DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS)

Notice of Cancellation: This notice was published in the Federal Register on December 23, 2015, Volume 80, Number 246, pages 79899–79900. The meeting previously scheduled to convene on January 21–22, 2016, has been cancelled.

Contact Person for More Information: Virginia S. Cain, Ph.D., Director of Extramural Research, NCHS/CDC, 3311 Toledo Road, Room 7208, Hyattsville, Maryland 20782, Telephone (301) 458–4395, Fax (301) 458–4020, Email: vcain@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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

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

Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices”. FDA is issuing this draft guidance to assist industry and FDA staff in identifying specific considerations related to the ability of electronic medical devices to safely and effectively exchange and use exchanged information. This document highlights considerations that should be included in the development and design of interoperable medical devices and provides recommendations for the content of premarket submissions and labeling for such devices. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 28, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions
Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions
Submit written/paper submissions as follows:

Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions”.

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