the agency does not consider a reference tablet-based procedure such as a PVT to be a critical component when the enhanced MC procedures recommended in the agency guidance are followed.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on a new process for making available to sponsors FDA guidance on how to design product-specific bioequivalence studies to support ANDAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: January 21, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–1517 Filed 1–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Task Force on Community Preventive Services

Name: Task Force on Community Preventive Services meeting.

Times and Dates: 8 a.m.–5:30 p.m. EST, February 17, 2010; 8 a.m.–1 p.m. EST, February 18, 2010.

Place: Centers for Disease Control and Prevention, 2500 Century Parkway, Atlanta, Georgia 30345.

Status: Open to the public, limited only by space available.

Purpose: The mission of the Task Force is to develop and publish the *Guide to Community Preventive Services (Community Guide),* which is based on the best available scientific evidence and current expertise regarding essential public health and what works in the delivery of those services.

Matters To Be Discussed: Updates of reviews of interventions to increase screening for breast, cervical and colorectal cancer, interventions to increase vaccination rates, and interventions to increase physical activity; reviews of effectiveness of collaborative care for the management of depressive disorders and of interventions to reduce the overservice of alcohol; and the scope of reviews of interventions to reduce inequalities in health outcomes.

Agenda items are subject to change as priorities dictate.

Contact person or additional information: Nasheka Powell, Community Guide Branch, Centers for Disease Control and Prevention, 1600 Clifton Road, M/S E–69, Atlanta, GA 30333, phone: 404.498.1123.

Dated: January 20, 2010.

Tanja Popovic,

Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–1569 Filed 1–26–10; 8:45 a.m.]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of National Conversation on Public Health and Chemical Exposures Leadership Council Conference Call

Time and Date: 1 p.m.–3 p.m., Friday, January 29, 2010.

Location: Teleconference.

Status: The public is invited to listen to the meeting by phone, see "contact for additional information" below.

Purpose: This is the second meeting of the National Conversation on Public Health and Chemical Exposures Leadership Council. The National Conversation on Public Health and Chemical Exposures is a collaborative initiative through which many organizations and individuals are helping develop an action agenda for strengthening the nation's approach to protecting the public's health from harmful chemical exposures. The Leadership Council provides overall guidance to the National Conversation project and will be responsible for issuing the final action agenda. For additional information on the National Conversation on Public Health and Chemical Exposures, visit this Web site: *http://www.atsdr.cdc.gov/nationalconversation/.*

Meeting agenda: The call will include discussing (1) Revised project milestones and process elements, (2) revised National Conversation Operating Procedures, (3) the Policies and Practices work group charge, and (4) plans for developing and utilizing a community conversation toolkit on the issue of public health and chemical exposures.

Contact for additional information: If you would like to receive additional information on listening to the meeting by phone, please contact: *nationalconversation@cdc.gov* or Ben Gerhardstein at 770–488–3646.

Dated: January 19, 2010.

Tanja Popovic,

Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–1571 Filed 1–26–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0054]

Strengthening the Center for Devices and Radiological Health's 510(k) Review Process; 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) is announcing a public meeting entitled "Strengthening the Center for Devices and Radiological Health's 510(k) Review Process." The purpose of the public meeting is to identify actions that the Center for Devices and Radiological Health (CDRH) can consider taking to strengthen the premarket notification process for review of medical devices, also known as the 510(k) process. FDA is seeking input on a number of identified challenges associated with the 510(k) process and is requesting comments on this topic.

Dates and Time: The public meeting will be held on February 18, 2010, from 8 a.m. to 5:30 p.m. Persons interested in attending and/or participating in the meeting must register by 5 p.m. on

February 12, 2010. Submit electronic or written comments by March 5, 2010.

Location: The public meeting will be held at the Hilton Washington DC North/ Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877. A live webcast of this meeting will be viewable on the day of the meeting at *http://www.ConnectLive.com/events/fda021810*. Closed captioning for this webcast will be available at *http://www.speche.com/sbload.aspx?Load=Web,All,New&Height=90%25&Width=100%25&ClientID=31213*.

Contact Person: James Swink, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 1609, Silver Spring, MD 20993, 301–796–6313, e-mail: *james.swink@fda.hhs.gov*.

Registration: If you wish to attend the public meeting, you must register online at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list). Provide complete contact information for each attendee, including: Name, title, affiliation, address, e-mail, and telephone number. Registration requests should be received by February 12, 2010.

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 has included general discussion topics and specific questions for comment in section III of this document. You should also identify which discussion topic you wish to address in your 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. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is to begin.

