

Executive Secretary, NVAC, through the contact person listed above prior to close of business one week before each meeting (conference call). A draft agenda and any additional materials will be posted on the NVAC Web site (<http://www.hhs.gov/nvpo/nvac/>) prior to the meeting.

Dated: November 24, 2009.

Bruce Gellin,

*Deputy Assistant Secretary for Health,
Director, National Vaccine Program Office,
Executive Secretary, NVAC.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Organization, Functions, and Delegations of Authority; Office of the National Coordinator for Health Information Technology

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Statement of Organization, Functions, and Delegations of Authority The Office of the National Coordinator for Health Information Technology has reorganized its substructure components in order to more effectively meet the mission outlined by The Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act of 2009 (ARRA). The reorganization affects all four of the original Director-level offices: the Office of Health Information Technology Adoption (OHITA); the Office of Interoperability and Standards (OIS); Office of Programs and Coordination (OPC); and the Office of Policy and Research (OPR). The new organizational structure is composed of five offices with direct reporting capability to the National Coordinator for Health Information Technology (National Coordinator); the Office of Economic Modeling and Analysis; the Office of the Chief Scientist; the Office of the Deputy National Coordinator for Programs & Policy; the Office of the Deputy National Coordinator for Operations, and the Office of the Chief Privacy Officer.

FOR FURTHER INFORMATION CONTACT:

Marc Weisman, Office of the National Coordinator, Office of the Secretary, 200 Independence Ave., NW., Washington, DC 20201, 202-690-6285.

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human

Services, Part A, as last amended at 70 FR 48718-48720, dated August 19, 2005, is amended to reflect the restructuring of the Office of the National Coordinator for Health Information Technology (ONC) as follows:

I. Under Part A, Chapter AR, Office of the National Coordinator for Health Information Technology delete, "Section AR.10 Organization," in its entirety and replace with the following:

Section AR.10 Organization. The Office of the National Coordinator for Health Information Technology (ONC) is under the direction of the National Coordinator for Health Information Technology who reports directly to the Secretary. The office consists of the following components:

A. Immediate Office of the National Coordinator (ARA)

B. Office of Economic Modeling and Analysis (ARB)

C. Office of the Chief Scientist (ARC)

D. Office of the Deputy National Coordinator For Programs & Policy (ARD)

E. Office of the Deputy National Coordinator For Operations (ARE)

F. Office of the Chief Privacy Officer (ARF)

II. Under Part A, Chapter AR, Office of the National Coordinator for Health Information Technology, Section AR.20 Functions, Chapter B, delete, "Office of the Health Information Technology Adoption (ARB)," in its entirety and replace with the following:

B. Office of Economic Modeling and Analysis (ARB): The Office of Economic Modeling and Analysis works with and reports directly to the National Coordinator. The Office: (1) Applies advanced mathematical or quantitative modeling to the U.S. health care system for simulating the microeconomic and macroeconomic effects of investing in health information technology and (2) provides advanced policy analysis of health information technology strategies and policies to the National Coordinator. Such modeling will be used with varying public policy scenarios to perform advanced health care policy analysis for requirements of the Recovery Act, such as reductions in health care costs resulting from adoption and use of health information technology. The results of these analyses provided to the National Coordinator will inform strategies to enhance the use of health information technology in improving the quality and efficiency of health care and improving public health.

III. Under Part A, Chapter AR, Office of the National Coordinator for Health Information Technology, Section AR.20

Functions, Chapter C, delete, "Office of Interoperability and Standards (ARC)," in its entirety and replace with the following:

C. Office of the Chief Scientist (ARC):

The Office of the Chief Scientist is headed by the Chief Scientist. The Office of the Chief Scientist is responsible for: (1) Applying research methodologies to perform evaluation studies of health information technology grant programs; (2) identifying, tracking and supporting innovations in health information technology; (3) leading research activities mandated under the HITECH Act provisions of ARRA; (4) promoting applications of health information technology that support basic and clinical research; (5) collecting and communicating knowledge of health care informatics from and to international audiences; (6) collaborating with other agencies and departments on assessments of new health information technology programs; and (7) developing and maintaining educational programs for staff of the Office of the National Coordinator and advising the National Coordinator concerning the educational needs of the field of HIT. The Office of the Chief Scientist possesses and utilizes specialized knowledge of medical bioinformatics, which involves the study and application of advanced information methods and technologies in support of health care and population health.

