4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0384]

Draft Guidance for Industry and Food and Drug Administration Staff; Pediatric Information for X-Ray Imaging Device Premarket Notifications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Pediatric Information for X-ray Imaging Device Premarket Notifications." This draft guidance document outlines FDA's current thinking on information that should be provided in premarket notifications for x-ray imaging devices with indications for use in pediatric populations. FDA intends for this guidance to minimize uncertainty during the premarket review process of 510(k)s for x-ray imaging devices for pediatric use, to encourage the inclusion of pediatric indications for use for x-ray imaging device premarket notifications, and to provide recommendations on information to support such indications. This draft guidance applies only to complete x-ray imaging devices that could be used on pediatric patients. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 7, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Pediatric Information for X-ray Imaging Device Premarket Notifications" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Thalia Mills,

Center for Devices and Radiological Health,

Food and Drug Administration,

10903 New Hampshire Ave.,

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SUPPLEMENTARY INFORMATION:

I. Background

Currently, most x-ray imaging devices are marketed with a general indication for use (IFU) statement. Many general use x-ray imaging devices have neither addressed the unique issues associated with pediatric use nor contain labeling specific for use on pediatric patients, even though many (if not all) of these devices are used or could be used to image pediatric patients.

Exposure to ionizing radiation is of particular concern in pediatric patients for three reasons: (1) Younger patients are more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher for younger patients) (Ref. 1); (2) younger patients have a longer expected lifetime for the effects of radiation exposure to manifest as cancer; and (3) use of equipment and exposure settings designed for adult use can result in excessive radiation exposure for the smaller patient. The third point is of special concern because many pediatric imaging exams are performed in facilities lacking specialized expertise in pediatric imaging (Ref. 2).

In 2004, the Agency issued general pediatric guidance entitled “Premarket Assessment of Pediatric Medical Devices” (Ref. 3). The guidance, which applies to all devices, defines pediatric subpopulations and the general information that should be provided for different types of premarket submissions for devices intended for use in pediatric populations.

In February 2010, FDA launched an “Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging" (Ref. 4)” and on March 30 and 31, 2010, the Agency held a public meeting entitled “Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging” (Ref. 5). At the meeting, FDA sought advice on “steps that manufacturers of

CT (computerized tomography) and fluoroscopic devices could take to reduce unnecessary radiation exposure through improved product design, enhanced labeling, or improved instructions and training for equipment use and quality assurance at medical imaging facilities." The Agency asked whether manufacturers should incorporate special provisions for pediatric patients, particularly with regard to hardware and software features. Recommendations received by FDA, which apply to all general-use x-ray imaging modalities, included making available pediatric protocols and control settings, targeted instructions and educational materials emphasizing pediatric dose reduction, quality assurance tools for facilities emphasizing radiation dose management, and dose information applicable to pediatric patients. Many of the recommendations from pediatric experts focused on expanding the flexibility or range of features already available on x-ray imaging devices, which may also improve adult imaging for nonstandard applications (Ref. 5).

Experts have commented that many radiological devices are sold without the design features or labeling information that would help users optimize benefit (clinically-usable images) in comparison to risk (radiation exposure) for pediatric imaging. Imaging professionals can safely use existing equipment that may not have specific features or instructions for pediatric use by consulting recommendations provided by the Alliance for Radiation Safety in Pediatric Imaging (ARSPI) and other organizations. FDA has reviewed the recommendations from ARSPI and believes they are appropriate. Because of the special concerns about excessive exposure to radiation in children, FDA believes the new x-ray imaging devices should be demonstrated to be appropriate for pediatric use or use in pediatric populations should be cautioned against. The end user can then make more informed decisions about use of the device on pediatric patients.

Manufacturers seeking marketing clearance for a new x-ray imaging device with a pediatric indication should provide data supporting the safety and effectiveness of the device in pediatric populations. Manufacturers who seek marketing clearance only for general indications or do not submit adequate data to the FDA to support a pediatric indication for use for x-ray imaging devices where pediatric use is likely should label their x-ray imaging device with the statement "CAUTION: Not for use on patients less than approximately [insert patient size (e.g., body part thickness or height and weight appropriate to your device)]." as part of the IFU statement. This statement should be revised depending on the size subgroups (see section 4 of the draft guidance) for which manufacturers submit data and be prominently displayed on the device itself (e.g., control panel).

This draft guidance applies only to complete x-ray imaging devices that could be used on pediatric patients. This document does not apply to imaging equipment sold as components or accessories (such as tube-housing assemblies, tables, or detectors). This guidance should be used in conjunction with other guidance specific to your type of x-ray imaging device (e.g., x-ray CT, general radiography and dental radiography, and diagnostic and interventional fluoroscopy devices) that addresses how you should meet premarket notification (510(k)) submission requirements under 21 CFR part 807. This guidance supplements other FDA documents regarding the general content and format requirements of a 510(k) submission.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on information necessary to establish substantial equivalence to a predicate device and thus provide reasonable assurance of the safety and effectiveness for x-ray imaging

devices that may be used on pediatric populations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. The FDA draft guidance entitled "Pediatric Information for X-ray Imaging Device Premarket Notifications" is available at. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm300850.htm. Guidance documents are also available at http://www.regulations.gov. To receive "Pediatric Information for X-ray Imaging Device Premarket Notifications," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1771 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485; and the collections of information in 21 CFR parts 1002, 1010, 1020, 1030, 1040, and 1050 have been approved under OMB control number 0910-0025. In addition, FDA concludes that the Indications for Use warning label does not constitute a "collection of information" under the PRA. Rather, the

labeling statements are "public disclosure[s] of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public." (5 CFR 1320.3(c)(2)).

V. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. NAS National Research Council Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation, "Health risks from exposure to low levels of ionizing radiation: BEIR VII phase 2." Washington, D.C.: National Academy of Sciences, National Academies Press, 2006.

2. Larson, D.B. et al., "Rising Use of CT in Child Visits to the Emergency Department in the United States, 1995-2008," Radiology, vol. 259(3), pp. 793-801, 2011.

3. The FDA pediatric guidance entitled "Premarket Assessment of Pediatric Medical Devices," available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm, 2004.

4. The FDA initiative entitled "Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging," available at http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/default.htm.

5. The recommendations from pediatric experts at FDA's Public Meeting: Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging,

available at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm201448.htm, March 30-31, 2010.

VI. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 4, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-11260 Filed 05/09/2012 at 8:45 am; Publication Date: 05/10/2012]