that government agencies are taking appropriate steps to protect dental patients and that oral health care should not be postponed.

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If we can provide any assistance to your media relations staff, we would be happy to do so 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. Thank you for your continued efforts to protect public safety and health

Sincerely,

Mark J Feldman DMD

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

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

MF:JB:fk

cc: Dr. Janet L. Collins

American Dental Association
www.ada.org

March 18, 2008

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

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Commissioner von Eschenbach
March 18, 2008
page 2

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Sincerely,

Mark J Feldman DMD

Mark J. Feldman, D.M.D
President

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

MF:JB:fk

cc: Dr. Daniel G. Schultz

March 16, 2009

Richard E. Besser, M.D.
Acting Director
Centers for Disease Control and Prevention
Building 21
1600 Clifton Road, N.E.
Atlanta, GA 30333

Dear Doctor Besser:

As promised in the letter dated March 6, 2008 that the ADA sent to Julie L. Gerberding, M.D., M.P.H., I am writing to share with you the data the ADA obtained from testing for lead in dental crowns. These results are based on a new research protocol to measure lead concentration that was developed specifically for this research at the Paffenbarger Research Center (PRC) in Gaithersburg, Maryland. The ADA purchased 44 different porcelain powders from manufacturers comprising virtually all FDA approved porcelains available in the U.S., as well as 102 finished porcelain-metal crowns produced by domestic and foreign dental laboratories. The powders and crowns were then tested at PRC to determine the amount of lead present, where the lead may be located and, most importantly, whether any lead could be released from the crown.

In assessing for total lead content, ADA scientists completely dissolved the powders and finished crowns and measured the amount of lead remaining in the solution, finding only trace amounts of the naturally occurring element. The results ranged from below detectable to 228 parts per million (ppm) in the 44 porcelain powders, and an average of 47 ppm in the 102 porcelain dental crowns (detection limit at 1 ppm) (see attachment, Concentration and Leaching Summary Table). Seventy percent of the all the crowns had lead content below 25 ppm. Of the 102 crowns analyzed, only a single crown [CD#29] was found to have a lead content above 250 ppm at 252 ppm. This sample was a darkly stained incisor (See the attached Figure – Frequency Distribution of Lead Concentration in Sample PFM Crowns)

Scientists at PRC also tested the finished crowns to detect any leaching of lead in order to test the potential body exposure to the element. These tests were conducted in 4% glacial acetic acid at 80°C for 16 hours. This testing yielded no detectable lead leached from any of the porcelain crowns (with a limit of detection at one ppm). As an additional analysis, the researchers artificially doped separate samples of porcelain powder to produce samples over a wide range of total lead content. No released lead was detected even for samples that contained concentrations greater than 500 ppm, twice as high as the concentration of any laboratory-fabricated crown tested.

We look forward to answering any questions you may have about this data and ask that you share with the ADA your comments and analysis, as well as any additional data you have on the subject. The ADA is committed to providing its 155,000 members the best information available on this subject based on reliable scientific data. Input from your agency will be most welcome in that regard

If you have any questions, please feel free to contact Dr. Daniel M. Meyer in the ADA's Division of Science at 312-440-2543 or meyerd@ada.org.

Sincerely,

John S. Findley, D.D.S.
President
American Dental Association

March 16, 2009

Frank M. Torti, M.D., M.P.H., F.A.C.P.
Acting Commissioner
Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Dear Doctor Torti:

As promised in the letter dated March 6, 2008 that the ADA sent to Dr. Andrew C. von Eschenbach, I am writing to share with you the data the ADA obtained from testing for lead in dental crowns. These results are based on a new research protocol to measure lead concentration that was developed specifically for this research at the Paffenbarger Research Center (PRC) in Gaithersburg, Maryland. The ADA purchased 44 different porcelain powders from manufacturers comprising virtually all FDA approved porcelains available in the U.S., as well as 102 finished porcelain-metal crowns produced by domestic and foreign dental laboratories. The powders and crowns were then tested at PRC to determine the amount of lead present, where the lead may be located and, most importantly, whether any lead could be released from the crown.

