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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on information necessary to establish substantial equivalence to a predicate device and thus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Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. The FDA draft guidance entitled ''Pediatric Information for X-ray Imaging Device Premarket Notifications'' is available at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This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents.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

each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. If you need special accommodations due to a disability, please contact Cindy Garris (email: *Cynthia.Garris@fda.hhs.gov* or phone: 301–796–5861) no later than July 9, 2012.

To register for the meeting, please visit the following Web site: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences* (select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Cindy Garris (email: *Cynthia.Garris@fda.hhs.gov* or phone: 301–796–5861) for registration. Registrants will receive confirmation once they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of Pediatric X-ray Imaging Meeting: This meeting will also be webcast. Persons interested in viewing the webcast must register online by 5 p.m. on July 9, 2012. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration, and will be sent connection access information after July 12, 2012. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.*

Requests for Oral Presentations: This meeting includes a public comment session. During online registration you may indicate if you wish to make an oral presentation during the public comment session, and the topic you wish to address in your presentation. If you wish to make a presentation during the public comment session, you must register online by 5 p.m. on June 25, 2012. FDA has included topics and questions for comment in this document. FDA will do its best to accommodate requests to make public comment. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the public comment session. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants. All requests to make oral presentations must be made at the time of registration. Presentation materials for selected oral presentations must be emailed to Thalia Mills no later than July 9, 2012. No commercial or promotional material will be permitted to be presented or distributed at the meeting.

Requests to Participate in Roundtable Discussion: This workshop also includes a roundtable discussion. During online registration you may indicate if you wish to participate in the roundtable discussion. If you wish to request to participate, you must register online by 5 p.m. on June 25, 2012. The number of roundtable participants will be limited, but all meeting participants will have the opportunity to view and submit questions to the roundtable. A request to be a participant does not guarantee a place in the roundtable discussion; participants will be chosen to represent a broad variety of specialties.

Comments: FDA is holding this public meeting to obtain public comment on the draft guidance ''Pediatric Information for X-ray Imaging Device Premarket Notifications.'' Relevant issues include device design features, labeling information, and testing specific to pediatric use. The deadline for submitting comments related to this public meeting is September 7, 2012.

Regardless of attendance at the public meeting, interested persons may submit written or electronic comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.* It is only necessary to submit one set of comments. Please identify comments with the docket number found in the brackets in the heading of this notice. In addition, when responding to specific questions as outlined in section IV of this document, please identify the question that you are addressing. Received written comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Electronic comments can be viewed in the public docket for this meeting at *http://www.regulations.gov.*

Transcripts: As soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may also be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

I. Background

The development of this draft guidance is part of FDA's larger Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging (Ref. 1). While the benefit of a clinically appropriate x-ray imaging exam far outweighs the risk, efforts should be made to minimize this risk by reducing unnecessary exposure to ionizing radiation. Ionizing radiation exposure to pediatric patients from medical imaging procedures is of particular concern to the Agency for three reasons: (1) Younger patients are more radiosensitive than adults (*i.e.,* the cancer risk per unit dose of ionizing radiation is higher) (Ref. 2); (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 adults 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. 3).

On March 30 and 31, 2010, the Agency held a public meeting entitled ''Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging'' (Ref. 4). The Agency asked whether manufacturers should incorporate special provisions for pediatric patients, particularly with regard to hardware and software features (Ref. 5). 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 non-standard applications.

At the March 2010 meeting, experts 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 (Ref. 6). 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 that 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. FDA has therefore published a draft guidance entitled ''Pediatric Information for X-ray Imaging Device Premarket Notifications'' and is holding this public meeting to solicit public comment on the draft guidance and broader radiation safety issues for use of x-ray imaging devices on pediatric populations (Ref. 7).

In addition to drafting guidance, FDA is also engaged in complementary outreach efforts aimed at providing imaging practitioners with tools to reduce dose to pediatric patients. The Center for Devices and Radiological Health and FDA's Critical Path Program funded two contracts awarded in 2010 and 2011 to the Alliance for Radiation Safety in Pediatric Imaging. The goal of the work is to develop improved training material and instructions for pediatric digital radiography (Ref. 8) and fluoroscopy (ongoing project). These materials will be publicly available as a resource to both imaging facilities and device manufacturers. FDA believes that engaging in such partnerships with professional organizations helps ensure that the end user perspective is incorporated into improved device features, instructions, and training.

