SUPPORTING STATEMENT FOR

0584-0043

"WIC PROGRAM REGULATIONS"

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Women, Infants and Children (WIC)

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Background

The proposed food package rule was published in the Federal Register [71 FR 44784] with a 60-day notice on August 7, 2006, which provided the public an opportunity to submit comments on the information collection burden resulting from the proposed rule. FNS received no public comments in response to this solicitation. On November 1, 2006, OMB filed comment in accordance with 5 CFR 1320.11(c), requiring FNS to review public comments in response to the proposed rule and address any such comments in the preamble of the final rule.

The interim food package rule was published in the Federal Register [72 FR 68966] on December 6, 2007, and included an estimated annual information collection burden of 14,919 burden hours, which was approved as OMB Number 0584-0545. These information collection burden hours were merged into the information collection, WIC Program Reporting and Recordkeeping Requirements, OMB Number 0584-0043, changing the total approved burden hours for OMB Number 0584-0043 from 3,595,075 to 3,609,994. Information collection OMB Number 0584-0545 was then discontinued. Information collection OMB Number 0584-0043 was renewed as of December 27, 2012, changing the total approved burden hours from 3,609,994 to 4,024,697.

In this final rule, FNS will no longer require a health care professional licensed to write medical prescriptions to provide documentation for children to receive soy-based beverage and tofu as milk substitutes. Also, FNS will no longer require documentation from a health care professional licensed to write medical prescriptions for women to receive tofu in excess of the maximum substitution allowance. As a result of this final rulemaking, the overall information collection burden associated with OMB Number 0584-0043 is estimated to have decreased by 4,200 burden hours annually due to program changes in this

rulemaking. The total estimated burden hours for OMB Number 0584-0043 will decrease from 4,024,697 to 4,020,497.

Justification

1. Circumstances that make the collection of information necessary.

Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

This submission is a revision of a currently approved collection which covers the information collections of the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), OMB #0584-0043; Expiration date December 31, 2015. The WIC Program is authorized by the Child Nutrition Act (CNA) of 1966, as amended, and is administered by State agencies in accordance with WIC Program regulations at 7 CFR Part 246.

Per §246.2 of the WIC regulations, "State agencies" are health departments or comparable agencies of the States, U.S. Territories, and Indian Tribal Organizations (ITO). The State agencies administer the WIC Program with funds provided by the USDA Food and Nutrition Service (FNS) pursuant to annual Federal-State agreements.

Per §246.2 of the WIC regulations, "vendors" are businesses operating retail stores authorized by State agencies to transact the WIC "food instruments" (checks, vouchers or EBT cards) used by WIC participants to purchase WIC authorized foods.

Per §246.2 of the WIC regulations, “local agencies” include public or private non-profit health or human service agencies, Indian Health Service units, and health clinics of ITOs and intertribal councils or groups. The local agencies administer the WIC Program pursuant to annual or multi-year written agreements with State agencies. The local agencies provide client services directly to Program participants; services include, but are not limited to, certification, issuance of food instruments, and nutrition education.

2. Purpose and use of the information.

Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The reporting and recordkeeping burdens covered by this ICR include requirements that involve the certification of WIC participants; the nutrition education that is provided to participants; the authorization, training and monitoring of vendors; and the collection of vendor pricing information in order to comply with the Federal regulations regarding WIC cost containment. State Plans are the principal source of information about how each State agency operates its WIC Program. Information collected from participants and local agencies is collected through State-developed forms or Management Information Systems. The information collected is used by the Department of Agriculture to manage, plan, evaluate, make decisions and report on WIC Program operations.

The entire information collection involves regulatory provisions at 7 CFR 246. This

submission incorporates the information collection request (ICR) associated with program changes due to rulemaking. These program changes are outlined in the attached burden table and burden narrative.

a. What information will be collected - reported or recorded?

The information collections for these provisions include participant certification information (e.g., income and nutrition risk); nutrition education documentation; local agency and vendor application and agreement information; vendor sales and shelf price data; data related to vendor monitoring and training; and, financial and food delivery system records.

b. From whom will the information be collected?

The respondents for the information collection are State agencies, local agencies, applicants for Program benefits, and retail vendors.

c. What will this information be used for? Provide ALL uses.