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If you have any questions, please feel free to contact Dr. Daniel M. Meyer in the ADA's Division of Science at 312-440-2543 or meyerd@ada.org.

Sincerely,

John S. Findley, D.D.S.
President
American Dental Association

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

April 17, 2008

Mark J. Feldman, D.M.D. and James B. Bramson, D.D.S.
American Dental Association
1111 14th Street NW, Suite 1100
Washington, DC 20005

Dear Drs. Feldman and Bramson:

Thank you for your correspondence regarding media reports about the lead content in a dental prosthesis made in a dental laboratory in China. The Centers for Disease Control and Prevention (CDC) became aware of this issue through conversations with staff at the American Dental Association's (ADA) Divisions of Science and Government and Public Affairs and through media interest in this story. As you indicated, the Food and Drug Administration (FDA) has regulatory authority over dental products, including dental prosthetic materials, and for the registration of foreign laboratories that import dental products into the United States. It is our understanding that the FDA already is acting on this information. At this time, CDC has had no formal request for any type of engagement from a state or local health authority.

CDC assists state and local lead poisoning prevention programs to provide a scientific basis for policy decisions to ensure that health issues are addressed in decisions about the environment. In addition, the Agency for Toxic Substances and Disease Registry (ATSDR), as directed by congressional mandate, also performs specific functions concerning the effect on public health of various hazardous substances in the environment, including lead.

Although CDC has no specific information regarding the case to which you refer, we can provide you with some general information on lead and lead exposure. Many consumer products contain lead in trace amounts, and federal regulations limit the amount of lead in consumer products. Those levels are established based on both the way the body absorbs lead, the potential hazard, and the lead level product manufacturers can achieve using good manufacturing practices given the level of ambient lead contamination. If a person is exposed to lead, many factors will determine whether he/she will be harmed, including the dose, the duration, and how that person came in contact with the material. In making such a determination, one also must consider any other chemical exposure(s) and the overall state of health of that individual. Certainly, CDC recommends against the unnecessary use of lead in consumer products, including dental crowns.

The recent media reports of lead in dental porcelain/metal crowns suggest a level of approximately 200 parts per million. Such small amounts of lead as reported, however, are extremely unlikely to cause adverse health effects in adults because the dental products wear out slowly, so the lead would be released in tiny amounts over time. Even if released at an increased rate, it is highly unlikely that this amount would be a health risk to an adult.

Given the current information, CDC does not recommend that individuals defer needed oral procedures or have existing prostheses removed. Individuals who are concerned that they may have been exposed to hazardous lead levels, particularly those with occupational or other high dose exposures to lead, should be referred to a physician or health department for a blood lead test. A blood lead test is a relatively straightforward medical procedure covered by Medicaid and most health insurance companies.

It is our understanding that testing for potential leaching of lead from these products is being conducted in ADA laboratories. CDC would be happy to assist ADA in interpreting the health impact of the testing of dental porcelains/metals that is currently underway. CDC also will provide any support if requested from the FDA, as that agency conducts further testing of these products.

As the director for the Coordinating Center for Health Promotion, which oversees the National Center for Chronic Disease Prevention and Health Promotion's Division of Oral Health, and on behalf of the Coordinating Center for Environmental Health and Injury Prevention, I would like to thank you for your concern for the health of both dental health care workers and the American public. If we can be of further assistance, please let me know.

Sincerely,

Kathleen E. Toomey, M.D., M.P.H.
Director, Coordinating Center for Health Promotion
Centers for Disease Control and Prevention

cc:
Julie Gerberding, M.D., M.P.H., Director, Centers for Disease Control and Prevention and Administrator, Agency for Toxic Substances and Disease Registry
Henry Falk, M.D., M.P.H., Director, Coordinating Center for Environmental Health and Injury Prevention
Howard Frumkin, M.D., Dr.P.H., Director, National Center for Environmental Health
Janet Collins, Ph.D., Director, National Center for Chronic Disease Prevention and Health Promotion
William Maas, D.D.S., M.P.H., Director, Division of Oral Health

資料8 FDA会長からADA長官に出した書簡(2008年4月14日)

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

III. 研究成果の刊行に関する一覧表

なし

IV. 研究成果の刊行物・別刷

なし