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]

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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

the Agency that represents FDA's commitments during fiscal years 2013–2017. These commitments are fully described in the document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017'' (''PDUFA Goals Letter''), available on FDA's Web site at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.* Section IX of the PDUFA Goals Letter, titled Enhancing Regulatory Science and Expediting Drug Development,'' includes an enhancement to advance the use of biomarkers and pharmacogenomics. As part of this enhancement, FDA committed to hold a public meeting to discuss the current status of biomarkers and pharmacogenomics and potential strategies to facilitate scientific exchanges in regulatory and non-regulatory contexts. The public meeting announced by this notice will fulfill this commitment.

II. Purpose and Scope of the Meeting

The objectives of the meeting are as follows:

- Initiate constructive discussion and information-sharing about challenges and best practices in biomarker acceptance and utility in the context of therapeutic product development programs,
- share current experience regarding critical issues in the transition of exploratory biomarkers to their use in clinical trial design and analysis plans, including best practices in the coordination of codevelopment of therapeutic products with in vitro diagnostic devices, and
- obtain input on evidentiary criteria for biomarkers as outcome measures in clinical trials.

Although many external stakeholders propose using predictive, prognostic, pharmacodynamic, or surrogate biomarkers to enhance therapeutic product development, the scientific rationale, quality, and quantity of supportive data to support the transition from exploratory studies to confirmatory trials are variable. This meeting will discuss common uses of biomarkers in therapeutic product development programs. Discussion topics include specific considerations for early- and late-phase clinical trials when employing biomarker-based trial designs, emerging best practices in codevelopment of therapeutic products with in vitro diagnostic devices, and discussion of context-specific scenarios in which biomarkers may be used as outcome measures.

The public input from the meeting will be used to identify opportunities for biomarker-related regulatory guidance, improve understanding and consistency in regulatory review of therapeutic product applications that incorporate biomarkers in clinical trial designs, and identify potential strategies to facilitate scientific exchanges in regulatory and non-regulatory contexts.

III. Scope of Public Input Requested

FDA seeks input on a range of topics related to common challenges and emerging strategies for application of biomarkers in clinical trials, whether for patient selection or as an outcome measure in therapeutic product development. Potential topics for discussion include the following:

1. Critical Issues in the Transition of Exploratory Biomarkers to Companion Diagnostic Devices

- Early-phase trial designs and exploratory biomarker analysis approaches to effectively inform whether biomarker-enriched confirmatory trial strategies or other strategies are appropriate,
- evidentiary standards for incorporating novel biomarkers into the design and analysis of pre-marketing confirmatory trials (e.g., for patient selection), and need for and timing of data collection in non-targeted populations,
- prospective/retrospective approaches to validate biomarkers in the context of confirmatory trials,
- approaches to establish and modify thresholds for quantitative biomarkers prior to conducting confirmatory trials,
- best practices for biospecimen collection and in vitro diagnostic assay development in early-phase therapeutic trials to support subsequent biomarker/diagnostic codevelopment,
- best practices for effective communication between regulatory agencies and therapeutic or diagnostic sponsors in the setting of codevelopment, and
- codevelopment considerations for biomarkers that are predictive, but not necessarily essential to the safe and effective use of the therapeutic product.

2. Use of a Biomarker as a Clinical Trial Outcome Measure

- Criteria for consideration of biomarker outcomes in clinical trials as correlates,
- principles to consider for biomarker outcomes as replacement endpoints of clinical endpoints considering the following:
  - Multiple causal pathways of a disease process,
  - biomarker endpoint is not in the causal pathway of the disease process,
  - interventions with mechanisms of action independent of the disease process,
- evidence for a compelling context for the use of a biomarker as a surrogate endpoint, and
- roles, if any, on metaanalysis of clinical trials data to establish the utility of biomarker outcomes as surrogates.

In this **Federal Register** notice, FDA has included specific issues that will be addressed by the presenters and panelists. Time will be reserved during the meeting for general comments and questions from the audience following the panel discussions. FDA will do its best to accommodate requests to speak.

The agenda and background materials will be available approximately 2 weeks before the meeting at *http://www.brookings.edu/events/2014/09/05-biomarkers-pharmaceutical-FDA.*

Dated: July 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Endocrinologic and Metabolic Drug Products 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: Endocrinologic and Metabolic Drugs 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 September 12, 2014, from 8 a.m. to 5 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland University College (UMUC), Potomac Ballroom, 3501 University Blvd. East, Hyattsville, MD 20783. The conference center's telephone number is 301–985–7300. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: