

expenditures in greater detail to anticipate any funding issues and to meet the requirements of ORR regulations at CFR 400.211 to collect these data for use in estimating future costs of the refugee resettlement program. ORR must implement the methodology at CFR 400.211 each year after receipt of its annual appropriation to ensure that appropriated funds will be adequate for reimbursement to States

of the costs for assistance provided to entering refugees. The estimating methodology prescribed in the regulations requires the use of actual past costs by program component. In the event that the methodology indicates that appropriated funds are inadequate, ORR must take steps to reduce federal expenses, such as by limiting the number of months of eligibility for Refugee Cash Assistance and Refugee

Medical Assistance. This proposed single-page financial report allows ORR to collect the necessary data to ensure that funds are adequate for the projected need and thereby meet the requirements of both the Refugee Act and ORR regulations.

*Respondents:* State governments, Wilson/Fish Alternative Projects.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR Financial Status Report .....	58	4	0.50	116

*Estimated Total Annual Burden Hours:* 116.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0535]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body**

**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.

**DATES:** Fax written comments on the collection of information by April 2, 2015.

**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: 202-395-7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0374. Also include the FDA docket number found in brackets in the heading of this document.

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

**Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body—(OMB Control Number 0910-0374)—Extension**

Section 403(r)(2)(G) and (r)(3)(C) of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(r)(2)(G) and (r)(3)(C)), as amended by the FDA Modernization Act of 1997, provides that any person may market a food product whose label bears a nutrient content claim or a health claim that is based on an authoritative statement of a scientific body of the U.S. Government or the National Academy of Sciences (NAS). Under this section of 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), we 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. We believe 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. We intend to review the notifications we receive to

ensure that they comply with the criteria established by the FD&C Act.

In the **Federal Register** of November 21, 2014 (79 FR 69494), FDA published a 60-day notice requesting public

comment on the proposed collection of information. No comments were received in response to the notice.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

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

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on our 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, we estimate that there will be one or fewer respondents annually for nutrient content claim and health claim notifications. We estimate that we 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, we believe 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, we estimate that one respondent will take 250 hours to collect and assemble the information required by the statute for

a nutrient content claim notification. Further, we estimate that one 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. We have determined that this information should be readily available to a respondent and, thus, we estimate that it will take a respondent 1 hour to incorporate the information into each notification. We expect there will be two respondents for a total of 2 hours.

Dated: February 24, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2005-N-0161]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and “Lookback”**

**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.

**DATES:** Fax written comments on the collection of information by April 2, 2015.

**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: 202-395-7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0116. Also include the FDA docket number found in brackets in the heading of this document.

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

**Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and “Lookback”—(OMB Control Number 0910-0116)—Extension**

All blood and blood components introduced or delivered for introduction into interstate commerce are subject to section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)). Section 351(a) requires that manufacturers of biological products, which include blood and blood components intended for further