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

Gary Johnson,

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

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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 the Agricultural, Forestry and Fishing Safety and Health Research (U01) PAR–14–175, 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: 12:00 p.m.–4:30 p.m., July 15, 2014 (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 for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Agricultural, Forestry and Fishing Safety and Health Research (U01) PAR–14–175.''

Contact Person for More Information: Joan F. Karr, Ph.D., Scientific Review Officer, CDC/NIOSH, 1600 Clifton Road, Mailstop E–74, Atlanta, Georgia 30333, Telephone: (404) 498–2506.

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.

Gary Johnson,

Acting 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–2014–N–0797]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program.

DATES: Submit either electronic or written comments on the collection of information by August 25, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program—(OMB Control Number 0910–0700)—Extension

Under section 228 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), as amended by section 704(g)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)(7)), the owner or operator of an establishment may submit an audit report that assesses conformance with appropriate quality system standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice.

The ''Guidance for Industry, Third Parties and FDA Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program'' describes how FDA's Center for Devices and Radiological Health and Center for Biologics Evaluation and Research are implementing this provision of the law and providing public notice as required. The proposed collections of information are necessary to satisfy the previously mentioned statutory requirements for implementing this voluntary submission program. The collected information is used for setting risk-based inspectional priorities.

The ''Guidance for Industry, Third Parties, and FDA Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program'' describes how FDA's Center for Devices and