The information collections for all provisions includes participant certification information (e.g., income and nutrition risk); nutrition education documentation; local agency and vendor application and agreement information; vendor sales and shelf price data; data related to vendor monitoring and training; and, financial and food delivery system records. The information is needed for the general operation of the Program, including regulatory compliance, and for ongoing program integrity and cost-saving efforts.

d. How will the information be collected?

Most State agencies submit their State Plans as attachments to email or through the regular mail. State agencies have also developed various methods for local agencies to submit certification and financial data; although State agency practices vary, this includes submission of data either directly through an integrated computer network, via email attachments or by facsimile. Most vendors submit information or forms to the State agencies in a paper format, although some use e-mail to streamline this process, and a few States have established automated downloads of price data for vendors which have this capability.

e. How frequently will the information be collected?

The State Plan, the vendor sales information, the vendor infant formula list, and the vendor incentive item requests for approval are collected annually. Certification information is collected once or twice per year for each participant, depending on category. Nutrition education is delivered and documented quarterly. Vendor price data is collected semiannually. Local agency and vendor applications and agreements are done every two years. Each State agency provides a notification of violations, on average, to 26 vendors per year, or documents the reason for not doing so; this is done on an as-needed basis. More information on the frequency of each type of information can be found in the attached burden table and burden narrative.

f. Will the information be shared with any other organizations inside or outside USDA or the government?

The information may be made available to the Government Accountability Office (GAO) or other Congressional offices.

The information may also be made available to private contractors conducting research for FNS. The research information may subsequently be made public when the reports developed by the contractors are issued. To protect the privacy of participants and vendors, information made available to the public is provided only in aggregate form, without identifying individual participants or vendors.

g. If this is an ongoing collection, how have the collection requirements changed over time?

This ICR is being submitted due to program changes to an existing collection. As a result of rulemaking, FNS no longer requires a health care professional licensed to write medical prescriptions to provide documentation for children to receive soy-based beverage and tofu as milk substitutes. Also, FNS no longer requires documentation from a health care professional licensed to write medical prescriptions for women to receive tofu in excess of the maximum substitution allowance.

3. Use of information technology and burden reduction.

Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also, describe any consideration of using information technology to reduce burden.

FNS makes every effort to comply with the E-Government Act of 2002. Any information that must be submitted to FNS may be submitted via email or PartnerWeb. The majority of State agencies choose to submit via email or PartnerWeb; those with limited access to or familiarity with technology may mail or fax their information. FNS encourages its State agency partners to offer electronic

submission to local agencies and vendors whenever it is feasible and offers funding for enhancing State agency Management Information Systems (MIS).

Approximately 90% of WIC State agencies have automated management information (MIS) and/or food delivery systems that were created with funding from FNS. Ongoing improvements in these systems at the State and local levels continue to reduce the time and effort required to collect and transmit data. For example, State agency use of automated MIS minimizes the burden associated with the performance of many other activities, including performing and documenting vendor training, collecting certification data, developing local agency nutrition education plans, and documenting monitoring visits to retail vendors. Improved and extended use of automated approaches to Program management and services delivery is a priority of the WIC Program.

Additionally, FNS continues to use an automated method for matching a vendor's WIC redemptions with that vendor's SNAP redemptions in order to determine whether that vendor is an above-50-percent or regular vendor. If a vendor's SNAP redemptions exceed its WIC redemptions, then that vendor is considered a regular vendor and no further documentation, such as tax records, are needed to determine its status. This process has shown that the SNAP redemptions exceed WIC redemptions for 95 percent of authorized vendors, thus eliminating the need for further documentation for 95 percent of the authorized vendors.

4. Efforts to identify duplication and use of similar information.

Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

There are no similar information collection efforts.

5. Impacts small businesses or other small entities.

If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The information collection has been held to the minimum required for the intended use. FNS has determined that the requirements for this information collection do not adversely impact small businesses or other small entities. Although smaller local agencies, retail vendors, and contractors submit fewer business transactions involving the WIC Program, they delivered the same Program benefits and perform the same function as any other business' or entities. Thus, they must collect and maintain the same types of information on file.

FNS estimates that 75 percent of the 48,621 retail vendors are small businesses (.75 x 48,621 vendors = 36,466 vendors that are small businesses). FNS also estimates that 20 percent of the 1,839 State and local agencies are small entities (.2 x 1,839 State and local agencies = 368 State and local agencies that are small entities). In total, there are an estimated 36,834 small businesses or small entities (36,466 + 368 = 36,834) impacted by this information collection.

