(OCRA), Attention to Detail, 5319 University Dr., suite 641, Irvine, CA 92612, Voice: 949–387–9046, FAX: 949–387–9047, Web site: *www.ocra-dg.org*.

Registration and Meeting Information: See OCRA's Web site at *www.ocra-dg.org*. Contact Attention to Detail at 949–387–9046.

Registrations fees are as follows: $725.00 for members, $775.00 for non-members, and $475.00 for FDA/Government/Students. OCRA student rate applies to those individuals enrolled in a regulatory or quality related academic program at an accredited institution. Proof of enrollment is required.

The registration fee will cover actual expenses including refreshments, lunch, materials, parking, and speaker expenses.

If you need special accommodations due to a disability, please contact Linda Hartley (see *Contact*) at least 10 days in advance.

Dated: May 20, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–12615 Filed 5–25–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0237]

Identifying Unmet Public Health Needs and Facilitating Innovation in Medical Device Development; Notice of Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Identifying Unmet Public Health Needs and Facilitating Innovation in Medical Device Development." The purpose of the workshop is to obtain public input on what are the most important unmet public health needs and what are the barriers to the development of medical devices that can cure, significantly improve, or prevent these illnesses and injuries.

Dates and Times: This workshop will be held on June 24, 2010, from 8 a.m. to 5 p.m. Persons interested in attending the meeting must register by 5 p.m. on June 10, 2010. Submit electronic or written comments by July 23, 2010.

Location: The public workshop will be held at Hilton Washington DC/North Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Melanie Fleming, Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5407, Silver Spring, MD 20993, 301–796–5424, FAX: 301–847–8510, *melanie.fleming@fda.hhs.gov*.

Registration and Requests for Oral Presentations: Interested persons may register at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list). Registrants must provide the following information: (1) name, (2) title, (3) company or organization (if applicable), (4) mailing address, (5) telephone number, and (6) e-mail address. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you wish to make an oral presentation during any of the open comment sessions at the meeting (see section II of this document), you must indicate this at the time of registration. FDA requests that presentations focus on the areas defined in section III of this document. You should also identify which discussion topic you wish to address in your presentation and you must submit a brief statement that describes your experience and/or expertise relevant to your proposed presentation. In order to keep each open session focused on the discussion topic at hand, each oral presentation should address only one discussion topic. FDA will do its best to accommodate requests to speak.

If you need special accommodations due to a disability, please contact Melanie Fleming (see *Contact Person*) at least 7 days in advance.

Comments: FDA is holding this public workshop to obtain information on a number of specific questions regarding unmet public health needs and steps the Federal Government can take to reduce barriers to the development of medical devices that can cure, significantly improve, or prevent these illnesses and injuries. The deadline for submitting comments regarding this public workshop is July 23, 2010.

Regardless of attendance at the public workshop, 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 comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section III of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's Center for Devices and Radiological Health (CDRH) has undertaken an initiative to proactively facilitate medical device innovation to address unmet public health needs defined as illnesses and injuries that meet the following criteria: (1) Are serious or have moderate adverse impact on health, but affect many individuals; (2) could be cured, significantly improved, or prevented by the development or redesign of a device; and (3) the device(s) is not being developed or redesigned due to barriers that the Federal Government can directly or indirectly remove or minimize, where those barriers are out of proportion to what is warranted based on the public health needs.

Medical device development and/or redesign is responsible for significant public health benefits, including the prevention, treatment, diagnosis, and monitoring of serious or life-threatening diseases and improved quality of life. However, unnecessary barriers to market may exist either due to market failures or regulatory inefficiencies. For example, payment practices can affect financial incentives for manufacturers to develop a new or improved technology. A predictable and consistent regulatory pathway can encourage would-be innovators to invest in the development of an innovative device.

