

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Burmese Refugees .....	Follow-up Survey .....	133	1	5/60	11
	Eligibility Screening Survey .....	42	1	5/60	4
	Contact Information Form .....	33	1	5/60	3
	Study Questionnaire .....	33	1	40/60	22
	Clinic Visit Checklist and Body Measurements.	33	1	35/60	19
	Network Size Questions .....	33	1	5/60	3
	Follow-up Survey .....	33	1	5/60	3
Total .....	.....	.....	.....	.....	231

**Leroy A. Richardson,**  
*Chief, Information Collection Review Office,  
 Office of Scientific Integrity, Office of the  
 Associate Director for Science, Office of the  
 Director, Centers for Disease Control and  
 Prevention.*

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**DEPARTMENT OF HEALTH AND  
 HUMAN SERVICES**

**Agency for Toxic Substances and  
 Disease Registry**

[60Day-17-17IV; Docket No. ATSDR-2016-0008]

**Proposed Data Collection Submitted  
 for Public Comment and  
 Recommendations**

**AGENCY:** Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the information collection request titled “APPLETREE Performance Measures.” Under the APPLETREE cooperative agreement program (Funding Opportunity Announcement No. CDC-RFA-TS17-1701), awardees will be required to submit an Annual Plan of Work (APOW), several standardized outcome and performance measures, and an Annual Performance Report (APR).

**DATES:** Written comments must be received on or before March 6, 2017.

**ADDRESSES:** You may submit comments, identified by Docket No. ATSDR-2016-0008 by any of the following methods:

- *Federal eRulemaking Portal:* [Regulations.gov](http://www.Regulations.gov). Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to [Regulations.gov](http://www.Regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](http://www.Regulations.gov).

*Please note:* All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](http://www.Regulations.gov)) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of

previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

**Proposed Project**

APPLETREE Performance Measures—New—Agency for Toxic Substances and Disease Registry (ATSDR).

*Background and Brief Description*

The Agency for Toxic Substances and Disease Registry (ATSDR) serves the public through responsive public health actions to promote healthy and safe environments and to prevent harmful exposures in communities across the nation. ATSDR's Partnership to Promote Local Efforts to Reduce Environmental Exposure (APPLETREE) Program is critical to ATSDR's success in this mission. The purpose of the program is to: (1) Identify pathways of exposure to hazardous substances at hazardous waste sites and releases; (2) identify, implement, and coordinate public health interventions to reduce exposures to hazardous substances which occur at levels of health concern; and (3) provide training at the state level to promote and achieve the safe siting of child care facilities in the United States. The APPLETREE Program is also a mechanism which enhances ATSDR's communication with state, local, and federal health and environmental agencies. This program is authorized under Sections 104(i)(15) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986 [42 U.S.C. 9604(i)(15)].

Under the new three-year APPLETREE cooperative agreement (Funding Opportunity Announcement No. CDC-RFA-TS17-1701), eligible applicants include federally recognized American Indian/Alaska Native tribal governments; American Indian/Alaska native tribally designated organizations; political subdivisions of states (in consultation with states); and state and local governments or their bona fide agents. ATSDR technical project officers (TPOs) will assist approximately 25 APPLETREE awardees to address site-specific issues involving human exposure to hazardous substances. Key capacities include identification of

human exposure pathways at ATSDR sites, education of affected communities and local health professionals about site contamination and potential health effects; making appropriate recommendations to prevent exposure; reviewing health outcome data to evaluate potential links between site contaminants and community health; and documenting the effects of environmental remediation on health.

ATSDR will collect information related to awardee activities, and the process and outcome performance measures outlined by the cooperative agreement program. Information will be used to monitor progress toward program goals and objectives, and for quality improvement.

*Annual Plan of Work (APOW):* Each budget year, awardees shall deliver an APOW. The APOW will include awardee workplans for site-specific activities, environmental health assessment outputs, and overarching milestones for child care safe siting activities. The estimated annual time burden to prepare and report the APOW is eight hours per awardee.