6. Consequences of collecting the information less frequently.

Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If the information were collected less frequently, the efficiency and effectiveness of the Program would be jeopardized, the likelihood of misuse or improper use of Federal funds would increase, and FNS' ability to detect violations or abusive behavior would diminish greatly. The Department and State agencies would be out of compliance with Federal laws, and therefore at risk of losing funding for the WIC Program.

7. Special circumstances relating to the Guideline of 5 CFR 1320.5.

Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**

Under §246.25(a)(2) of the WIC regulations, all records shall be retained for a minimum of three years following the date of submission of the final expenditure report for the period to which the report pertains; if any litigation, claim, negotiation, audit or other action involving the records has been started before the end of the three-year period, the records shall be kept until all issues are resolved, or until the end of the regular three-year period, whichever is later. This provision is based on 36 CFR 1207.42(b)(2) of the National Archives and Records Administration regulations.

- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**

There are no other special circumstances. The collection of information is conducted in a manner consistent with the guidelines in 5 CFR 1320.5(d)(2).

8. Comments in response to the Federal Register Notice.

If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported.

The proposed food package rule revising the WIC food packages was published in the Federal Register [71 FR 44784] with a 60-day notice on August 7, 2006, which provided the public an opportunity to submit comments on the information collection burden resulting from the proposed rule. FNS received no public comments in response to this solicitation. On November 1, 2006, OMB filed comment in accordance with 5 CFR 1320.11(c), requiring FNS to review public comments in response to the proposed rule and address any such comments in the preamble of the final rule.

Under the interim rule, medical documentation by a health care professional licensed to write medical prescriptions is required for the issuance of certain milk alternatives for children and women. The interim food package rule revising the WIC food packages was published in the Federal Register [72 FR 68966] on December 6, 2007. The interim rule provided an extensive public comment period to obtain comments on the impact of the changes experienced during implementation of the new food packages, including this information collection. The interim rule comment period ended February 1, 2010.

A total of 180 comment letters (53 of these form letters) opposed this requirement in the interim rule, primarily the documentation for children to receive soy-based beverage. Commenters stated that the provision is unnecessary, costly and burdensome for participants and physicians, creates barriers to services, and undermines FNS' efforts to provide foods that meet the cultural needs of participants. The National WIC Association and the American Dietetic Association (now known as the Academy of Nutrition and Dietetics) stressed that WIC dietitians and nutritionists are trained health professionals capable of doing a complete nutrition assessment, selecting WIC foods, and providing appropriate education to participants and caregivers, in consultation with the health care provider when warranted.

Based on the experiences cited by WIC State and local agencies related to medical documentation throughout implementation of the new food packages, As a result of rulemaking, FNS no longer requires a health care professional licensed to write

medical prescriptions to provide documentation for children to receive soy-based beverage and tofu as milk substitutes. Also, FNS no longer requires documentation from a health care professional licensed to write medical prescriptions for women to receive tofu in excess of the maximum substitution allowance.

9. Explanation of any payment or gift to respondents.

Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

There are no payments or gifts to respondents.

10. Assurance of confidentiality provided to respondents.

Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

State agencies are required to comply with confidentiality requirements set forth in §246.26(d)(e)(f)(g) and (h) of the WIC regulations. Section 246.26(d)(1)(ii) states that "…the State agency must restrict the use and disclosure of confidential applicant and participant information to persons directly connected with the administration or enforcement of the WIC Program whom the State agency determine have a need to know the information for WIC Program purposes." Section 246.26(e) states that "the State agency must restrict the use or disclosure of confidential vendor information to […] Persons directly connected with the administration or enforcement of the WIC Program or SNAP who the State agency determines have a need to know the information for purposes of these programs," and to "Persons directly connected with the administration or enforcement of any Federal or State law or local law or ordinance." Information obtained from Program applicants, participants and vendors, is kept confidential and will not be disclosed to anyone but the individuals involved

with this data collection or investigation, except as otherwise permitted or required by law or the above-noted provisions of the WIC regulations.

11. Justification for sensitive questions.

Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This submission does not ask any questions of a sensitive nature.

