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.

[FR Doc. 2014–17090 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–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:

http://www.fda.gov/AdvisoryCommittees/default.htm; under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Karen Abraham-Burrell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., White Oak Bldg. 31, Rm. 2147, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *EMDAC@fda.hhs.gov,* 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: The committee will discuss biologics license application (BLA) 125511, proposed trade name NATPARA (established name: Recombinant Human Parathyroid Hormone (rDNA) or (rhPTH[1–84]), submitted by NPS Pharmaceuticals, Inc., for the proposed indication of replacement for endogenous parathyroid hormone (1–84) for the long-term treatment of hypoparathyroidism.

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 August 27, 2014. Oral presentations from the public will be scheduled between approximately between 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 August 19, 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 August 20, 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 Karen Abraham-Burrell 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: July 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17086 Filed 7–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD).

Date and Time: August 5, 2014 (9:30 a.m.–5:00 p.m.) August 6, 2014 (8:30 a.m.–3:00 p.m.)

Place: Combined In-Person and Webinar Format, Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services, 5600 Fishers Lane, Room 18–67, Rockville, Maryland 20857.

Status: The meeting will be open to the public.

Purpose: The ACTPCMD provides advice and recommendations on a broad range of issues relating to grant programs authorized by sections 222 and 749 of the Public Health Service Act, as amended by section 5103(d) and re-designated by section 5303 of the Patient Protection and Affordable Care Act of 2010.

Agenda: The meeting will begin with introductions of seven new members to the committee and then move to opening remarks from HRSA senior officials who will provide an update on HRSA's newly created Bureau of Health Workforce. The new members will receive a comprehensive update on the committee's latest 11th Report to Congress, which will focus on the training of health professionals in community settings, the members will then break-out into workgroups and continue development of the report. A short timeline for finalizing the report will be created.

Public Comment: An opportunity will be provided for public comment at the end of each day of the meeting, or written comments to the members may be sent prior to the meeting to Shane Rogers at *srogers@hrsa.gov.*

The agenda will be available 2 days prior to the meeting on the HRSA Web site (*http://www.hrsa.gov/advisorycommittees/bhpradvisory/actpcmd/index.html*). Agenda items are subject to change as priorities dictate.

SUPPLEMENTARY INFORMATION: As this meeting will be a combined format of both in-person and webinar, members of the public and interested parties who wish to participate ''in-person'' should make an immediate request by emailing their first name, last name, and contact email to the Designated Federal Official for the committee, Mr. Shane Rogers, at *srogers@hrsa.gov* or call (301) 443–5260. Space is limited. Due to the fact that this meeting will be held within a federal government building and public entrance to such facilities require prior planning, access will be granted upon request only and will be on a first come, first served basis. Members of the public who wish to participate via webinar should view the committee's Web site for the specific webinar access information at least 2 days prior to the date of the meeting: *http://www.hrsa.gov/advisorycommittees/bhpradvisory/actpcmd/index.html.*