violation of the requirements of the Agreement or other good cause shown. The termination shall not be effective earlier than 30 days after the date of notice to the Manufacturer of such termination.

(c) The Secretary shall provide, upon request, a Manufacturer a hearing with a hearing officer concerning such termination if requested in writing within 15 days of receiving notice of the termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate. If the Manufacturer receives an unfavorable decision from the hearing officer, the Manufacturer may request review by the CMS Administrator. The decision of the CMS Administrator is final and binding.

(d) The Manufacturer may terminate this Agreement for any reason. Any such termination shall be effective as of the day after the end of the plan year if the termination occurs before January 30 of a plan year or as of the day after the end of the succeeding plan year if the termination occurs on or after January 30 of a plan year.

(e) Any termination shall not affect applicable discounts for applicable drugs of the Manufacturer that were incurred under the Agreement before the effective date of its termination.

(f) Manufacturer reinstatement will be available only upon payment of any and all outstanding applicable discounts incurred during any previous period of the Agreement. The timing of any such reinstatements will be consistent with the requirements for entering into an Agreement under section 1860D–14A(b)(1)(C) of the Act.

VIII. General Provisions

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

1. Notice to the Secretary will be sent to: Center for Medicare, Division of Pharmaceutical Manufacturer Management, Mailstop C1–26–16, 7500 Security Boulevard, Baltimore, MD 21244–1850.

2. The CMS address may be updated upon written notice to the Manufacturer.

3. Notices to the Manufacturer will be sent to the address as provided with this Agreement and updated upon Manufacturer notification to CMS at the address in this Agreement.

(b) In the event of a transfer in ownership of the Manufacturer or product, this Agreement is automatically assigned to the new owner, and all terms and conditions of this Agreement remain in effect.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law with competent jurisdiction, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, other Federal laws, or State laws.

(e) This Agreement shall be construed in accordance with Federal law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(f) The terms "Medicare" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the Agreement unless specifically provided for in this Agreement or specifically agreed to by an appropriate CMS official in accordance with paragraph (g) of this section.

(g) Except for the conditions specified in section VIII.(a) of this Agreement, this Agreement once finalized, will not be altered by the parties.

(h) Nothing in this Agreement shall be construed as requiring coverage under Part D of a Manufacturer's product if that product does not otherwise meet the definition of a covered Part D drug under 42 CFR 423.100.

IX. Signatures

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____

(please print name)

_____

(signature)

Title: _____

Date: _____

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments or other changes to this Coverage Gap Discount Program Agreement.

By: _____

(please print name)

_____

(signature)

Title: _____

Name of Manufacturer: _____

Manufacturer's Mailing Address: _____

Manufacturer's E-mail Address: _____

Manufacturer labeler Code(s): _____

Date: _____

Authority: Section 3301 of the Patient Protection Affordable Care Act and section 1101 of the Health Care and Education Reconciliation Act of 2010 (Sections 1860D–43 and 1860D–14A of the Social Security Act) Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: May 13, 2010.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 20, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–12559 Filed 5–21–10; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

The 13th Annual Food and Drug Administration-Orange County Regulatory Affairs Educational Conference in Irvine, California: "Regulatory Affairs: The Business of Regulatory Affairs"

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of conference.

The Food and Drug Administration (FDA) is announcing the following conference: 13th Annual Educational Conference co-sponsored with the Orange County Regulatory Affairs Discussion Group (OCRA). The conference is intended to provide the drug, device, biologics and dietary supplement industries with an opportunity to interact with FDA reviewers and compliance officers from the centers and District Offices, as well as other industry experts. The main focus of this interactive conference will be product approval, compliance, and risk management in the four medical product areas. Industry speakers, interactive Q & A, and workshop sessions will also be included to assure open exchange and dialogue on the relevant regulatory issues.

Date and Time: The conference will be held on June 16 and 17, 2010, from 7:30 a.m. to 5 p.m.

Location: The conference will be held at the Irvine Marriott, 18000 Von Karman Ave., Irvine, CA 92612.

Contact: Linda Hartley, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612, Voice: 949–608–4413, FAX: 949–608–4417; or Orange County Regulatory Affairs Discussion Group

(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