If you would like to participate in the planned end-of-day round-table discussion (see section II of this document), you must indicate this at the time of registration, and also submit a brief statement that describes your experience with the 510(k) program. FDA is seeking participants interested in engaging in an end-of-day round-table discussion reflecting on the presentations given earlier in the day. The round-table discussion will include no more than 10 non-FDA participants. Only one participant from an organization or company will be assigned to the discussion group. FDA will attempt to have a range of constituencies participate in the discussion group. Others in attendance at the public meeting will have an opportunity to listen to the discussion.

Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public meeting will be provided on a space-available basis beginning at 7 a.m.

If you need special accommodations due to a disability, please contact James Swink at 301–796–5610, *james.swink@fda.hhs.gov* at least 7 days in advance of the public meeting.

Comments: FDA is holding this public meeting to obtain information on a number of questions regarding the 510(k) process. The deadline for submitting comments related to this public meeting is March 5, 2010.

Regardless of attendance at the public meeting, interested persons may submit electronic or written comments. Submit electronic comments to *http://www.regulations.gov*. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined below, 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

The premarket notification (or 510(k)) process for the review of medical devices was established under the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act (act). A post-MDA device may be legally marketed without an approved premarket approval application (PMA) if FDA concludes, through review of a 510(k) submission (unless the device is exempt from this submission requirement), that the device meets the comparative standard of "substantial equivalence" to a "predicate" device. By regulation, substantial equivalence may be determined by a comparison to a device that was legally marketed prior to May 28, 1976 (a pre-amendments device), or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process. (21 CFR 807.92(a)(3)).

Congress enacted the Safe Medical Devices Act of 1990 (SMDA) to define "substantial equivalence" consistent with the agency's administration of the 510(k) program. "Substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the FDA by order has found the device either has the same technological characteristics as the predicate device, or has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the FDA, that demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than the predicate device. (Section 513(i)(1)(A) of the act (21 U.S.C. 360c(i)(1)(A))).

The current 510(k) program reflects the statutory framework and FDA's implementation of that framework. It is intended to meet two important public health goals: To make available to consumers devices that are safe and effective, and to promote innovation in the medical device industry. The 510(k) premarket notification process provides a mechanism for the classification of a device that is found to be substantially equivalent to a predicate device that does not require premarket approval. Over the past several years, concerns have been raised about whether the 510(k) program optimally achieves its intended goals.

In light of these concerns, FDA commissioned the Institute of Medicine (IOM) to conduct an independent review of the program and, if necessary, to recommend administrative, regulatory, and/or statutory changes. Given that the IOM study is not expected to conclude until March 2011, CDRH has also convened an internal 510(k) Working Group to recommend possible actions that CDRH could take in the short term to strengthen the program, and to identify longer term

options FDA could consider to strengthen the program.

II. Public Meeting

The objective of this public meeting is to receive public input on key challenges related to the 510(k) program, focusing on the following four areas: (1) Issues related to predicate devices, (2) issues related to new technologies and scientific evidence, (3) issues related to practices CDRH has adopted in response to a high volume of 510(k)submissions, and (4) issues related to postmarket surveillance and new information about marketed devices.

During the meeting, FDA staff will present a brief overview of each of the areas of challenge listed previously. Each of the four FDA presentations will be followed by an open comment session, during which members of the public may present oral comments related to the topic under discussion. Specific questions related to each discussion topic are listed below (see section III of this document). As described previously, individuals who are interested in making an oral presentation during any of the open comment sessions must indicate this at the time of registration and must also identify which discussion topic they intend to address (see the *Registration* section of this document). In order to keep each open session focused on the discussion topic at hand, each oral presentation should address only one discussion topic. Commentators are free to submit written comments on any discussion topic(s) to the open docket (see the *Comment* section of this document). FDA will schedule speakers for each open session as time permits.

After the four open comment sessions, the meeting will close with a round-table discussion between FDA staff and selected participants representing a range of constituencies (for more information about participating in the round-table discussion, see the *Registration* section of this document). The participants in the round-table discussion will reflect on the day's presentations, engage in a dialogue with each other and FDA staff, and provide closing thoughts. The participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives. Others in attendance at the meeting will have an opportunity to listen to the round-table discussion.

In advance of the meeting, additional information, including a meeting agenda with a speakers' schedule for each open comment session, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at *http://www.regulations.gov*. This information will also be available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list).

III. Issues for Discussion

The discussion of the four general topics described in the following section of this document should not be limited by current statutes or regulations, as the recommendations the 510(k) Working Group develops may include recommendations for changes to current law.

