FDA Public Health Notification:
Lead Exposure from Dental Films Stored in Lead-Lined Table-top Containers

(You are encouraged to copy and distribute this information)

March 13, 2001

Dear Dental Health Professional:

This is to notify you of the potential for harmful lead exposure from dental films stored in containers lined with unpainted lead. We believe that there may be hundreds of these lead-lined boxes currently being used to store dental films. Some of them may have been in use for decades. Most of these boxes are the size and shape of shoe-boxes, made of wood, and lined with lead that has apparently not been painted or coated.

Dental films stored in these boxes have been found to be coated with a whitish film that is about 80% lead. In many cases there are highly dangerous levels of lead on the films, enough to potentially cause serious adverse health effects in patients and health care professionals. These adverse health effects include anemia and serious neurological damage.[1]

You may obtain more information about public health concerns related to lead from the OSHA website: http://www.osha-slc.gov/SLTC/lead/index.html

What you should do

- **Discard any dental film that has been put in these boxes. *None of that film should be used.* Wiping the film does not significantly reduce the lead levels.**

- **Remove these boxes and dispose of them properly. THE OLD BOXES CANNOT BE MADE SAFE by painting, coating or lining them.** Scrap lead should be discarded according to EPA regulations. You may call the EPA's RCRA hotline at 1 (800) 424-9346 and speak to a representative to find your State's lead disposal requirements.

- **Make it a practice to store your dental film according to the manufacturer's instructions.**

[1] Hu Howard: Heavy metal poisoning. In: Harrison's Principles of Internal Medicine, 14th edition, AS Fauci et al (eds) New York, McGraw Hill, 1998, pp 2565-2566.

Reporting adverse events to FDA

If you have experienced problems with dental devices or dental device malfunctions, you can report this directly to the manufacturer. Alternatively, you can report directly to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch four ways: online to http://www.accessdata.fda.gov/scripts/medwatch/ by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

Getting more information

If you have questions regarding this letter, please contact, Marian Kroen, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. Additionally, a voice mail message may be left at 301-594-0650 and your call will be returned as soon as possible.

All of the FDA medical device postmarket safety notifications can be found on the World Wide Web at http://www.fda.gov/cdrh/safety.html. Postmarket safety notifications can also be obtained through e-mail on the day they are released by subscribing to our list server. You may subscribe at http://list.nih.gov/archives/dev-alert.html. You may also subscribe by sending an email to listserv@list.nih.gov. In the body of the text, type "SUBSCRIBE DEV-ALERT firstname lastname".

Sincerely yours,

David W. Feigal, Jr., MD, MPH
Director
Center for Devices and Radiological Health
Food and Drug Administration

The picture below is an example of a shoe-box sized lead-lined wooden box which may be a source of lead contamination