In order to inform health care professionals and the public, FDA has also posted a new Web page on Pediatric X-ray Imaging (Ref. 9). More information on the benefits and risks of x-ray imaging, as well as radiation safety recommendations and resources specific to pediatric patients, can be found on this Web page.

II. Draft Guidance: Pediatric Information for X-Ray Imaging Device Premarket Notifications

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance entitled ''Pediatric Information for X-ray Imaging Device Premarket Notifications.'' This draft guidance document provides industry and Agency staff with 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. The Agency 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 is not final nor is it in effect at this time.

The draft guidance provides as follows: ''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 also be prominently displayed on the device itself (*e.g.,* control panel). The statement should be revised depending on the size subgroups (see section 4 of the draft guidance) for which manufacturers submit data.'' (Ref. 10).

This draft guidance applies only to complete x-ray imaging devices that could be used on pediatric patients (*e.g.,* x-ray computed tomography, general and dental radiography, and diagnostic and interventional fluoroscopy devices). The guidance is intended to be used in conjunction with other guidance specific to particular x-ray imaging modalities.

III. Purpose and Scope of the Meeting

Before the draft guidance ''Pediatric Information for X-ray Imaging Device Premarket Notifications'' is finalized, FDA believes it is crucial to receive public input from both industry and x-ray imaging device users, particularly from those with pediatric expertise, on the overall effort and on a number of specific questions (see section IV of this document). In order to assist the public in providing targeted comments, the FDA will present general background information on the 510(k) clearance process, the role of guidance, and the FDA's approach to pediatric use of medical devices.

In addition to discussion of the guidance itself, another goal of this meeting is to help identify issues relevant to radiation safety in pediatric x-ray imaging that may benefit from standards development or further research. FDA recognizes that a one-day meeting cannot cover all the relevant issues; we are therefore soliciting ideas on how device manufacturers, professional organizations, and FDA can best follow up on the issues identified through a coordinated effort.

IV. Specific Questions for Discussion at the Public Meeting

In your submissions to the public docket and in oral presentations, please consider the following questions. FDA will also consider your comments on topics related to safe and effective use of x-ray imaging devices on pediatric populations that are not covered by the questions below or the draft guidance:

1. While radiation-induced cancer risk depends on a number of factors including the patient's age, patient size (not age) is a major factor in optimization of radiation exposure vs. image quality. Although CDRH has defined the ''pediatric population'' as including patients from birth to 21 years (Ref. 11), Section 4—''Pediatric population'' of the draft guidance divides the pediatric population into subgroups based on patient size rather than age. The intent of the draft guidance is to extend the range of testing and labeling information to small pediatric patients that may not be covered in adult size ranges. Please provide comments on how pediatric subgroups are covered in the guidance with respect to labeling information and testing data. Specifically:

a. In the suggested language for the example caution statement to appear in the labeling, FDA assumed that if a device is designed for a broad range of adults, it will be capable of imaging patients over about 50 kg in weight and 150 cm in height. In your experience, are most general-use x-ray imaging devices adequately designed for patients over this size? Is the overall wording of the suggested example caution statement appropriate? The example statement referred to in this question reads: ''*CAUTION: This device is not intended for use on patients less than approximately 50 kg (110 lb) in weight and 150 cm (59 in) in height; these height and weight measurements*

approximately correspond to that of an average 12 year old or a 5th percentile U.S. adult female [Ref. 12]. Use of equipment and exposure settings designed for adults of average size can result in excessive radiation exposure for a smaller patient. Studies have shown that pediatric patients may be more radiosensitive than adults (i.e. the cancer risk per unit dose of ionizing radiation is higher), and so unnecessary radiation exposure is of particular concern for pediatric patients [Ref. 13].''

b. The draft guidance states that patient thickness is a more appropriate metric than height and weight for describing populations and gives references to literature data for thickness or circumference. Which metric should be used in defining subgroups (*e.g.,* anteroposterior and transverse body diameter or circumference)? Is it appropriate to choose one body region (*e.g.,* chest or abdomen) to generally categorize population subgroups in terms of thickness or circumference?

c. For tests that require phantoms, how many different sized phantoms should be tested for a sponsor to demonstrate safe pediatric use? Would a large adult-sized phantom and a small pediatric-sized phantom be sufficient to demonstrate coverage of the entire range of patient sizes? (Currently the draft guidance recommends at a minimum a range of phantoms that represent birth-1 month, 1-year old, 5-year old, 12-year old, and adult sizes.)

d. For tests that do not involve phantoms, the document states ''that the range of settings and conditions for testing include those that would normally be used during pediatric imaging'' (see Section 9 of the draft guidance). Do you have suggestions on how this range should be covered? (*e.g.,* would it be acceptable to perform tests with settings matching those used only on the smallest and largest patients?)

