

**SUPPORTING STATEMENT - SPECIAL SUPPLEMENTAL
NUTRITION PROGRAM FOR WOMEN, INFANTS AND CHILDREN (WIC)
REGULATIONS - DISCRETIONARY WIC VENDOR PROVISIONS IN THE
CHILD NUTRITION AND WIC REAUTHORIZATION ACT OF 2004,
P.L. 108-265**

Justification

1. Explain the circumstances that make the collection of information necessary.

The WIC Program is authorized by the Child Nutrition Act of 1966 (Attachment 1), as amended, and is administered by State and local agencies in accordance with WIC Program regulations at 7 CFR Part 246 (Attachment 2). 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). 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 State agencies administer the WIC Program with funds provided by the USDA Food and Nutrition Service (FNS) pursuant to annual Federal-State agreements. The local agencies administer the WIC Program pursuant to annual or multi-year written agreements with State agencies. The local agencies certify participants and provide them with food instruments and nutrition education. The participants transact the food instruments for food at authorized retail vendors.

This submission revises a currently approved collection, OMB No. 0584-0043. The revision would incorporate the information collection burden associated with requirements contained in the draft FNS Proposed Rule, “Discretionary WIC Vendor Provisions in the Child Nutrition and WIC Reauthorization Act of 2004, P.L. 108-265.” (Attachment 3). This draft proposed rule has been submitted to OMB for clearance.

The reporting and recordkeeping burdens addressed in the proposed rule are necessary to fulfill the responsibilities of the U.S. Department of Agriculture (USDA) Food and Nutrition Service (FNS) for the WIC Program under P.L. 108-265, as discussed below.

2. **Indicate how, by whom, and for what purpose the information is to be used.**

P.L. 108-265 requires WIC State agencies to: 1) notify WIC-authorized retail vendors of an initial violation in writing, for violations requiring a pattern of occurrences in order to impose a sanction, before documenting a subsequent violation, unless notification would compromise an investigation; 2) maintain a list of State-licensed wholesalers, distributors, and retailers, and infant formula manufacturers registered with the Food and Drug Administration, from which WIC-authorized retail vendors would be required to purchase infant formula; and, 3) prohibit the authorization of or

payments to WIC-authorized vendors that derive more than 50 percent of their annual food sales revenue from WIC food instruments (“above-50-percent vendors”) and which provide incentive items or other free merchandise, except food or merchandise of nominal value, to program participants or customers unless the vendor provides the State agency with proof that the vendor obtained the incentive items or merchandise at no cost. Finally, this rule also proposes to adjust the vendor civil money penalty (CMP) levels to reflect inflation.

The proposed rule would require a State agency to set forth policies and procedures in their WIC State Plan regarding the notification of violations provided to vendors; this would involve a reporting burden. The notice of violation, or the State agency’s determination not to send the notice because it would compromise an investigation, must be documented in the vendor file; this would involve a recordkeeping burden.

The proposed rule would require a State agency to set forth policies and procedures in their WIC State Plan regarding the list of infant formula suppliers; this would involve a reporting burden. Also, the creation of the list would involve a recordkeeping burden.

The proposed rule would require a State agency to approve or disapprove the requests of above-50-percent vendors to provide incentive items to customers. The State agency would need to maintain a record of these approvals and disapprovals in the vendor files, thereby incurring a recordkeeping burden.

Finally, the proposed rule would require State agencies to use new maximum amounts, as adjusted for inflation, when calculating the civil money penalties (CMPs) imposed on vendors in lieu of disqualifications when disqualification would jeopardize participant access to supplemental food. The CMP calculation process remains the same; only the maximum amounts per violation and per investigation would change. Thus there would be no new reporting or recordkeeping burdens. The sanction determination process, involving either disqualifications or CMPs, is an integral part of the compliance investigation process, which is currently covered under the approved information collection OM8 No. 0584-0043 regarding § 246.12(j)(4) of the WIC regulations.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques.

The Food and Nutrition Service makes every effort to comply with the E-Government Act (eGov). FNS encourages its State agency partners to offer electronic submission to vendors whenever it is feasible.

Most WIC State agencies and vendors are equipped with Internet technology which could be used for the collections related to the proposed rule.

