Darius Taylor,

Deputy, Information Collection Clearance Officer.

[FR Doc. 2013–12828 Filed 5–29–13; 8:45 am]

BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Food and Drug Administration Safety and Innovation Act (FDASIA): Request for Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology

AGENCY: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The Food and Drug Administration (FDA), Office of the National Coordinator for Health Information Technology (ONC), and Federal Communication Commission (FCC) seek broad input from stakeholders and experts on the elements we should consider as we develop a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework for health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication. To that end, we are requesting comments on the topics identified in Section III.

DATES: This Docket on *regulations.gov* will remain open for public comments until 11:59pm Eastern Time, August 31, 2013.

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health IT, 202–690–7151.

SUPPLEMENTARY INFORMATION:

I. The Food and Drug Administration Safety and Innovation Act Workgroup Under ONC's HIT Policy Committee

Section 618(a) of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 (Pub. L. 112–144) directs the Secretary of the Department of Health and Human Services (HHS), acting through the Commissioner of the Food and Drug Administration (FDA), and in consultation with the HHS Office of the National Coordinator for Health Information Technology (ONC) and the Chairman of the Federal Communications Commission (FCC), to publish a report that will offer a proposed strategy and recommendations for an appropriate risk-based Health IT regulatory framework that would include mobile medical applications and promotes innovation, protects patient safety, and avoids regulatory duplication.

To assist the agencies' efforts in developing this report, the FDA in collaboration with ONC and FCC formed a new workgroup, referred to as the FDASIA Workgroup, under ONC's HIT Policy Committee to help the HIT Policy Committee provide appropriate input and recommendations to FDA, ONC, and FCC as suggested by section 618(b) of FDASIA. Accordingly, the FDASIA Workgroup is charged with providing input on issues relevant to the report FDA, ONC, and FCC will develop, which include:

- Types of risk that may be posed by health IT that impact patient safety, the likelihood that these risks will be realized, and the impact of these considerations on a risk-based approach;
- Factors or approaches that could be included in a risk-based regulatory approach for health IT that also promote innovation and protect patient safety; and
- Approaches to avoid duplicative or overlapping regulatory requirements.

The workgroup's membership includes agency officials and representatives from a wide range of stakeholders, including patients, consumers, health care providers, startup companies, health plans and other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, and employers.

Through this request for comments, FDA, ONC, and FCC would like to provide an opportunity for broad public input on section 618 of FDASIA. Timely submitted written comments will inform the new FDASIA Workgroup's deliberations on the input it will provide to the HIT Policy Committee regarding the report required by section 618 of FDASIA. We seek input on a number of specific topics identified in Section III, but welcome any other pertinent information stakeholders wish to share. *For commenters that wish to have their comments considered by the FDASIA Workgroup, we encourage you to submit your comments as early as possible and preferably before June 30, 2013.*

FDASIA Workgroup In-Person Meeting

On May 30 and 31, 2013, in Washington, DC, the FDASIA Workgroup will hold an in-person meeting which will also be Webcast. Persons interested in attending the in-person meeting or viewing the Webcast can access information about doing so at this URL: *http://www.healthit.gov/policy-researchers-implementers/policy-fdasia-1.*

Interested parties may submit electronic comments to *http://www.regulations.gov*. Submit written comments to Office of the National Coordinator for Health Information Technology, Attention: FDASIA Report Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave. SW., Washington, DC 20201.

II. Background

Health IT is being rapidly adopted by the health care industry and there is a growing need for the Federal government to develop a coordinated approach to its oversight of health IT that promotes innovation, protects patient safety, and avoids regulatory duplication. FDA, FCC, and ONC each have important roles with respect to the development and use of health IT that significantly impacts public health and welfare. Congress recognized the importance of a coordinated regulatory approach and through FDASIA, specifically tasked the FDA, ONC, and FCC with creating a report that includes a proposed strategy and recommendations for an appropriate, risk-based regulatory framework for health IT. To inform the report required by FDASIA, FDA, ONC, and FCC, in addition to receiving input from the HIT Policy Committee, intend to provide multiple opportunities, as appropriate, for input from other stakeholders at different stages throughout the report's development, including, if feasible, feedback on the draft framework prior to finalizing the report.

III. Topics for Discussion

Public comment is sought on any or all of the following topics below.

1. Taxonomy

a. What types of health IT should be addressed by the report developed by FDA, ONC, and FCC?

2. Risk and Innovation

a. What are the risks to patient safety posed by health IT and what is the likelihood of these risks?

b. What factors or approaches could be included in a risk-based regulatory approach for health IT to promote innovation and protect patient safety?

3. Regulation

a. Are there current areas of regulatory overlap among FDA, ONC, and/or FCC and if so, what are they? Please be specific if possible.

b. If there are areas of regulatory overlap, what, if any, actions should the agencies take to minimize this overlap? How can further duplication be avoided?

Dated: May 23, 2013.

Jodi Daniel,

Director, Office of Policy and Planning, Office of the National Coordinator for Health IT.

[FR Doc. 2013–12817 Filed 5–29–13; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the 2015 Dietary Guidelines Advisory Committee

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS), in collaboration with the U.S. Department of Agriculture (USDA), are hereby giving notice that a meeting of the 2015 Dietary Guidelines Advisory Committee (DGAC) will be held. This meeting will be open to the public.