2. In the 510(k) premarket review process, FDA relies on the concept of ''substantial equivalence'' to a predicate device to demonstrate safe and effective use. The submitter of a 510(k) must provide a statement of the intended use of the device. If the device has specific indications for use that are different from those of the predicate device, the 510(k) summary must contain an explanation as to why the differences do not affect the safety and effectiveness of the device when used as labeled (Ref. 14). Because many predicate x-ray imaging devices that are on the market do not have a specific indication for pediatric use, new x-ray imaging devices with a specific indication for pediatric use will have to demonstrate that they are as safe and effective as the predicate devices that are not indicated for pediatric use. Especially with regard to sections 9 (Laboratory Image Quality and Dose Assessment) and 10 (Clinical Image Quality Assessment) in the draft guidance, FDA has outstanding questions regarding how to demonstrate that an x-ray imaging device that has a specific indication for pediatric use is as safe and effective as an x-ray imaging device with only a general indication for use:

a. Can you think of a situation where phantom testing (objective image quality and dose assessment) alone would be insufficient to demonstrate safe and effective pediatric use and clinical data would be necessary?

b. In those cases, would it be acceptable to provide images of anthropomorphic phantoms instead of pediatric patients?

3. As currently written, the draft guidance document recommends that any performance characteristics expected to change based on the size of the object being imaged should be tested specifically for pediatric use. FDA requests help identifying what these tests are, *i.e.,* which device features are size-dependent? (Tube current modulation and/or automatic exposure control and data collection speed are examples.) Because this guidance document is intended to cover all x-ray imaging devices that could be used on pediatric patients, this question relates specifically to x-ray computed tomography, fluoroscopy, and general and dental radiography devices.

4. Table 3 in the Appendix of the draft guidance lists specific pediatric issues currently addressed by applicable standards. Establishing safe and effective use of x-ray imaging devices on pediatric populations may involve special design features, labeling (*e.g.* instructions for use) and training information, and performance tests. The guidance covers these topics generally, but each modality will have different issues. A variety of approaches for these topics exist in the literature, but in many cases it may be beneficial if the x-ray imaging community further developed prioritized, consensus recommendations. FDA participates in development of national and international standards. While FDA does not control the content of these standards, standards liaisons can make recommendations. Do you have specific recommendations for pediatric use issues that should be covered by standards for performance features, testing, or labeling?

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. FDA White Paper, ''Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging,'' available at *http://www.fda.gov/RadiationEmittingProducts/RadiationSafety/RadiationDoseReduction/default.htm,* February 2010.
2. National Research Council of the National Academies, 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,'' *National Academy of Sciences* (National Academies Press, 2006).
3. For example, the following study found that non-pediatric focused emergency departments made up 89.4 percent of emergency department visits associated with CT (computed tomography) in children: Larson, D.B., et al., ''Rising Use of CT in Child Visits to the Emergency Department in the United States, 1995–2008,'' *Radiology,* 259(3), 793–801, 2011.
4. FDA Public Meeting: Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging, March 30–31, 2010, agenda and transcripts, available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm201448.htm,* public docket submissions, available at *http://www.regulations.gov/#!docketDetail;rpp=10;po=0;D=FDA-2010-N-0080.*
5. The **Federal Register** notice (75 FR 8375–8377) lists all the questions asked at the meeting, February 24, 2010, available at *http://edocket.access.gpo.gov/2010/2010-3674.htm.*
6. The principles of radiation protection in medicine, including ''optimization'' are described in ''Radiological Protection in Medicine, International Commission on Radiological Protection,'' *Annals of the ICRP,* 37(6), 2007. Optimization of radiation exposure for x-ray imaging means the following: Examinations should use techniques that are adjusted to administer the lowest radiation dose that yields an image quality adequate for diagnosis or intervention (*i.e.,* radiation doses should be ''As Low as Reasonably Achievable'' (ALARA)).
7. 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.*
8. The Image Gently/FDA Digital Radiography Safety Checklist and accompanying documents are available at *http://www.pedrad.org/associations/*