*ATSDR Health Education Activity Tracking (HEAT) Performance Measure:* For each environmental health assessment and health education activity conducted at ATSDR sites, APPLETREE awardees shall quantitatively assess and report efforts to educate community members about site recommendations and health risks using indicators to assess community understanding of site findings about health risks and community understanding of agency recommendations to reduce health risks. This information will be entered in to the ATSDR HEAT system for each activity at ATSDR sites. Based on past experience, ATSDR assumes a maximum of 925 activities will be entered into the HEAT database each year; therefore, each of the 25 awardees

will enter an average of 37 activities into the HEAT database.

*ATSDR Site Impact Assessment (SIA) Performance Measure:* For each environmental health assessment and health education activity conducted at ATSDR sites, awardees shall estimate and report the number of people protected from exposure to toxic substances at each site where implementation of agency recommendations has taken place and at each child care center where safe siting guidelines have been implemented. To the extent possible, awardees shall estimate the disease burden prevented due to the implementation of site recommendations and safe siting guidelines. This information will be entered into the ATSDR SIA database by the awardee. ATSDR assumes a maximum of 150 ATSDR sites will undergo an environmental assessment, or an average of 6 sites per awardee, per year.

*APPLETREE Annual Performance Report (APR):* Awardees must provide an APR at the end of each budget year. The report must include a minimum of three site activity success stories; a synopsis of the number of people involved in environmental health assessments at sites, the number of public health recommendations accepted, the number of health education activities conducted at sites; and the outcomes achieved during the budget year. The APR must also demonstrate annual progress in implementing child care safe siting policies in their jurisdictions over the three-year program period. ATSDR assumes that ASARs will take 15 burden hours for each awardee to prepare.

ATSDR seeks to request a three-year clearance from OMB to collect the necessary information for this project.

The awardee reporting is a requirement of the APPLETREE cooperative agreement. The total annual time burden requested is 635 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents per year	Number of responses per respondent per year	Average burden per response (in hours)	Total burden (in hours)
APPLETREE Awardees .....	Annual Plan of Work (APOW) .....	25	1	8	200
	ATSDR Health Education Activity Tracking (HEAT) Form.	25	37	3/60	47
	ATSDR Site Impact Assessment (SIA) Form.	25	6	5/60	13
	APPLETREE Annual Performance Report (APR).	25	1	15	375
Total .....	.....	.....	.....	.....	635

**Leroy A. Richardson,**  
*Chief, Information Collection Review Office,  
 Office of Scientific Integrity, Office of the  
 Associate Director for Science, Office of the  
 Director, Centers for Disease Control and  
 Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-D-4436]

#### Premarket Notification (510(k)) Submissions for Bone Anchors; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Premarket Notification (510(k)) Submissions for Bone Anchors.” The guidance provides recommendations for the information and testing that should be included in premarket submissions for bone anchor (suture anchor) devices used in the appendicular skeleton for attachment of soft tissue to bone. 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 March 6, 2017.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact

information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2016-D-4436 for “Premarket Notification (510(k)) Submissions for Bone Anchors.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in

accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Premarket Notification (510(k)) Submissions for Bone Anchors” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Daniel Ramsey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1451, Silver Spring, MD 20993-0002, 301-796-6451.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled “Premarket Notification (510(k)) Submissions for Bone Anchors.” FDA has developed this guidance document for members of industry who submit and FDA staff who review premarket submissions regarding bone anchor (suture anchor) devices used in the appendicular skeleton for attachment of soft tissue to bone. When finalized, this guidance is intended to provide recommendations for information to include in premarket notifications (510(k)) for bone anchor (suture anchor) devices (e.g., descriptive characteristics, labeling, biocompatibility, sterility, and bench testing). This guidance is a reissuance of the April 20, 1996 “Guidance Document for Testing Bone Anchor Devices” with updated content.