companion diagnostic devices that have inadequate performance characteristics.

When an appropriate scientific rationale supports such an approach, FDA encourages the joint development of therapeutic products and diagnostic devices that are essential for the safe and effective use of those therapeutic products. To facilitate the development and approval of therapeutic products that are intended for use with IVD companion diagnostic devices, as well as the development of the IVD companion diagnostic devices themselves, FDA is clarifying relevant policies related to these devices and products.

In the **Federal Register** of July 14, 2011 (76 FR 41506), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by October 12, 2011 (76 FR 51993). Thirty two sets of comments were received and reviewed by FDA. The guidance was updated to address comments where appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on IVD companion diagnostic devices. 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 statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*, and a search capability for all CBER guidance documents is available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''In Vitro Companion Diagnostic Devices,'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1737 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 814, subparts B and E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR 201.56 and 21 CR 201.57 have been approved under OMB control number 0910–0572.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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, and will be posted to the docket at *http://www.regulations.gov.*

Dated: July 30, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18538 Filed 8–5–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 1, 2014, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC/North, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.

Contact Person: Patricio G. Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3628, Silver Spring, MD 20993–0002, *Patricio.Garcia@fda.hhs.gov,* 301–796–6875, 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 October 1, 2014, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the SONABLATE 450 device sponsored by SonaCare Medical, LLC. The proposed Indication for Use for the SONABLATE 450 device, as stated in the PMA, is as follows:

The SONABLATE 450 (SONABLATE) is intended for use in the treatment of

localized, clinically recurrent prostate cancer after failure of primary external beam radiation therapy.

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 September 16, 2014. Oral presentations from the public 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 September 8, 2014. 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 September 11, 2014.

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 James Clark at *James.Clark@fda.hhs.gov,* or 301–796–5293 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: August 1, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–18616 Filed 8–5–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than October 6, 2014.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: 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* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Information/Referral and Professional Training Surveys

(OMB No. 0915–xxxx)—[New]

Abstract: These surveys are designed to collect information from recipients of information/referral services and professional training provided by the following two HRSA-funded programs: (1) Traumatic Brain Injury (TBI) State Implementation Partnership Grants and (2) Protection and Advocacy for TBI Grants. Additionally, grant recipients administering these surveys will submit a summary report aggregating the responses from these two surveys.

The authority for this program is the Public Health Service Act, Title XII, Section 1252, as amended (42 U.S.C. 300d–52). 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.

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. These services are often located across many state/local agencies and providers. 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.

Need and Proposed Use of the Information: HRSA proposes that the data collection surveys be administered by grant recipients to individuals with TBI, their family members, and professional providers for two categories of activities—information/referral services and professional training. These surveys were developed to capture the following: (1) The effectiveness of information and referral services provided to individuals with TBI and their family members, and (2) the effectiveness of training about TBI for professionals who may encounter