As part of this initiative, CDRH established a Council on Medical Device Innovation composed of participants from federal agencies. Agencies represented include the National Institutes of Health, the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, the Agency for Healthcare Research and Quality, the Department of Defense, the Defense Advanced Research Projects Agency, and the Department of Veterans Affairs. The purpose of the Council is to identify the most important unmet public health needs, the barriers to innovative medical device development or redesign that could address those needs, and actions the Federal Government can

take to reduce those barriers while assuring the safety, effectiveness, and quality of medical devices marketed in the United States.

The Council seeks input from a wide range of constituencies to include but not be limited to industry, academia, patient/consumer advocacy groups, professional organizations, and other State and Federal bodies under aligned public health missions, to address the issues outlined in this document.

During the public workshop, there will be an open dialogue between Federal Government Council members and experts from the private and public sectors regarding the topics described in this document. Workshop participants will not be expected to develop consensus recommendations, but rather to provide their perspectives on priority areas in which medical device innovations can have the highest positive impact on public health. Participants will also be encouraged to comment on devices not being developed or redesigned due to barriers that the Federal Government can and should directly or indirectly remove or minimize.

Additional information on the public workshop, including an agenda, will be made available in advance of June 24, 2010, at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list).

II. Public Participation

If you wish to make an oral presentation during the public workshop, you must indicate this at the time of registration. There are two types of opportunities for participation planned for the public workshop. In one, formal presentations will address one of the two topics (see section III of this document) that will be limited to 15 minutes and require submission of the presentation in advance of the meeting. The other will be time-limited, based on the number of requests, as part of the public comment period. When registering, you will be required to identify the title of the topic you wish to address in your presentation and answer all the related questions on the web registration form. FDA will do its best to accommodate requests to present and will focus discussions to the topics described in this document (see section III of this document). Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for joint presentations. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is to begin.

III. Issues for Discussion

The workshop will focus on three topics: (1) Identification of the most important unmet public health needs; (2) delineation of the barriers to the development, redesign, and patient and healthcare professional access to medical devices that can cure, significantly improve, or prevent these illnesses or injuries; and (3) identification of the actions the Federal Government can take to remove or minimize these barriers. The discussion of these general topics should not be limited by current statutes or regulations and will include, but not be limited to, discussion of the following questions:

1. Identifying areas of public health need:

a. Which unmet public health needs could be most effectively addressed by the development of new, or the redesign of existing, medical devices?

b. How should the Council set priorities amongst the identified public health needs? Are there specific factors that should be considered? If so, which and why?

2. Addressing barriers to development and/or redesign of medical devices:

a. What are the significant barriers facing innovators, academics, and/or industry that limit the availability and clinical use of medical devices that have the potential to improve public health?

b. How should any perceived or actual barriers be evaluated to determine whether federal intervention is appropriate?

c. How should federal agencies—including those present and others not represented—address those barriers that are out of proportion to what is warranted based on the public health needs?

IV. Transcripts

Please be advised that as soon as a transcript is available, it can be obtained 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. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list).

Dated: May 20, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–12588 Filed 5–25–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Surveillance, Natural History, Quality of Care and Outcomes of Diabetes Mellitus with Onset in Childhood and Adolescence, RFA DP 10–001, Initial Review

Correction: This notice was published in the **Federal Register** on March 22, 2010, volume 75, Number 54, Page 13560. The Place and time should read as follows:

Time and Date: 8:30 a.m.–6 p.m., June 15, 2010 (Closed).

Place: W Hotel, 3377 Peachtree Road, NE., Atlanta, GA 30326, Telephone: 678–500–3100.

Contact Person for More Information: Donald Blackman, Ph.D., Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, Office of the Director, Extramural Research Program Office, 4770 Buford Highway, NE., Mailstop K–92, Atlanta, GA 30341, Telephone: (770) 488–3023, E-mail: *DBY7@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 20, 2010.

Andre Tyler,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010–12627 Filed 5–25–10; 8:45 am]

BILLING CODE 4163–18–P

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

AGENCY: Food and Drug Administration, HHS.