IV. Under Part A, Chapter AR, Office of the National Coordinator for Health Information Technology, Section AR.20 Functions, Chapter D, delete, "Office of Programs and Coordination (ARE)," in its entirety and replace with the following:

D. Office of the Deputy National Coordinator for Programs & Policy (ARD): The Office of the Deputy National Coordinator for Programs & Policy is headed by the Deputy National Coordinator for Programs & Policy. The Office of the Deputy National Coordinator for Programs & Policy is responsible for: (1) Implementing and overseeing grant programs that advance the nation toward universal meaningful use of interoperable health information technology in support of health care and population health; (2) coordinating among HHS agencies and offices and among relevant executive branch agencies and the public health information technology programs and policies to avoid duplication of efforts and inconsistent activities; (3) developing the mechanisms for establishing and implementing standards necessary for nationwide health information exchange; (4)

formulating policy for the privacy and security of health information; (5) developing policies as may be otherwise necessary for implementing its mission; and (6) maintaining a Federal Health IT Strategic Plan.

V. Under Part A, Chapter AR, Office of the National Coordinator for Health Information Technology, Section AR.20 Functions, Chapter E, delete, "Office of Policy and Research (ARF)," in its entirety and replace with the following:

E. *Office of the Deputy National Coordinator for Operations (ARE)*: The Office of the Deputy National Coordinator for Operations is headed by the Deputy National Coordinator for Operations. The Office of the Deputy National Coordinator for Operations is responsible for performing the activities that support the Office of the National Coordinator for Health Information Technology's numerous programs. These include: (1) Budget formulation and execution; (2) contracts and grants management; (3) facilities management; (4) human resources; (5) stakeholder communications; and (6) financial and human capital strategic planning.

VI. Under Part A, Chapter AR, Office of the National Coordinator for Health Information Technology, Section AR.20 Functions, immediately following Chapter E, insert the following:

F. *Office of the Chief Privacy Officer (ARF)*: The Office of the Chief Privacy Officer is headed by the Chief Privacy Officer, who advises the National Coordinator as directed by the ARRA. The Chief Privacy Officer may also report to other individuals, as necessary. The Chief Privacy Officer of the Office of the National Coordinator for Health Information Technology will be appointed by the Secretary. The Office of the Chief Privacy Officer is responsible for: (1) advising the National Coordinator on privacy, security, and data stewardship of electronic health information and (2) coordinating the Office of the National Coordinator for Health Information Technology's efforts with similar privacy officers in other Federal agencies, State and regional agencies, and foreign countries with regard to the privacy, security, and data stewardship of electronic, individually identifiable health information.

VII. *Delegation of Authority*. Pending further delegation, directives or orders by the Secretary or by the National Coordinator for Health Information Technology, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided

they are consistent with this reorganization.

Authority: 44 U.S.C. 3101.

Dated: November 20, 2009.

Kathleen Sebelius,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0220]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Studies of Nutrition Symbols on Food Packages

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by December 31, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Experimental Studies of Nutrition Symbols on Food Packages." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794, Jonna.Capezzuto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

I. Experimental Studies of Nutrition Symbols on Food Packages

With the increased interest in healthier foods, U.S. food processors and retailers have been adding nutrition information, particularly nutrition quality icons (e.g., Smart Choices Program) and selected nutrient level disclosures (e.g., Guideline Daily Amounts), in addition to other labeling statements (e.g., nutrient content claims), to the front of the package (FOP). This type of nutrition labeling scheme is seen in other countries (e.g., United Kingdom, Sweden, and Australia) as well. FDA believes the proliferation of these nutrition labeling schemes in the domestic market and the various nutrition criteria they use make it necessary for the agency to exercise the responsibility that Congress gave it to, among other things, carefully examine consumer understanding and use of the various schemes to evaluate how well they impart useful nutrition information to U.S. consumers and which schemes or types of schemes are better to impart the information. The agency held a public hearing in September 2007 and completed a focus group study in April 2008 to obtain comments and information about many consumer issues related to FOP nutrition labeling schemes. We are also aware of recent consumer research conducted by foreign governments, non-governmental organizations, and academics (e.g., Refs. 1 to 4). The existing information, however, does not fill many of the gaps in our understanding of the impacts of FOP nutrition labeling schemes on U.S. consumers. Most importantly, there is a lack of publicly available quantitative consumer research on the relative effectiveness of existing and alternative labeling schemes in helping U.S. consumers make better dietary decisions. Therefore, the agency is proposing to conduct two experimental studies to assess quantitatively consumer reactions to various FOP nutrition labeling schemes. The studies will provide critical input to ensure the usefulness of FOP nutrition information provided to U.S. consumers.

FDA conducts research and educational and public information programs relating to food safety under its broad statutory authority, set forth in section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(b)(2)), to protect the public health by ensuring that foods are "safe, wholesome, sanitary, and properly labeled," and in section 903(d)(2)(C) (21 U.S.C. 393(d)(2)(C)), to conduct research