The proposed rule permits a State agency to provide the list of infant formula suppliers to vendors on the State agency's web site or by linkage with the web site of the State's licensing agency. Many State agencies have advised FNS that they are doing this. Also, many State agencies are able to prepare and transmit their State Plans using simplified electronic formats developed by FNS, thereby simplifying and reducing the paperwork burdens related to the State Plan amendments which would be needed for this proposed rule.

Many WIC State agencies have automated management information and food delivery systems 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. State agency use of automated management information systems also 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 high priority of the WIC Program.

4. Describe efforts to identify duplication.

The collection which would be added by this proposed rule would not duplicate any other collection.

5. Describe impacts on small businesses or other small entities (items of OMB Form 83-I).

This proposed rule would not have any adverse information collection impact on any small businesses or other small entities. State agencies are not small businesses or small entities. Some retail vendors are small businesses.

The requirement for notification of violations would impact on a very small number of vendors. FNS estimates that only 2,300 of the 50,000 vendors would be impacted by this requirement, based on the number of vendors which annually commit violations which involve a pattern. Also, many of these vendors may not receive a notification of violation, since the State agency has the option to not send such notification if it would compromise an investigation. Moreover, there is no requirement for the vendors to keep their copies of this notification or to respond to the State agency concerning the matter.

A State agency may require a vendor to present receipts or invoices to confirm that the vendor had purchased infant formula only from a source set forth on the list of infant formula suppliers provided to the vendors by the State agency.

However, it is normal business practice to keep receipts of expenses, so that this would not be a new recordkeeping imposed by this rule. The reporting would only involve showing the receipt or invoice to the State agency or providing a copy of the receipt or

invoice to the State agency. Moreover, the proposed rule does not actually require this presentation of infant formula receipts and invoices, because the existing WIC regulations already provide the State agency with authority to identify records which must be maintained by the vendor; reviewing receipts and invoices for WIC supplemental foods is not a new monitoring practice in the WIC Program.

A State agency might also require an above-50-percent vendor to present receipts for their purchase of incentive items, in order to show that the incentive items do not exceed the less-than-\$2 nominal value established by USDA. However, as previously noted, it is normal business practice to keep receipts of expenses, so that this would not be a new recordkeeping burden imposed by this rule. Also, many State agencies are minimizing the information collection for both themselves and the vendors by combining the approval of incentive items with the existing process for the approval and periodic re-approval of vendor agreements. Moreover, the rule would permit State agencies to prohibit all vendor incentive items, obviating the need for an approval process; many State agencies have indicated an interest in doing this. Finally, FNS estimates that only 2,000 of the 50,000 vendors are above-50-percent vendors; other kinds of vendors are not subject to the incentive item restrictions.

As previously noted, there is no information collection involved with the inflation adjustment for civil money penalties.

6. Describe the consequences to Federal program or policy activities if the collection is not conducted or is conducted less frequently.

The mandates of P.L. 108-265 could not be implemented without the minimal information collections needed for this rule. If vendors are not provided with notification of violations, their due process rights would be abrogated. If vendors are not required to obtain infant formula from licensed suppliers, the health of WIC infant participants would be jeopardized. If the restrictions on incentive items are not implemented, costs for the WIC Program would increase.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner that is inconsistent with 5 CFR 1320.6.

All of the reporting requirements related to the proposed rule conform to the parameters of 5 CFR 1320.6.

8. Provide a copy and identify the date and page number of publication in the *Federal Register* of the agency's notice, required by 5 CFR 1320.8(d).

(a) 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 format (if any), and on the data elements to be recorded, disclosed, or reported.

This proposed rule has not yet been published. The proposed rule provides a 60-day notice for comments on the paperwork burden of the rule.

(b) Consultation with representatives of those from whom information is to be obtained.

As previously noted, WIC State agencies would be impacted by the information collection requirements associated with the provisions set forth in this proposed rule. In December and April 2005, FNS issued policy guidance to WIC State agencies on the implementation of the legislative requirements addressed in this proposed rule. In response, FNS received a number of questions which resulted in informal discussions with State agency officials and other stakeholders on program implementation. Much of the discussion in the preamble of this rule reflects the substance of those consultations. Also, FNS will inform the State agencies of the publication of the proposed rule to ensure adequate time for providing comments on the proposed rule's reporting requirements. FNS will analyze all comments received in response to the Notice and make any necessary changes in finalizing this rule.

