

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Special Interest Project (SIP): Assessing the Pregnancy Prevention Needs of HIV-Infected Young Women of Reproductive Age and Effects of Contraception, SIP12-064, Panel G, 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:

Time and Date: 9:00 a.m.–12:30 p.m., July 26, 2012 (Closed).

Place: Teleconference.

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 applications received in response to “Assessing the Pregnancy Prevention Needs of HIV-Infected Young Women of Reproductive Age and Effects of Contraception, SIP12-064, Panel G, initial review.”

Contact Person for More Information: M. Chris Langub, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F-46, Atlanta, Georgia 30341, Telephone: (770) 488-3583.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 22, 2012.

Elaine L. Baker,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0503]

Guidances for Industry and Food and Drug Administration Staff: Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Notification (510(k)) Submissions; and Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Approval and Premarket Notification (510(k)) Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two related guidance documents. The first guidance, entitled “Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Notification (510(k)) Submissions” (CADe 510(k) guidance), provides recommendations regarding premarket notification (510(k)) submissions of certain computer-assisted detection (CADe)¹ devices applied to radiology images and radiology device data. The second guidance, entitled “Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Approval (PMA) and Premarket Notification (510(k)) Submissions” (CADe clinical performance assessment guidance), provides recommendations on the design and conduct of clinical performance studies for CADe devices applied to radiology images and radiology device data.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Notification (510(k)) Submissions” or

¹ The use of the acronym CADe for computer-assisted detection may not be a generally recognized acronym in the community at large. It is used here to identify the specific type of devices discussed in this document.

the guidance document entitled “Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Approval (PMA) and Premarket Notification (510(k)) Submissions” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to these guidances.

Submit electronic comments on the guidances to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nicholas Petrick, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, rm. 4118, Silver Spring, MD 20993, 301-796-2563, and Mary Pastel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G310, Silver Spring, MD 20993, 301-796-6887.

SUPPLEMENTARY INFORMATION:

I. Background

CADe devices are computerized systems that incorporate pattern recognition and data analysis capabilities (*i.e.*, combine values, measurements, or features extracted from the patient radiological data) intended to identify, mark, highlight, or in any other manner direct attention to portions of an image, or aspects of radiology device data, that may reveal abnormalities during interpretation of patient radiology images or patient radiology device data by the intended user (*i.e.*, a physician or other health care professional).

The CADe 510(k) guidance provides recommendations on documentation and performance testing to be part of a 510(k) submission for class II CADe devices applied to radiology images and radiology device data. The CADe clinical performance assessment guidance provides recommendations regarding clinical performance studies