the FD&C Act, a person that intends to use such a claim must submit a notification of its intention to use the claim 120 days before it begins marketing the product bearing the claim. In the *Federal Register* of June 11, 1998 (63 FR 32102), FDA announced the availability of a guidance entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body.'' The guidance provides the Agency's interpretation of terms central to the submission of a notification and the Agency's views on the information that should be included in the notification. The Agency believes that the guidance will enable persons to meet the criteria for notifications that are established in section 403(r)(2)(G) and (r)(3)(C) of the FD&C Act. In addition to the information specifically required by the FD&C Act to be in such notifications, the guidance states that the notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. FDA intends to review the notifications the Agency receives to ensure that they comply with the criteria established by the FD&C Act.

In the *Federal Register* of August 3, 2011 (76 FR 46819), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
403(r)(2)(G) (nutrient content claims)	1	1	1	250	250
403(r)(2)(C) (health claims)	1	1	1	450	450
Guidance for notifications	2	1	2	1	2
Total					702

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on FDA's experience with health claims, nutrient content claims, and other similar notification procedures that fall under our jurisdiction. To avoid estimating the number of respondents as zero, the Agency estimates that there will be one or fewer respondents annually for nutrient content claim and health claim notifications. FDA estimates that it will receive one nutrient content claim notification and one health claim notification per year over the next 3 years.

Section 403(r)(2)(G) and (r)(3)(C) of the FD&C Act requires that the notification include the exact words of the claim, a copy of the authoritative statement, a concise description of the basis upon which such person relied for determining that this is an authoritative statement as outlined in the FD&C Act, and a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which a health claim refers or to the nutrient level to which the nutrient content claim refers. This balanced representation of the scientific literature is expected to include a bibliography of the scientific literature on the topic of the claim and a brief, balanced account or analysis of how this literature either supports or fails to support the authoritative statement.

Since the claims are based on authoritative statements of a scientific body of the U.S. Government or NAS, FDA believes that the information that is required by the FD&C Act to be submitted with a notification will be readily available to a respondent. However, the respondent will have to collect and assemble that information. Based on communications with firms that have submitted notifications, FDA estimates that 1 respondent will take 250 hours to collect and assemble the information required by the statute for a nutrient content claim notification. Further, FDA estimates that 1 respondent will take 450 hours to collect and assemble the information required by the statute for a health claim notification.

Under the guidance, notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. The guidance applies to both nutrient content claim and health claim notifications. FDA has determined that this information should be readily available to a respondent and, thus, the Agency estimates that it will take a respondent 1 hour to incorporate the information into each notification. The Agency expects there will be 2 respondents for a total of 2 hours.

Dated: December 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32025 Filed 12–13–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Cultural and Linguistic Competency and Health Literacy Data Collection Checklist (OMB No. 0915–xxxx)—[New].

The Health Resources and Services Administration's (HRSA) vision is ''Healthy Communities, Healthy People.'' In addition, the HRSA mission statement is ''To improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs.'' This framework supports a health care system that assures access to

comprehensive, culturally competent, quality care.

Performance measures have been useful in helping HRSA to assess the progress of each grantee. The measure used will be informed by the degree to which HRSA-funded programs have incorporated cultural and linguistic competence and health literacy elements into their policies, guidelines, contracts and training. HRSA bureaus and offices will be encouraged to incorporate this performance measure (or a modified version of this measure) into their funding opportunity announcements, as either a stand-alone or integrated measure.

Using a scale of 0–3, the grantee may use the Cultural and Linguistic Competency and Health Literacy Data Collection Checklist to assess if specified cultural/linguistic competence and health literacy elements have been incorporated into their policies, guidelines, contracts and training. Each HRSA program may add data sources and year of data used for scoring to provide a rationale for determining a score, and/or applicability of elements to a specific program.

The goal of this checklist is to increase the number of HRSA-funded programs that have integrated cultural and linguistic competence and health literacy into their policies, guidelines, contracts and training. In addition, variations of the proposed tool have proven useful for grantees' self-assessment. This proposed tool can also offer insights into technical assistance challenges and opportunities.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Data Collection Checklist	900	1	900	1	900
Total	900	1	900	1	900

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: December 8, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011–32014 Filed 12–13–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 76 FR 64953–64954 dated October 19, 2011).

This notice reflects organizational changes to the Health Resources and Services Administration. Specifically, this notice updates the functional statement for the Office of Federal Assistance Management (RJ). The update to the functional statement will better align functional responsibility with improved management and administrative efficiencies and improved alignment of current liaison functions and grant policy processes within the Office of Federal Assistance Management.

Chapter RJ—Office of Federal Assistance Management

Section RJ–10, Organization

Delete in its entirety and replace with the following:

The Office of Federal Assistance Management (RJ) is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources Services Administration. The Office of Federal Assistance Management includes the following components:

(1) Office of the Associate Administrator (RJ);

(2) Division of Financial Integrity (RJ1);

(3) Division of Grants Policy (RJ2);

(4) Division of Grants Management Operations (RJ3); and

(5) Division of Independent Review (RJ4).

Section RJ–20, Functions

(1) Delete the functional statement for the Office of Federal Assistance Management (RJ) and replace in its entirety.

Office of Associate Administrator (RJ)

Provides national leadership in the administration and assurance of the financial integrity of HRSA's programs and provides oversight over all HRSA activities to ensure that HRSA's resources are being properly used and protected. Provides leadership, direction and coordination to all phases of grants policy, administration, and independent review of competitive grant applications. Specifically: (1) Serves as the Administrator's principal source for grants policy and financial integrity of HRSA programs; (2) exercises oversight over the Agency's business processes related to assistance programs; (3) facilitates, plans, directs and coordinates the administration of HRSA grant policies and operations; (4) plans, directs and carries out the grants officer functions for all of HRSA's grant programs as well as awarding official functions for various scholarship, loan and loan repayment assistance programs; and (5) directs and carries out the independent review of grant applications for all of HRSA's programs.

Division of Financial Integrity (RJ1)

(1) Coordinates agency-wide efforts addressing HHS's Program Integrity Initiative; (2) serves as the Agency's focal point for coordinating financial audits of grantees; (3) coordinates the external financial assessment of HRSA grantees and the resolution of any audit findings; (4) conducts the pre-award and post-award review of grant applicants' and grantees' accounting systems; (5) conducts ad hoc studies and reviews related to the financial integrity of the HRSA business processes related to assistance programs; (6) serves as the Agency's liaison with the Office of Inspector General (OIG) for issues related to grants; (7) coordinates the Agency's response to HHS OIG Hotline complaints reporting fraudulent fiscal activities pertaining to HRSA grant funds; and (8) establishes an assessment model for grantee oversight.