

20877. The hotel phone number is 301-977-8900.

*Contact Person:* Sara J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 66, Rm. 1611, Silver Spring, MD, [Sara.Anderson@fda.hhs.gov](mailto:Sara.Anderson@fda.hhs.gov), 301-796-7047, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On July 18, 2013, the committee will discuss and make recommendations on the proposed regulatory classification for dental devices known as Endosseous Dental Implants (Blade-form), one of the remaining preamendments Class III devices. The Class III blade-form endosseous dental implant is a device placed into the maxilla or mandible and composed of biocompatible material, such as commercially pure titanium, with sufficient strength to support a dental restoration, such as a crown, bridge, or denture, intended for the purpose of replacing tooth (or teeth) roots and extending a support post through the gingival tissue into the oral cavity to restore chewing function. The blade-form implant is generally a rectangular shape or rounded corner rectangle shape (in the mesio-distal plane) with a narrow tapered (narrow at the apical edge) edge (in the buccolingual plane) similar in shape to a razor blade. Other blade designs, such as square, V-shaped, and triangles have also been used. The blade-form implants are either one-piece or two-piece implants designed with one to three cylindrical abutment posts extending from the coronal aspect of the blade through the soft tissue and into the oral cavity.

On January 4, 2013 (FDA-2012-N-0677), FDA issued a proposed order which, if made final, would reclassify the blade-form endosseous dental implant into class II (special controls). The committee's discussion will involve making recommendations regarding regulatory classification to either reaffirm Class III or reclassify these devices into Class II and comment on

whether the proposed Special Controls are adequate to reasonably ensure the safety and effectiveness of blade-form endosseous dental implants. The regulatory history of blade-form endosseous dental implant has been discussed as part of the proposed order (FDA-2012-N-0677).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 9, 2013. On July 18, 2013, oral presentations will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 28, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 1, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at [Annmarie.Williams@fda.hhs.gov](mailto:Annmarie.Williams@fda.hhs.gov) or 301 796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 8, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-11286 Filed 5-10-13; 8:45 am]

**BILLING CODE 4160-01-P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities; Proposed Collection; Comment Request

**ACTION:** Notice.

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**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Information Collection Request Title: Information and Referral and Professional Training Impact Surveys in Health Resources and Services Administration (HRSA)—Funded Traumatic Brain Injury Grants (OMB No. 0915-xxxx)—New**

*Abstract:* This survey is designed to collect information from HRSA-funded Traumatic Brain Injury (TBI) State Implementation Partnership Grants and Protection and Advocacy for Traumatic Brain Injury (TBI) Grants regarding the impact of grant activities on individuals with traumatic brain injury and their family members. The authority for this program is the Public Health Service Act, Title XII, Section 1252 (42 U.S.C. 300d-52) as amended by the Children's Health Act of 2000, sec. 1304, Public Law 106-310, as further amended by the Traumatic Brain Injury Act of 2008, sec. 6, Public Law 110-206.

Individuals with TBI present with a host of different symptoms, which exist with varying levels of severity. Comprehensive appropriate care often requires a variety of services such as physical rehabilitation, speech rehabilitation, cognitive rehabilitation, special education accommodations, vocational skills coaching, and

independent living skills training, which are located across many state and local agencies. For this reason, individuals with TBI and their family members often have difficulty identifying local providers with the skills and expertise to deliver services that will promote recovery and maximize independence.

Per the authorizing legislation, the intent of these programs is to improve access to rehabilitation and other services regarding traumatic brain injury. The HRSA State Implementation Partnership Grants and State Protection and Advocacy Grants support this charge by providing information to individuals with TBI and their families about TBI and making referrals to local providers equipped to meet the unique needs of each survivor. Additionally, these grant programs train providers in various settings to identify and effectively serve individuals with TBI and their families.

To date, a number of grantees have collected data independently to determine the impact of their work on individuals with TBI and their families. HRSA proposes uniform data collection surveys for these two categories of activities—information and referral

services, and professional training—to assess the extent to which these activities are increasing access to rehabilitation and other services. In addition to providing uniform data across these grant programs, the data will help determine what efforts might improve outreach and provision of services for future projects.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. 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. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Feedback Form for Individuals with TBI and/or their Family Members receiving Information and Referral Services ....	21,000	1	21,000	0.25	5,250
Feedback Form for Training Session Participants .....	10,500	1	10,500	0.25	2,625
Total .....	31,500	1 <sup>1</sup>	31,500	0.50	7,875

<sup>1</sup> Respondents for these two survey forms will be distinct; individuals will not complete both surveys. Therefore, there will be only one response per respondent.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Reports Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

*Deadline:* Comments on this ICR must be received within 60 days of this notice.

Dated: May 7, 2013.

**Bahar Niakan,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2013-11256 Filed 5-10-13; 8:45 am]

**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request**

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Health Resources and Services Administration (HRSA) will submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). Comments submitted during the first public review of this ICR will be

provided to OMB. OMB will accept further comments from the public during the review and approval period. To request a copy of the clearance requests submitted to OMB for review, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

**Information Collection Request Title: Organ Donation/Transplant Life Stories (OMB No. 0915-xxxx)—NEW**

*Abstract:* HRSA's Division of Transplantation (DoT) is the primary entity in the Department of Health and Human Services (HHS) responsible for the Organ Transplant Program established under the National Organ Transplant Act (Pub. L. 98-507, codified at sections 371-377D of the Public Health Service (PHS) Act). Section 377A of the PHS Act authorizes the Secretary