easier for laboratories to develop and offer tests on a rapid timeline, the absence of a level playing field creates a competitive disadvantage and potential disincentive to innovation by other manufacturers whose tests are approved or cleared by the agency for similar indications. In addition, as set out above, it means that some diagnostics critical for patient care may not be developed in a manner that provides a reasonable assurance of safety and effectiveness.

In response to these public health concerns, the agency believes it is time to reconsider its policy of enforcement discretion over LDTs. The public must be assured that the tests used in the provision of health care, whether developed by a laboratory or other manufacturer, are safe and effective. However, The FDA recognizes that there are issues unique to the laboratory community that should be taken into consideration so that patients will receive the desired benefits of innovative, yet safe and effective, diagnostic tests. FDA recognizes the importance of implementing an oversight framework that fosters innovation in this area while assuring that such tests are safe and effective. For example, the field of genomics and genetic testing has the potential to revolutionize patient care. As a second example, fostering innovation in tests for rare diseases and conditions is another important public health concern. In these and other categories, it is important that FDA provide a reasonable, predictable, and consistent regulatory policy for ensuring the safety and effectiveness of LDTs and provide sufficient time for implementation. Therefore, this policy should encourage innovation, improve patient outcomes, strengthen patient confidence in the reliability of these products, and help reduce health care costs.

At this time, FDA believes that a risk-based application of oversight to LDTs is the appropriate approach to achieve the desired public health goals and would like to hear from stakeholders, including laboratory professionals, clinicians, patients, and industry, as we develop our draft oversight framework, to define the issues that pose the greatest concern to the public health. The public meeting announced in this notice will serve as a forum to discuss issues and stakeholder concerns surrounding LDT oversight. Following the public meeting and the close of the public docket the FDA will move forward expeditiously to develop a draft oversight framework for public comment to provide predictability as quickly as possible. The FDA also intends to phase in such a framework over time based on the level of risk of the test.

II. Agenda

FDA will start the public meeting with a series of presentations introducing the history and current regulatory status of LDTs. The remainder of the meeting will be divided into four sessions highlighting areas in which FDA hopes to gain public input from critical perspectives in response to its proposal to develop an oversight framework, as well as to hear stakeholder opinions on which issues around laboratory developed testing present the greatest concern to the public health. These sessions include the following: (1) Patient Considerations, (2) Challenges for Laboratories, (3) Direct to Consumer Marketing of Testing, and (4) Education and Outreach. Each session will consist of approximately 2 hours of public presentations focused on the session topic followed by an expert panel discussion and a question-and-answer period. This public meeting agenda will be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*.

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. A link to the transcripts will also be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* approximately 45 days after the meeting. The transcript may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: June 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–14654 Filed 6–16–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; 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: Council on Graduate Medical Education (COGME).

Dates and Times: July 13, 2010, 12 p.m.–2 p.m. EST.

Place: This meeting will be held via conference call. The access information for the call is:

1–866–646–2286, and the Participant Passcode is: 3379871.

Status: The meeting will be open to the public.

Agenda: On July 13, the meeting will be called to order with remarks from the COGME Chair. The Council members will review the draft version of the 20th COGME report entitled, "Advancing Primary Care." The draft report was sent to select organizations for feedback. The purpose of this call is to discuss the comments offered. The Council members may vote to finalize the report.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Anyone interested in obtaining a roster of members or other relevant information should write or contact Jerald M. Katzoff, Executive Secretary, COGME, Division of Medicine and Dentistry, Bureau of Health Professions, Parklawn Building, Room 9A–27, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–4443. The Web address for information on the Council is: *http://cogme.gov*.

Dated: June 10, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–14562 Filed 6–16–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0004]
FDA 225–09–0012

Memorandum of Understanding Between the Food and Drug Administration and Drugs.Com; Correction of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is providing