A. Issues Related to Predicate Devices

1. FDA maintains a searchable online database to provide interested parties, including prospective 510(k) submitters, with information about devices that have been cleared for marketing through the 510(k) process. Currently, if a device has been cleared, CDRH's Office of Device Evaluation (ODE) and Office of In-Vitro Diagnostics (OIVD) post online FDA's "Substantially Equivalent" (SE) letter to the 510(k) submitter with the Indications for Use page for the device, as well as the 510(k) Summary (written by the 510(k) submitter) or the 510(k) Statement for the 510(k) (as specified by 21 CFR 807.93) (see 21 CFR 807.87(h)). OIVD also posts a "decision summary" (written by FDA reviewers) which includes a summary of submitted data and a comparison of the device to the predicate(s). With respect to the information described previously, please comment on the following:

a. How effective is the 510(k) database and search engine in helping prospective submitters find and evaluate the adequacy of predicate devices for 510(k) submissions, and write substantial equivalency rationales? What aspects of the database and search engine are useful? What could be improved? What, if anything, should be added to the 510(k) database and search engine?

b. How effectively do the publicly released documents listed previously describe the cleared indications for use of each device, the technological characteristics of the device, and the methods and type of information that were used to determine substantial equivalence to the device's predicate(s)? If these documents are not sufficient, please describe what additional information or documentation would be useful to interested parties.

c. Should FDA require 510(k) holders who receive a substantial equivalence decision for their device to submit a redacted version of their 510(k) submission after clearance, for public release? Please explain why or why not.

2. Some 510(k) submitters do not accurately portray the similarities and differences between the device under review and the predicate device(s). It is unclear whether this problem is due to the submitters' lacking complete information about devices that have been cleared previously and may be used as predicates, or whether there are other contributing factors. Please comment on this problem and what steps FDA should take to address it.

3. Generally, a device that has a clearance under the 510(k) process may be used as a predicate, regardless of whether or not the device is still in use, remains relevant to current standards of care, or has been replaced by new technology. Please comment on the utility of this generally inclusive strategy and its positive or negative impact on achieving the two public health goals of the 510(k) program. Should there be stricter criteria for what predicate devices are eligible for use in new 510(k) submissions? If so, what criteria should be used, and how should those criteria be defined so that they can be consistently and effectively applied? Where possible, please also provide specific examples of cases in which the use of an "outdated" predicate device may have been beneficial or problematic.

4. Incremental device changes may seem innocuous individually (i.e., in one 510(k) submission), but over time such changes may accumulate to create a device that is significantly different from the original device (referred to as "predicate creep"). Similarly, clinical non-inferiority studies may be submitted as evidence of substantial equivalence between a device under review and a predicate. When a series of such studies is conducted over time (i.e., device B is non-inferior to A, device C is non-inferior to B, and device D is non-inferior to C), the difference in effectiveness between device A and D may approach clinical significance (referred to as "non-inferiority creep"). Please comment on what if any changes should be made to the 510(k) program based on the occurrence of predicate creep and non-inferiority creep. Are there circumstances under which FDA should consider a more thorough review of multiple incremental device changes between 510(k) submissions, or a more thorough review of the appropriateness of clinical non-inferiority studies when

assessing differences in device safety and effectiveness? Please explain.

5. In some cases, more than one predicate device has been submitted by the 510(k) submitter in its evaluation of substantial equivalence. For example, if there is not a single predicate device that has the same indication for use and technological characteristics as the device under review, a submitter may cite one predicate device in an effort to demonstrate the same intended use, and a different predicate device in an effort to demonstrate the same technological characteristics. The use of more than one predicate in this manner, in an effort to demonstrate substantial equivalence, has been referred to as using a "split predicate." When a submitter uses a split predicate, the "new" device may be very different from any other device on the market. In other instances, a submitter has used more than one predicate device in the hope that each predicate individually (not combined with the other predicate) supports substantial equivalence. Please comment on whether the use of a split predicate or more than one predicate serves the public health goals of the 510(k) program. If possible, please include examples.