9. Explain any decision to provide any payment or gift to respondents.

There are no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents.

No confidential information is involved with the proposed rule.

11. Provide additional justification for any questions of a sensitive nature.

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

12. Provide estimates of the hour burden of the collection of information.

(a) Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

The attached narrative, "Estimate of the Collection of Information Burden for the Special Supplemental Nutrition Program for Women, Infants and Children (OMB #0584-0043)," explains the estimated burden for the information collection covered in this submission and also summarizes the previously approved reporting and recordkeeping burdens (Attachment 4). The attached spreadsheet, "WIC Program Reporting and Recordkeeping Requirements Spreadsheet (OMB #0584-0043)," shows how the burden hours for this information collection were calculated and also lists the previously approved information collection under OMB #0584-0043, including a number of adjustments (Attachment 5).

(b) Provide separate hour burden estimates for each form and aggregate the hour burden in Item 13 of OMB Form 83-I.

A form has not been developed for this proposed rule. The previously approved forms are:

- OMB #0584-0045 - FNS-798 & FNS 798A, WIC Monthly Financial Management and Participation Report and Addendum (Section 246.25(b)(1)).
- OMB #0584-0332 - Federal/State Agreements (Section 246.3 (c)).
- OMB #0584-0401 - The Integrity Profile (TIP) Report (Section 246.12(i)(3)).

Submissions to OMB for forms are made separately from submissions to OMB for the regulations.

(c) Provide estimates of the annualized cost to respondents for the hour-burdens for collections of information.

Currently Approved Burden Hours	3,050,545.00
Estimated Burden this submission	3,094,326.00
TOTAL RESPONDENT COSTS:	\$68,755,923.72

* At \$22.22 per burden hour, including overhead costs, office supplies, etc. This rate was obtained from the U.S. Department of Labor, Bureau of Labor Statistics, National Compensation Survey: Occupational Wages in the United States.

13. Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information.

- (a) Include a total capital and start-up component (annualized over its expected useful life), and a total operation and maintenance and purchase of services component.**
- (b) Present ranges of cost burdens and explain the reasons for the variance.**

There are no startup or annual maintenance costs. All costs associated with the hour burden are shown in the responses to Items 12 and 14 of this document.

14. Provide estimates of annualized cost to the Federal government.

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

(1) FNS National Office Staff:	10 staff years
FNS Regional Staff:	<u>10</u> staff years
	20 staff years

Subtotal: \$1,400,000

(2) Overhead cost, travel, office supplies, etc.:	\$165,000
Mailing and telephone:	3,000
Publication costs:	3,000
Distribution costs:	<u>1,000</u>

Subtotal: \$172,000

Federal Program Maintenance Costs: \$1,572,000*

(b) Federal cost of prom-am maintenance (reporting and recordkeeping, monitoring, assistance, review and analysis):

(1) FNS National Office Staff:	16 staff years
FNS Regional Staff:	40 staff years
	56 staff years

Subtotal: \$3,920,000*

* At \$70,000 per staff year

(2) Overhead cost, travel, office supplies, etc.:	\$275,000
Mailing and telephone:	<u>\$3,000</u>

Subtotal: \$278,000

Federal Program Maintenance Costs: \$4,198,000

TOTAL FEDERAL COSTS: \$5,770,000 (\$1,572,000 + \$4,198,000)

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

The reasons for the program changes are set forth under #2 above. Most of the adjustments are needed for the approved information burdens which have been calculated using the number of State agencies or vendors. Since the last submission, the

Commonwealth of the Northern Mariana Islands has joined the WIC Program as a new State agency, effective October 1, 2005. This means that the WIC Program is now administered by 90 State agencies (50 Geographic States, 34 Indian Tribal organizations, the District of Columbia, and 5 Territories). Also, FNS estimates that the number of retail vendors has increased from 45,178 to about 50,000 since the last submission.

FNS is requesting 3,094,326 hours, of which 12,095 hours are due to program change associated with this rule and 31,686 are due to an adjustment. This would be an increase of 43,781 hours to the currently approved 3,050,545 hours.

16. For collection of information whose result will be published, outline plans for tabulation and publication.

There are no plans to publish the results of this information collection for statistical use.

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

We are not seeking OMB approval to not display the expiration date.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-1.

There are no exceptions to the certification statement.