STED-only sites, approximately 6, 12, and 24 months after study entry. There will be up to three follow-up surveys, at approximately 6, 12 and 36 months, in the five ETJD sites that are not part of STED. In the two sites which are part of both the STED and ETJD projects, there will be follow-up surveys at approximately 6, 12, 24, and 36 months.

The 6-month survey is intended to gather information from treatment and control group members while treatment group members are still participating in—or have very recently completed—a subsidized job. It will focus on self efficacy, well-being, worksite experiences, and other domains that are most likely to be directly affected by employment.

The 12-month survey will collect data on study participants' receipt of services and attainment of education credentials, labor market status, material hardship, household income, criminal justice, self-sufficiency and family engagement, including, child support payments and parent-child contact. Participants will again be contacted 24 or 36 months after random assignment to follow-up and measure progress on similar domains as were measured at the 12-month point.

In addition to the surveys, each respondent will be contacted periodically by mail and asked to provide updated contact information.

3. *Implementation Research and Site Visits.* Data on the context for the programs and their implementation will be collected during two rounds of site visits to each of the twelve sites, including interviews, focus groups, observations, and case file reviews. These data will be supplemented by short questionnaires for program staff, clients, worksite supervisors, and participating employers, as well as a time-use study for program staff.

The purpose of this submission is to request approval of the baseline forms, the 6- and 12-month surveys, the implementation research protocols, and to request a waiver for subsequent 60-day notices for the other documents listed above.

Respondents: Study participants in the treatment and control groups will respond to the baseline and follow-up surveys. Program staff or employers who work with the subsidized employment programs, as well as clients participating in subsidized or transitional employment programs will respond to the implementation research interviews and questionnaires.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Annual estimated burdent hours[1]
Participant Contact Information Form (5 STED sites)	1,667	1	.08	133
Participant Baseline Information Form (5 STED sites)	1,667	1	.17	283
Participant STED tracking letters	770	5	.05	193
Participant ETJD tracking letters	550	6	.05	165
Participant 6-month survey	1,867	1	.5	934
Participant 12-month survey	3,200	1	.75	2,400
Participant Implementation Questionnaire	200	1	.17	34
Participant Focus Group Discussion Guide	80	1	.75	60
Program Staff Implementation Questionnaire	40	1	.17	7
Worksite Supervisor Implementation Questionnaire	80	1	.17	14
Employer Implementation Questionnaire	80	1	.17	14
Program Staff Interview Guides	40	2	1	80
Program Staff Cost Data Collection Protocol	4	1	1	4
Employer Interview Guides	8	2	1	16
Referral Partner Interview Guides	8	2	1	16
Program Staff Time-Use Worksheet	40	1	1	40

Estimated Total Annual Burden Hours: 4,393.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Steven M. Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. 2012–11188 Filed 5–9–12; 8:45 am]

BILLING CODE 4184–09–M

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. Bldg. 66, rm. 4527, Silver Spring, MD 20993–0002, 301–796–6641.

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, DC: 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 5–9–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0385]

Device Improvements for Pediatric X-Ray Imaging; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; request for comments.

SUMMARY: FDA is announcing the following public meeting on the draft guidance ''Pediatric Information for X-ray Imaging Device Premarket Notifications.'' This guidance will apply to x-ray computed tomography, general and dental radiography, and diagnostic and interventional fluoroscopy devices. FDA has organized this meeting to solicit public feedback on the draft guidance and to help identify issues relevant to radiation safety in pediatric x-ray imaging that may benefit from standards development or further research.

DATES: *Date and Time:* The meeting will be held on July 16, 2012, from 8 a.m. to 5 p.m.

Location: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact: Thalia Mills, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4527, Silver Spring, MD 20993, 301–796–6641, FAX: 301–847–8502, email: *Thalia.Mills@fda.hhs.gov.*

Registration: Registration is free and on a first-come, first-served basis. Persons interested in attending this meeting, but not requesting to speak or participate in the roundtable, must register online by 5 p.m. on July 9, 2012. Note that all meeting participants will be able to listen to all the presentations and roundtable discussion, as well as submit questions for the roundtable during the meeting. Early registration is recommended because facilities are limited, and therefore, FDA may also limit the number of participants from