DATES: The meeting will be held on June 13, 2013 from 8:30 a.m.–11:30 a.m. e.d.t. and June 14, 2013 from 8:30 a.m.–3:45 p.m. e.d.t.

ADDRESSES: The meeting will be accessible by webcast on the Internet or by attendance in-person. For in-person participants, on June 13, 2013, the meeting will take place in the National Institutes of Health (NIH) Masur Auditorium. On June 14, 2013, the meeting will be held in the NIH Foundation for Advanced Education in the Sciences (FAES) Academic Center. Both facilities are located at the NIH Clinical Center, Building 10, 10 Center Drive, 9000 Rockville Pike, Bethesda, MD 20892.

FOR FURTHER INFORMATION CONTACT: Designated Federal Officer (DFO), 2015 DGAC, Richard D. Olson, M.D., M.P.H.; Alternate DFO, 2015 DGAC, Kellie (O'Connell) Casavale, Ph.D., R.D., Nutrition Advisor; Office of Disease Prevention and Health Promotion, OASH/HHS; 1101 Wootton Parkway, Suite LL100 Tower Building; Rockville, MD 20852: Telephone: (240) 453–8280; Fax: (240) 453–8281; Lead USDA Co-Executive Secretary, Colette I. Rihane, M.S., R.D., Director, Nutrition Guidance and Analysis Division, Center for Nutrition Policy and Promotion, USDA; 3101 Park Center Drive, Room 1034; Alexandria, VA 22302; Telephone: (703) 305–7600; Fax: (703) 305–3300; and/or USDA Co-Executive Secretary, Shanthy A. Bowman, Ph.D., Nutritionist, Food Surveys Research Group, Beltsville Human Nutrition Research Center, Agricultural Research Service, USDA; 10300 Baltimore Avenue, BARC-West Bldg 005, Room 125; Beltsville, MD 20705–2350; Telephone: (301) 504–0619. Additional information about the 2015 DGAC is available on the Internet at *www.DietaryGuidelines.gov.*

SUPPLEMENTARY INFORMATION: Under Section 301 of Public Law 101–445 (7 U.S.C. 5341, the National Nutrition Monitoring and Related Research Act of 1990, Title III) the Secretaries of Health and Human Services (HHS) and Agriculture (USDA) are directed to issue at least every five years a report titled *Dietary Guidelines for Americans.* The law instructs that this publication shall contain nutritional and dietary information and guidelines for the general public, shall be based on the preponderance of scientific and medical knowledge current at the time of publication, and shall be promoted by each federal agency in carrying out any federal food, nutrition, or health program. The *Dietary Guidelines for Americans* was issued voluntarily by HHS and USDA in 1980, 1985, and 1990; the 1995 edition was the first statutorily mandated report, followed by subsequent editions at the appropriate intervals. To assist with satisfying the mandate, a discretionary federal advisory committee is established every five years to provide independent, science-based advice and recommendations. The DGAC consists of a panel of experts who are selected from the public/private sector. Individuals who are selected to serve on the Committee must have current scientific knowledge in the field of human nutrition and chronic disease.

Appointed Committee Members: As outlined (stipulated) in the charter, the 2015 DGAC will be composed of not more than 17 members, with the minimum number being 13. Individuals are appointed to serve on the Committee who are jointly agreed upon by the Secretaries of HHS and USDA. The Secretaries of HHS and USDA recently appointed 15 individuals to serve as members of the 2015 DGAC. Information on the DGAC membership will be available at *www.DietaryGuidelines.gov.*

Authority: The 2015 DGAC is authorized under 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended.

Committee's Task: The work of the DGAC will be solely advisory in nature and time-limited. The Committee will develop recommendations based on the preponderance of current scientific and medical knowledge using a systematic review approach. The DGAC will examine the current *Dietary Guidelines for Americans,* take into consideration new scientific evidence and current resource documents, and develop a report to the Secretaries of HHS and USDA that outlines its science-based recommendations and rationale which will serve as the basis for developing the eighth edition of the *Dietary Guidelines for Americans.* The Committee will hold approximately five public meetings to review and discuss recommendations. Meeting dates, times, locations, and other relevant information will be announced at least 15 days in advance of each meeting via **Federal Register** notice. As stipulated in the charter, the Committee will be terminated after delivery of its final report to the Secretaries of HHS and USDA or two years from the date the charter was filed, whichever comes first.

Purpose of the Meeting: In accordance with FACA and to promote transparency of the process, deliberations of the Committee will occur in a public forum. At this meeting, the Committee will be oriented to the *Dietary Guidelines* revision process and begin its deliberations.

Meeting Agenda: The meeting agenda will include (a) review of operations for the Committee members, (b) presentations on the history of the *Dietary Guidelines* and how they are used, (c) presentation on USDA's Nutrition Evidence Library, and (d) plans for future Committee work.

Meeting Registration: The meeting is open to the public. The meeting will be accessible by webcast or by attendance in-person. Pre-registration is required for both web viewing and in-person attendance. To pre-register, please go to *www.DietaryGuidelines.gov* and click on the link for ''Meeting Registration.'' To register by phone or to request a sign language interpreter or other special accommodations, please call for registration and logistics assistance through National Capitol Contracting, Laura Walters at (703) 243–9696 by 5:00 p.m. E.D.T., June 10, 2013. Pre-registration must include name, affiliation, phone number or email, days