12. Estimates of hour burden including annualized hourly costs.

Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.**

As a result of rulemaking, FNS no longer requires a health care professional licensed to write medical prescriptions to provide documentation for children to receive soy-based beverage and tofu as milk substitutes. Also, FNS no longer requires documentation from a health care professional licensed to write medical prescriptions for women to receive tofu in excess of the maximum substitution allowance. Previously, these requirements had an estimated burden of 4,200 hours. Therefore, the overall information collection burden is estimated to have decreased by 4,200 burden hours annually due to program changes. The total estimated burden hours will decrease from 4,024,697 to 4,020,497. For details, see the attached burden table.

The following table shows the monetary costs of these burden hours for each type of respondent, and the total monetary costs for all of the respondents:

Table A.12.1 Burden Estimates and annualized cost to respondents

(a) Description of the Collection Activity	**(b) Estimated Total Annual Burden on Respondents (Hours)**	**(c)* Estimated Average Income per Hour**	**(d) Estimated Cost to Respondents**
#0584-0043 State and local staff	3,212,682	$23.54	$75,626,534
#0584-0043 Applicants	615,829	$7.25	$4,464,759
#0584-0043 Vendor staff	191,987	$12.55	$2,409,437
Totals	4,020,497		$82,500,730

* These median hourly rates were obtained from the U.S. Department of Labor, Bureau of Labor Statistics, May 2012 National Industry-Specific Occupational Employment and Wage Estimates (http://www.bls.gov/oes/).

The average of the State and local staff mean hourly wages is $23.54 (($24.31 + $22.77) / 2). (http://www.bls.gov/oes/current/naics4_999200.htm and

http://www.bls.gov/oes/current/naics4_999300.htm respectively). For vendor staff, the average hourly rate is $12.55, which is the mean of all occupations in the Grocery Stores category of the Retail Trade section (http://www.bls.gov/oes/current/naics4_445100.htm). The $7.25 hourly rate for applicants for Program benefits is the Federal minimum wage as of July 2009 (U.S. Department of Labor,

http://www.dol.gov/dol/topic/wages/minimumwage.htm).

13. Estimates of other total annual cost burden.

Provide estimates of the total annual cost burden to respondents or record keepers resulting from the collection of information, (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

There are no capital/start-up or ongoing operation/maintenance costs

associated with this information collection.

14. Annualized cost to the Federal government.

Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

(a) Federal cost of rulemaking (promulgation, preparation of guidance, training and implementation):

(1) FNS National Office Staff: (promulgation, preparation of guidance, training)	10 Full Time Equivalents (FTEs)
FNS Regional Staff: (training, implementation)	10 FTEs
	20 FTEs x $80,903* =
	Subtotal: $1,618,060
(2) Mailing and telephone:	2,000
Publication costs:	4,000
	Subtotal: $6,000

Federal Rulemaking Cost Total: $1,624,060

(b) Federal cost of program maintenance (reporting and recordkeeping, monitoring, technical assistance, review and analysis):

(1) FNS National Office Staff: 16 FTEs
(recordkeeping, analysis)

FNS Regional Staff: 40 FTEs
(reporting and recordkeeping, monitoring, technical assistance, review, analysis)

56 FTEs x 80,903*

Subtotal: $4,530,568

(2) Mailing and telephone: $2,000

Subtotal: $2,000

Federal Program Maintenance Cost Total: $4,532,568

TOTAL FEDERAL COSTS: $6,156,628

* Based on an average $80,903 annual salary (Average of GS-11, 12, 13 salaries, Step 6, from the U.S. Office of Personnel Management Salary Table 2012-RUS, effective January 2012.)

15. Explanation for any program changes or adjustments.

Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

FNS is requesting 4,020,497 burden hours for an overall decrease of 4,200 burden hours and 83,991 annual responses due to program changes in rulemaking. FNS no longer requires a health care professional licensed to write medical prescriptions to provide documentation for children to receive soy-based beverage and tofu as milk substitutes. Also, FNS no longer requires documentation from a health care professional licensed to write medical prescriptions for women to receive tofu in excess of the maximum substitution allowance.

16. Plans for tabulation and publication and project time schedule.

For collections of information whose results are planned to be published, outline plans for tabulation and publication.

The information covered by this collection is not for publication. Some information, however, may be shared with contractors that are completing studies about the WIC Program and may be used, in aggregate form, in resulting publications.

17. Reason display of OMB expiration date is inappropriate.

If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

This submission is not seeking OMB approval to not display the expiration date.

18. Exceptions to certification for Paperwork Reduction Act submissions.

Explain each exception to the certification statement identified in Item 19 "Certification for Paperwork Reduction Act."

There are no exceptions to the certification statement.