

making such representation, respondent possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, and that are generally accepted in the profession to yield accurate and reliable results.

Part III of the proposed order prohibits any representation, other than those covered under Part I, about the health benefits of any drug, cosmetic, or pesticide, unless the representation is non-misleading, and at the time of making such representation, the respondent possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, and that are generally accepted in the profession to yield accurate and reliable results.

Part IV of the proposed order addresses the allegedly false claim that scientific tests prove that use of Lice Shield products significantly reduces the risk or likelihood of a head lice infestation. Part IV prohibits respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, when advertising any drug, cosmetic, or pesticide.

Part V of the proposed order states that the order does not prohibit respondent from making representations for any drug that are permitted in labeling for that drug under any tentative or final standard promulgated by the Food and Drug Administration ("FDA"), or under any new drug application approved by the FDA.

Part VI of the proposed order requires respondent to pay five hundred thousand dollars (\$500,000) to the Commission. This payment shall be deposited in the United States Treasury as disgorgement.

Parts VII, VIII, IX, and X of the proposed order require respondent to

keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to its personnel; to notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part XI provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2014-12734 Filed 6-2-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

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

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Chapter AR, Office of the National Coordinator for Health Information Technology (ONC), as last amended at 77 FR 29349-50 (May 17, 2012), 76 FR 65196 (Oct. 20, 2011), 76 FR 6795 (Feb. 8, 2011), 75 FR 49494 (Aug. 13, 2010), 74 FR 62785-86 (Dec. 1, 2009), and 70 FR 48718-20 (Aug. 19, 2005), is amended as follows:

- I. Under AR.10, Organization, delete all of components and replace with the following:
 - A. Immediate Office of the National Coordinator (ARA)
 - B. Office of Clinical Quality and Safety (ARG)
 - C. Office of Planning, Evaluation, and Analysis (ARB)
 - D. Office of Standards and Technology (ARC)
 - E. Office of Programs (ARD)
 - F. Office of Public Affairs and Communications (ARH)
 - G. Office of the Chief Operating Officer (ARE)
 - H. Office of the Chief Privacy Officer (ARF)
 - I. Office of Policy (ARI)
 - J. Office of Care Transformation (ARJ)
 - K. Office of the Chief Scientist (ARK)

- II. Delete AR.20, Functions, in its entirety and replace with the following:

Section AR.20, Functions

A. Immediate Office of the National Coordinator (ARA): The Immediate Office of the National Coordinator (IO/ONC) is headed by the National Coordinator, who provides leadership and executive and strategic direction for the ONC organization. The National Coordinator is responsible for carrying out ONC's mission and implementing the functions of the ONC. The IO/ONC: (1) Ensures that key health information technology initiatives are coordinated across HHS programs; (2) ensures that health information technology policy and programs of HHS are coordinated with those of relevant executive branch agencies (including federal commissions and advisory committees) with a goal of avoiding duplication of effort and of helping to ensure that each agency undertakes activities primarily within the areas of its greatest expertise and technical capability; (3) reviews federal health information technology investments to ensure federal health information technology programs are meeting the objectives of the strategic plan, required under Executive Order 13335, to create a nationwide interoperable health information technology infrastructure; (4) at the request of OMB, provides comments and advice regarding specific federal health information technology programs; (5) develops, maintains, and reports on measurable outcome goals for health information technology to assess progress within HHS and other executive branch agencies; and in the private sector, in developing and implementing a nationwide interoperable health infrastructure (HIE coordination); (6) provides oversight of the ONC federal health architecture; and (7) fulfills the administrative (i.e., executive secretariat), reporting, program management, legislative affairs, infrastructure, and budget support needs of the office.

The Deputy National Coordinator, a part of the IO/ONC, works with and reports directly to the National Coordinator and is responsible for supporting the National Coordinator in day-to-day operations and strategy for ONC, internal information technology strategy, and staff management of ONC for those reporting to the Deputy or as requested by the National Coordinator. The Deputy in conjunction with the National Coordinator and Chief of Staff provides executive oversight for the activities of all ONC offices.

B. Office of Clinical Quality and Safety (ARG): The Office of Clinical Quality and Safety is headed by a Director and is responsible for working with public and private sector medical organizations to achieve widespread use of health information technology by the medical community with special emphasis in the areas of clinical quality and patient safety. The office includes the Chief Nursing Officer (CNO) who advocates for patient care, clinical, and staffing nursing standards at the national level for ONC. The Office of Clinical Quality and Safety also engages with a wide array of clinical stakeholders and provides a clinically based perspective on ONC policies and activities. This includes clinical issues involving health IT safety, usability, clinical decision support, and quality measurement.

C. Office of Planning, Evaluation, and Analysis (ARB): The Office of Planning, Evaluation, and Analysis is headed by a Director. The Office: (1) Provides advanced analysis of health information technology strategies to ONC; (2) applies research methodologies to perform evaluation studies of federal investments in health information technology; and (3) 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. Such modeling will be used with varying public policy scenarios to perform advanced health care policy analysis for requirements of the Recovery Act and other legislation as required, such as reductions in health care costs resulting from adoption and use of health information technology. Functions include strategic planning, building a national consensus agenda, developing external measures, evaluating external advancement, developing internal priorities and plans tied to measures, and evaluating organizational performance.