6. To find that a device is substantially equivalent, FDA must determine, among other things, whether or not a new device has the same "intended use" as the predicate device (Section 513(i) of the act). FDA uses a standardized series of questions, organized into a flowchart (available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM081395.pdf*), to guide all 510(k) reviews. Currently, the flowchart distinguishes between an "indication for use" and an "intended use": A device under review may have a different "indication for use" than the predicate, yet still be determined to have the same "intended use" and therefore may be found substantially equivalent.

a. Please describe your understanding of an "indication for use" as compared to an "intended use." Please describe what criteria, if any, FDA should use to determine whether or not to consider a different "indication for use" to be a different "intended use." Please provide examples of different "indications for use" that you believe should or should not be considered different "intended uses" and explain your reasoning.

b. What are the advantages and disadvantages of distinguishing between the terms "indication for use" and "intended use" during the review process? What are the advantages and disadvantages of combining these concepts into one term?

B. Issues Related to New Technologies and Scientific Evidence

1. Section 513(i) of the act defines the term "different technological characteristics" as "a significant change in the materials, design, energy source, or other features of the device from those of the predicate device." Without regard to the statutory definition, what "other features" should FDA consider (or not consider) to be "different technological characteristics"? If you do not believe any other features should be considered different technological characteristics, please state why.

2. When a 510(k) submitter receives a Not Substantially Equivalent (NSE) determination from FDA, the submitter may petition FDA, if this type of device has not been approved through the PMA process, to classify this new type of device through the Evaluation of Automatic Class III Designation (or de novo) process. FDA may classify such a device as Class I is if the device type is generally of low risk and general controls are determined to be adequate to provide reasonable assurance of safety and effectiveness, or as Class II if special controls can be developed and are adequate, along with general controls, to provide reasonable assurance of safety and effectiveness for the device type. What criteria should FDA use to determine which risks can be mitigated through general controls alone or with special controls, and which risks are sufficient to make the device ineligible for de novo classification?

3. If a device under review has "different technological characteristics" than the predicate(s), it may still be determined to be substantially equivalent if "the information submitted that the device is substantially equivalent to the predicate contains information, including appropriate clinical or scientific data if deemed necessary by the [FDA] * * *, that demonstrates the device is as safe and effective as a legally marketed device and (II) [the device under review] does not raise different questions of safety and effectiveness than the predicate device" (section 513(i) of the act). How should FDA identify and characterize the risks associated with a new technology that do not raise "different questions of safety and effectiveness?" Are there types of new technology that should not be considered appropriate to be cleared for market through the 510(k) process? Should FDA define "different questions of safety and effectiveness?" If so, please provide suggestions for such a definition.

4. In some circumstances, FDA may consider data from one of the following four types of comparison studies, or a combination of any of them, to determine whether a new device is substantially equivalent to a predicate device: (1) A comparison of specifications to an FDA-recognized standard; (2) a comparison of specifications through bench testing; (3) a comparison of specifications through bench and animal or bench and clinical testing; or (4) a comparison of specifications through bench, animal, and clinical testing.

a. For each particular type of comparison, describe when the comparison is appropriate for a new device.

b. When clinical testing is deemed necessary, such testing is often used to determine whether a device is at least as safe and effective as the predicate (i.e., no worse than the predicate by a small, clinically insignificant difference called the non-inferiority margin). If the device is not expected to perform any better than the predicate, then a large sample size may be necessary to show non-inferiority in accordance with the small margin. By contrast, clinical studies conducted to demonstrate superiority to a control, instead of non-inferiority to a predicate, may require a relatively small sample size. Considering that devices under the 510(k) program may represent relatively minor changes compared with a predicate, are there circumstances under which one could show that a device is at least as safe and effective as the predicate without the need to conduct a large non-inferiority study? Please explain.

c. The previous comparisons in (2), (3), and (4) each require some type of testing. Under what circumstances should such testing be performed on the new device alone, and under what circumstances should such testing be performed on the new device in addition to a predicate device as a concurrent comparison? Are there circumstances when a clinical study that does not use the predicate device as the comparator (e.g., uses a standard of care or a reference method instead) would be appropriate to evaluate substantial equivalence? Please explain.

5. Some 510(k) submitters do not always initially provide sufficient engineering and design information for their devices under review, to enable FDA to have a sufficient understanding of how the device operates, and whether there are any design issues that would prevent it from operating as intended. Has FDA established sufficiently clear

guidelines concerning the provision of such information in 510(k) submissions? If not, what additional guidance might be helpful?

6. Section 513(f)(5) of the act (21 U.S.C. 360c(f)(5)) states that FDA may not withhold an initial classification determination based on "a failure to comply with any provision of the act unrelated to a substantial equivalence decision," including current good manufacturing practice (cGMP) requirements, unless there is a substantial likelihood that such failure will potentially present a serious risk to human health. Would it be beneficial for FDA to have greater authority to withhold an initial classification determination based on a failure to comply with cGMP requirements or other provisions of the act? Please explain.

