

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.

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.

March 16, 2009
Page 2

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