D. Office of Standards and Technology (ARC): The Office of Standards and Technology is headed by a Director. The Office of Standards and Technology is responsible for: (1) Leading research activities mandated under the HITECH Act provisions of ARRA; (2) promoting applications of health information technology that support basic and clinical research; (3) collecting and communicating knowledge of health care informatics from and to international audiences; (4) collaborating with other agencies and departments on assessments of new health information technology programs; (5) 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; and (6) developing the mechanisms for establishing and implementing standards necessary for nationwide health information exchange. The Office of Standards and Technology possesses specialized knowledge of biomedical informatics, which involves the study and application of advanced information methods and technologies in support of health care delivery and population health.

E. Office of Programs (ARD): The Office of Programs is headed by a Director. The Office of Programs is responsible for implementing and overseeing grant programs and other initiatives that advance the nation toward universal adoption and meaningful use of interoperable health information technology in support of health care and population health. This Office supports care providers in the adoption, implementation and optimization of health information technology and adaptation to new care and payment models. The Office also oversees consumer use of electronic personal health information and activities for certification of health information technology.

F. Office of Public Affairs and Communications (ARH): The Office of Public Affairs and Communications is headed by a Director. The Office is responsible for: (1) Setting the strategic direction for ONC communications efforts; (2) guiding the development of a comprehensive stakeholder communications and constituency relations plan; and (3) ensuring that all communications activities are developed and implemented consistent with and in support of this plan.

G. Office of the Chief Operating Officer (ARE): The Office of the Chief Operating Officer is headed by the Chief Operating Officer. The Office of the Chief Operating Officer is responsible for performing the activities that support the Office of the National Coordinator for Health Information Technology's programs. These include: (1) Budget formulation and execution; (2) contracts and grants management; (3) facilities management and information technology infrastructure; (4) human resources; and (5) financial and human capital strategic planning.

H. 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 American Recovery and Reinvestment Act. The

Chief Privacy Officer may also report to other individuals, as necessary. The Office of the Chief Privacy Officer is responsible for: (1) Advising the National Coordinator, the Secretary, or other Department of Health and Human Services leaders where indicated on privacy, security, and data stewardship of electronic health information; (2) overseeing privacy and security of the consumer use of electronic personal health information; and (3) 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 nations with regard to the privacy, security, and data stewardship of electronic, individually identifiable health information.

I. Office of Policy (ARI): The Office of Policy is headed by a Director. This Office is responsible for providing expertise and strategic direction for health information technology policy initiatives. The Office of Policy leads ONC's domestic policy initiatives and coordinates international policy efforts. In addition, the Office of Policy provides advanced analysis of health information technology policies to ONC. This office coordinates with executive branch agencies and other relevant organizations (including federal commissions and advisory committees) with a goal of avoiding duplication of efforts and of helping to ensure that each agency undertakes activities primarily within the areas of its greatest expertise and technical capability.

J. Office of Care Transformation (ARJ): The Office of Care Transformation is headed by a Director. This Office is responsible for providing expertise and strategic direction in the domain of transforming and optimizing health care through the leveraged use of health information technology throughout the Department of Health and Human Services, with the private sector, and with other federal partners. This office facilitates and informs payment and care delivery reform for physicians and other providers in the health system, and provides guidance for the facilitation and development of cross-cutting innovative payment reform programs in the public and private sector.

K. Office of the Chief Scientist (ARK): The Office of the Chief Scientist is headed by the Chief Scientist. This office is responsible for developing and evaluating ONC's overall scientific efforts and activities and, as necessary, develops, establishes, or recommends scientific policy to the National Coordinator. The office is also responsible for identifying, tracking,

and anticipating innovations in health care technology across the ONC organization.

III. 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.

Dated: May 29, 2014.

E.J. Holland, Jr.,

Assistant Secretary for Administration.

[FR Doc. 2014-12981 Filed 5-30-14; 4:15 pm]

BILLING CODE 4150-24-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extension of Certification of Maintenance of Effort for the Title III and the Certification of Long-Term Care Ombudsman Program Expenditures

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by July 3, 2014.

ADDRESSES: Submit written comments on the collection of information by fax 202.395.5806 or by email to OIRA_submission@omb.eop.gov, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Greg Case at 202-357-3442 or email: Greg.Case@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. ACL invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL'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. The Certification on Maintenance of Effort for the Title III and Certification of Long-Term Care Ombudsman Program Expenditures provides statutorily required information regarding state's contribution to programs funded under the Older American's Act and conformance with legislative requirements, pertinent Federal regulations and other applicable instructions and guidelines issued by the Administration on Aging. This information will be used for Federal oversight of Title III Programs and the Title VII Ombudsman Program.

ACL estimates the burden of this collection of information as follows: 56 State Agencies on Aging respond annually with an average burden of one half (1/2) hour per State agency or a total of twenty-eight hours for all state agencies annually. In the **Federal Register** of March 21, 2014 (Vol. 79 No. 55 Page 15751) the agency requested comments on the proposed collection of information. No comments were received.

Dated: May 29, 2014.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2014-12803 Filed 6-2-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1432]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guide To Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and

Vegetables" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: On January 28, 2014, the Agency submitted a proposed collection of information entitled "Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0609. The approval expires on May 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: May 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-12815 Filed 6-2-14; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1620]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Request for Information From United States Processors That Export to the European Community

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Request for Information from U.S. Processors that Export to the European Community" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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