7. Currently, some 510(k) submissions include as the "indication for use" a device function that is not associated with a specific clinical utility (e.g., treatment or diagnosis of a specific condition).

a. For new devices, should a requirement of the 510(k) program be that a device's "indication for use" be proven to FDA to provide clinical utility?

b. Please provide examples of devices whose "indications for use" statements do not describe a clinical utility, and whether this may be beneficial, harmful, or neither. Examples may include devices that are capable of monitoring or measuring a new physiologic parameter that has no standard clinical context, or tool-type devices such as scalpels or lasers that may be cleared to cut and coagulate tissue.

8. How effective is FDA's current implementation of section 513(i)(1)(E) of the act with respect to curbing off-label use that could cause harm? The current implementation is described in "Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff (Update to K98–1)" which is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082162htm*. Without regard to current law, should FDA consider modifying its approach? Please explain why or why not. If FDA should consider modifying its approach, how should FDA modify it?

C. Issues Related to Practices CDRH has Adopted in Response to a High Volume of 510(k) Submissions

FDA receives a very large number of 510(k) submissions each year. In response to this high volume of work, CDRH has adopted a number of practices to allow for less resource-intensive reviews, including the third party review program, the Special 510(k) under the 510(k) Paradigm, bundling of devices in 510(k) submissions, and reliance on 510(k) submitters' assertions of conformance to recognized standards (as in the Abbreviated 510(k) program). Due to resource constraints, CDRH often must rely on a single reviewer to assess each 510(k) submission. Please comment on the advantages and disadvantages of each of these practices, as related to the quality and timeliness of 510(k) reviews.

D. Issues Related to Postmarket Surveillance and New Information about Marketed Devices

1. FDA generally does not require postmarket surveillance studies as a condition of medical device 510(k) clearance. Without regard to current law, please comment on whether or not it might be beneficial for FDA to impose such studies as a condition of medical device 510(k) clearance.

2. Without regard to current law, should FDA allow for the rescission of 510(k) clearance decisions under a broad range of circumstances? If so, what specific criteria might justify the rescission of a 510(k) clearance decision?

3. FDA obtains a significant amount of postmarket information for 510(k)-cleared devices, including adverse event reports, recalls, and inspectional findings. Without regard to current law, should such information influence the premarket 510(k) review of similar devices? If so, how?

4. FDA regulations require the submission of proposed labeling (including indications for use, directions for use, precautions, warnings, and contraindications) in a 510(k) prior to clearance of a device. However, 510(k) holders sometimes alter the labeling after clearance, so that the final printed labeling is different from that submitted to FDA in the 510(k). Please comment on whether or not it might be beneficial for FDA to review and clear the final printed labeling for all 510(k) devices or for selected 510(k) devices prior to marketing.

5. FDA does not always know when there has been a purchase, sale, or transfer of ownership of a 510(k) for a particular device. Even though the new owner of the 510(k) is required to register and list, FDA may not be aware that the ownership of the 510(k) for the device has legally transferred. Should FDA exercise more authority in this area? If so, how?

IV. Transcripts

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public meeting at a cost of 10 cents per page. A transcript of the public meeting will be available on the Internet at *http://www.regulations.gov*.

Dated: January 22, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–1620 Filed 1–22–10; 4:15 pm]

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: Occupational Safety and Health Training Projects Grants, Request for Applications (RFA) 06–484; and Occupational Safety and Health Educational Research Centers, RFA 06–485, Initial Review

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Times and Dates:

8:30 a.m.–5 p.m., February 18, 2010 (Closed).
8:30 a.m.–5 p.m., February 19, 2010 (Closed).

Place: Marina Del Ray Marriott, 4100 Admiralty Way, Marina Del Ray, California 90292, Telephone (310) 301–3000.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the initial review, discussion, and evaluation of "Occupational Safety and Health Training Projects Grants, RFA 06–484; and Occupational Safety and Health Educational Research Centers, RFA 06–485."

There were site visits conducted at the University of California, Berkeley and San Francisco, October 12–14, 2009; the University of Massachusetts, Lowell, October 21, 2009; the University of West Virginia, October 27, 2009; the University of Colorado, November 2–4, 2009; the University of Minnesota, November 18–20, 2009; and the University of Washington, December 16–18, 2009 to advise and make recommendations to the Disease, Disability, and Injury Prevention and Control SEP: Occupational Safety and Health Training Projects Grants, RFA 06–484; Occupational Safety and Health Educational Research Centers, RFA 06–485.