and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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: Jennifer Dickey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5262, Silver Spring, MD 20993–0002, 301–796–5028.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance provides recommendations to assist industry in designing studies to establish the analytical and clinical performance characteristics of radiation biodosimetry medical countermeasure devices.

Radiation biodosimetry countermeasure devices are devices used for the purpose of reconstructing the ionizing radiation dose received by individuals or populations using physiological, chemical or biological markers of exposure found in humans. Radiation biodosimetry technologies may be used at various stages during triage and treatment after the exposure of a population to ionizing radiation as a result of intentional harm or as an unintended consequence of a disaster. Devices may be designed to give quantitative outputs or qualitative information around a clinical decision making cut-point. Likewise, devices may be designed for use in field triage settings, at patient bedsides, or in Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578) certified clinical laboratories. FDA considered both high-throughput and single-use devices in developing this draft guidance document.

This draft guidance only applies to validation of biodosimetry devices intended to be used to assess exposure in non-therapeutic or accidental scenarios (*e.g.* a deliberate attack, such as use of an improvised nuclear device, or a natural disaster). This draft guidance neither applies to devices that assess deliberate radiation dosing that may occur in the course of medical treatment nor to devices that measure effects from long term exposure. In addition, dosimeters, which are devices that detect radiation exposure on a physical substrate rather than through a biological response and are worn by people who might be exposed to radiation during the course of their normal work (such as film badges), are not addressed in this guidance document. Finally, biological assays that might be used to detect the presence of ingested radioisotopes in sputum or urine are not considered in this draft guidance document.

This draft guidance document does not provide specific study designs; it describes design principles for studies that may be used to establish the safety and effectiveness of radiation biodosimetry devices.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on evaluating the performance characteristics of radiation biodosimetry devices. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Radiation Biodosimetry Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400045 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in the guidance document entitled ''Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable'' have been approved under OMB control number 0910–0582; and the collections of information in the guidance document entitled ''Guidance for Industry and FDA Staff: Administrative Procedures for CLIA Categorization'' have been approved under OMB control number 0910–0607.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: December 22, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30453 Filed 12–29–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Science Board to the Food and Drug Administration; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Science Board to the Food and Drug Administration (Science Board).

General Function of the Committee: The Science Board provides advice primarily to the Commissioner of Food and Drugs and other appropriate officials on specific complex scientific and technical issues important to the FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific developments including in regulatory science, input into the Agency's research agenda, on upgrading its scientific and research facilities, and training opportunities. It will also provide, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs.

Date and Time: The meeting will be held on March 4, 2015, from 8:30 a.m. to 4 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503 B and C) Silver Spring, MD 20993–0002. For those unable to attend in person, the meeting will also be Webcast. The link for the Webcast is available at *https://collaboration.fda.gov/sb315/.* Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Martha Monser, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993–0002, 301–796–4627, *martha.monser@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The Science Board will be provided with a progress report or a final draft report the Commissioner's Fellowship Program Evaluation subcommittee and will hear a progress report from Science Moving Forward subcommittee. The Science Board will be asked to provide feedback on FDA's public access policy. FDA will seek the Science Board's input regarding approaches to regulatory science training coordination. The Science Board will be provided with a follow up on FDA's activities regarding the re-introduction of bovine heparin and will hear an overview of science-related activities from one of the centers. A recipient of one of the Fiscal Year 2014 Scientific Achievement Awards (selected by the Science Board) will provide an overview of the activities for which the award was given.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 25, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 17, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 18, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Ms. Martha Monser at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 23, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30516 Filed 12–29–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1936]

Electronic Cigarettes and the Public Health; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Tobacco Products, is announcing a public workshop to obtain information on electronic cigarettes and the public health. This will be the second in a series of three workshops. The workshop will include presentations and panel discussions about the current state of the science and will focus on individual health impacts. FDA intends to follow this workshop with an electronic cigarette workshop on population health effects.

DATES AND TIMES: The public workshop will be held on March 9, 2015, from 8 a.m. to 5 p.m. and on March 10, 2015, from 8 a.m. to 5 p.m. Individuals who wish to attend the public workshop must register by February 20, 2015.

LOCATION: The public workshop will be held at the Marriott Inn and Conference Center, University of Maryland University College, Potomac Ballroom, 3501 University Blvd. East, Hyattsville, MD 20783. The conference center's telephone number is 301–985–7300.

CONTACT PERSON: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm.