costs noted on the business proposal forms. Subsequent contract and modification negotiations will be based on historic cost data. The business proposal forms will be one element of the historical cost data from which we can analyze future proposed costs. In addition, the business proposal format will standardize the cost proposing and pricing process among all QIOs. With well-defined cost centers and line items, proposals can be compared among QIOs for reasonableness and appropriateness.

Form Number: CMS–718–721 (OMB control number: 0938–0579); *Frequency:* Annually; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 20; *Total Annual Responses:* 20; *Total Annual Hours:* 1,000. (For policy questions regarding this collection contact Clarissa Whatley at 410–786–7154.)

Dated: July 16, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–17137 Filed 7–21–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0913]

Agency Information Collection Activities; Proposed Collection; Comment Request; 513(g) Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection burden estimate for requests for a written statement from FDA regarding the classification and regulatory requirements that may be applicable to a particular device (513(g) requests).

DATES: Submit either electronic or written comments on the collection of information by September 22, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the 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. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

513(g) Request for Information—(OMB Control Number 0910–0705)—Extension

Section 513(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining the Agency's views about the classification and regulatory requirements that may be applicable to a particular device. Section 513(g) provides that within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act, the Secretary of Health and Human Services shall provide such person a written statement of the classification (if any) of such device and the requirements of the FD&C Act applicable to the device.

The guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act'' establishes procedures for submitting, reviewing, and responding to requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) of the FD&C Act. FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) request for information. FDA's responses to 513(g) requests for information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act. Additionally, the FD&C Act, as amended by the FDA Amendments Act of 2007 (Public Law 110–85), requires FDA to collect user fees for 513(g) requests for information. The guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff User Fees for 513(g) Requests for Information'' assists FDA staff and regulated industry by describing the user fees associated with 513(g) requests. The Medical Device User Fee Cover Sheet (Form FDA 3601), which accompanies the supplemental material described in this information collection, is approved under OMB Control No. 0910–0511 and expires April 30, 2016.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Devices and Radiological Health 513(g) requests	114	1	114	12	1,368
Center for Biologics Evaluation and Research 513(g) requests	4	1	4	12	48
Total					1,416

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are mostly device manufacturers; however, anyone may submit a 513(g) request for information. The total number of annual responses is based on the average number of 513(g) requests received each year by the Agency.

Dated: July 10, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–16564 Filed 7–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0926]

Advancing the Use of Biomarkers and Pharmacogenomics; Notice of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA or the Agency) is announcing a public meeting to discuss current scientific and regulatory approaches to biomarker development, acceptance, and utility in drug and biologic (hereafter referred to as therapeutic product) development programs. The purpose of the public meeting is to initiate constructive discussion and information sharing on the advancement of biomarker science in the context of therapeutic product development among relevant stakeholders. Specifically, the meeting will focus on identifying challenges for biomarker applications in early- and late-phase clinical trials and emerging best practices for successful biomarker-based programs, including codevelopment of in vitro diagnostic devices and use of biomarkers as outcome measures in clinical trials. FDA is conducting this meeting in collaboration with Brookings Institution. This meeting satisfies an FDA commitment that is part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V).

Date and Time: The meeting will be held on September 5, 2014, from 9 a.m. to 5 p.m.

Location: The public meeting will be held at the Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005. For additional travel and hotel information, please refer to *http://www.brookings.edu/events/2014/09/05-biomarkers-pharmaceutical-FDA.* (FDA has verified the Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**).

Contacts: Padmaja Mummaneni, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 2164, Silver Spring, MD 20993, 301–796–2027, email: *padmaja.mummaneni@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911, email: *stephen.ripley@fda.hhs.gov.*

Registration: The meeting venue has limited seating. Individuals who wish to attend the public meeting must register on or before August 5, 2014, by visiting *http://events.SignUp4.com/PDUFA Public2014.* Early registration is recommended. When registering, please provide the following information: Name, title, company or organization (if applicable), postal address, telephone number, and email address. Registration is free and will be on a first-come, first-served basis. However, Brookings may limit the number of participants from each organization based on space limitations. Onsite registration on the day of the meeting by Brookings will be based on space availability.

If you need special accommodations because of disability, please contact Joanna Klatzman at the Brookings Institution (email: *jklatzman@brookings.edu*) at least 7 days before the meeting.

Streaming Webcast of the Public Meeting: A live Webcast of this meeting will be viewable at *http://www.brookings.edu/events/2014/09/05-biomarkers-pharmaceutical-FDA* on the day of the meeting. A video record of the meeting will be available at the same Web address for 1 year.

Comments: Regardless of attendance at the public meeting, interested persons may submit electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify all comments with the corresponding docket number found in brackets in the heading of this document. To ensure consideration, submit comments by November 5, 2014. 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.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr, Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144). Title I of FDASIA reauthorizes PDUFA and provides FDA with the user fee resources necessary to maintain an efficient review process for human drug and biological products. The reauthorization of PDUFA includes performance goals and procedures for