



Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000
Governor Mike Beebe
Paul K. Halverson, DrPH, FACHE, Director and State Health Officer

TO: All X-ray Registrants

FROM: Bernard Bevill, Section Chief
Radiation Control, Arkansas Department of Health

DATE: February 17, 2012

SUBJECT: **Arkansas Information Notice 12-01**

Attached please find a recent Communication from the Food and Drug Administration regarding illegal sale and distribution of potentially unsafe hand-held x-ray equipment. As stated in the attached memo, all hand-held devices must be approved by the FDA prior to marketing in the United States. If in question, please verify that the hand-held equipment you may now be using has been reviewed by the FDA via the searchable database entitled "*FDA Medical Device Approvals and Clearances*" on the FDA website: <http://www.fda.gov>

If you have questions regarding this information, or if our office may be of assistance please contact Bernard Bevill, Section Chief Radiation Control or Sherry Watkins, X-ray Program Supervisor at (501) 661-2301.

FDA Safety Communication: Illegal Sale of Potentially Unsafe Hand-held Dental X-Ray Units

Date Issued: Feb. 10, 2012

Audience:

- Health care providers including dentists, dental care professionals and veterinarians who have purchased or are considering purchasing a hand-held dental X-ray unit.

Device:

A small, hand-held device intended for dental X-ray examinations.

Purpose:

The FDA is issuing this communication to alert health care providers, including dentists, dental care professionals and veterinarians, about the illegal sale of hand-held dental X-ray units that have not been reviewed by the FDA. The FDA is concerned that these devices may not be safe or effective and could potentially expose the user and the patient to unnecessary and potentially harmful X-rays.

Summary of Problem and Scope:

In order to be legally marketed in the U.S., hand-held dental X-ray units must comply with FDA's radiation safety and medical device requirements. Manufacturers of these devices must submit premarket notifications for evaluation by the FDA for safety and effectiveness before the product is cleared for sale in the U.S. Manufacturers of these devices are required to register annually with the FDA¹ in addition to other requirements.

The FDA is aware of hand-held dental X-ray units that do not meet these requirements being sold online by manufacturers outside the U.S. and directly shipped to customers in the U.S.

All hand-held dental X-ray units that have been certified by the manufacturer to meet the FDA's radiation safety standards bear a certification label/tag, a warning label, and an identification (ID) label/tag on the unit's housing. All labels/tags should be in the English language and permanently affixed or inscribed on each product so that they are legible and readily accessible when the X-ray unit is fully assembled for use.

The CERTIFICATION LABEL should state: **"This product complies with 21 CFR 1020.30 - 1020.31", "This product complies with 21 CFR Subchapter J"** or other similar language.

The WARNING LABEL must be on the x-ray panel of the unit and state these exact words: **"This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed."**

The IDENTIFICATION (ID) LABEL must contain:

- The full name and address of the manufacturer of the unit.
- The place of manufacture
- The month and year of manufacture

Recommendations:

To ensure that you purchase and use hand-held dental X-ray units reviewed and tested to meet the FDA's standards for radiation-emitting electronic products:

1. Verify that your device bears certification, warning and ID labels as described above.
2. Ask your vendor whether the device has been reviewed and cleared by the FDA.
3. Access the FDA Medical Device Approvals and Clearances² searchable database to verify that the X-ray unit you are using has been reviewed by the FDA.

For additional information on state requirements applicable to hand-held X-ray systems, refer to your state's radiation control program regulations.

If you become aware of a device that you think is hazardous or does not meet FDA's radiation safety or premarket clearance requirements, contact your state regulatory agency, which will then notify the FDA. The Conference of Radiation Control Program Directors (CRCPD)³ website has a list of contacts for each state.

FDA Activities:

- The FDA is notifying state regulatory authorities, dental professional organizations, veterinary medical associations, and other health organizations about the safety risks associated with use of these devices.
- The FDA will continue to monitor this problem and keep the public informed as new information becomes available.
- The FDA will forward any substantive information that appears criminal in nature to the FDA's Office of Criminal Investigations.

Contact Information:

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.

This document reflects the FDA's current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices.

Links on this page:

1. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm>
2. [/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/ucm2007460.htm#databases](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/ucm2007460.htm#databases)
3. <http://www.crcpd.org/Map/RCPmap.htm>
4. <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>