5364/ig/index.cfm?page=775.
9. The FDA Web page for information on Pediatric X-ray Imaging, is available at *http://www.fda.gov/RadiationEmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm*.
10. Under section 513(i)(1)(E)(i) of the Federal Food, Drug, and Cosmetic Act, when determining that a device is substantially equivalent to a predicate device, FDA may require limitations in device labeling about off-label use of the device when ''there is a reasonable likelihood'' of such use, and if ''such use could cause harm.'' Such determinations are made on a case by case basis and other requirements must be met, including a consultation between FDA and the 510(k) submitter, before such limitations can be required. FDA's policy on when a device may be found ''substantially equivalent with limitations'' is discussed further in the guidance entitled ''Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff (Update to K98–1),'' available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082162.htm,* December 3, 2003.
11. The FDA guidance entitled ''Premarket Assessment of Pediatric Medical Devices,'' is available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089742.pdf,* May 14, 2004.
12. McDowell, M.A., C.D. Fryar, C.L. Ogden, and K. M. Flegal, ''Anthropomorphic Reference Data for Children and Adults: United States, 2003–2006,'' *National Health Statistics Reports,* vol. 10, 1–48, available at *http://www.cdc.gov/nchs/data/nhsr/nhsr010.pdf,* October 22, 2008.
13. National Research Council of the National Academies, 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,'' *National Academy of Sciences* (National Academies Press), is available at *http://www.nap.edu/openbook.php?isbn=030909156X,* 2006.
14. See 21 CFR 807.92.

Dated: May 4, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–11262 Filed 5–9–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Proposed Information Collection; Request for Public Comment: Indian Health Service Loan Repayment Program (LRP)

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, which requires 30 days for public comment on proposed information collection projects, the Indian Health Service (IHS) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection project was previously published in the **Federal Register** (77 FR 11558) on February 27, 2012 and allowed 60 days for public comment. No public comment was received in response to the notice. The purpose of this notice is to allow 30 days for public comment to be submitted directly to OMB.

Proposed Collection: Title: 0917–0014, ''Indian Health Service Loan Repayment Program.'' *Type of Information Collection Request:* Revision of currently approved information collection, 0917–0014, ''Indian Health Service Loan Repayment Program.'' The LRP application has been revised so that it is now available in an electronically fillable and fileable format. *Form(s):* The IHS LRP Information Booklet contains the instructions and the application formats. *Need and Use of Information Collection:* The IHS LRP identifies health professionals with pre-existing financial obligations for education expenses that meet program criteria and who are qualified and willing to serve at, often remote, IHS health care facilities. Under the program, eligible health professionals sign a contract through which the IHS agrees to repay part or all of their indebtedness for professional training time in IHS health care facilities. This program is necessary to augment the critically low health professional staff at IHS health care facilities.

Any health professional wishing to have their health education loans repaid may apply to the IHS LRP. A two-year contract obligation is signed by both parties, and the individual agrees to work at an IHS location and provide health services to American Indian and Alaska Native individuals.

The information collected via the on-line application from individuals is analyzed and a score is given to each applicant. This score will determine which applicants will be awarded each fiscal year. The administrative scoring system assigns a score to the geographic location according to vacancy rates for that fiscal year and also considers whether the location is in an isolated area. When an applicant accepts employment at a location, they in turn ''pick-up'' the score of that location. *Affected Public:* Individuals and households. *Type of Respondents:* Individuals.

The table below provides: Types of data collection instruments, Estimated number of respondents, Number of responses per respondent, Annual number of responses, Average burden hour per response, and Total annual burden hour(s).

ESTIMATED BURDEN HOURS

Data collection instrument(s)	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual responses (in hours)
LRP Application	510	1	1.5	765

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Requests for Comments: Your comments and/or suggestions are invited on one or more of the following points:

(a) Whether the information collection activity is necessary to carry out an agency function;

(b) Whether the agency processes the information collected in a useful and timely fashion;

(c) The accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information);

(d) Whether the methodology and assumptions used to determine the estimates are logical;

(e) Ways to enhance the quality, utility, and clarity of the information being collected; and