

SUPPORTING STATEMENT FOR
0584-0043

“WIC DISCRETIONARY VENDOR FINAL RULE”

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A. Justification

1. Circumstances that make the collection of information necessary.

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. The WIC Program is authorized by the Child Nutrition Act of 1966, as amended, (CNA) 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" (e.g., checks or vouchers) used by WIC participants to purchase WIC-authorized food. 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, such as certification, issuance of food instruments, and nutrition education.

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 FNS Final Rule, "Discretionary WIC Vendor Provisions in the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108-265." (Attachment 3). This final rule has been submitted to OMB for clearance. This final rule follows up on the FNS Proposed Rule, "Discretionary WIC Vendor Provisions in the Child Nutrition and WIC Reauthorization Act of 2004, P.L. 108-265," 71 FR 43371, August 1, 2006, which contains the request for comments on the information collection burden at page 43374 (Attachment 4). The final rule implements three provisions of the CNA, as amended:

- 1) As required by 203(c)(5) of P.L. 108-265, which amended section 17(f) of the CNA, this final rule requires WIC State agencies to 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. The intent of this provision is to enhance the due process rights of vendors by ensuring that they have an opportunity to correct violations before sanctions become necessary.
- 2) As required by section 203(e)(8) of P.L. 108-265, which amended section 17(h)(8)(A) of the CNA, State agencies are required to maintain a list of State-licensed wholesalers, distributors, and retailers, and infant formula manufacturers registered with the Food and Drug Administration (FDA), and WIC-authorized retail vendors are required to purchase infant formula only from suppliers on the list. The intent of

this provision is to prevent defective infant formula from being consumed by infant WIC participants.

3) As required by section 203(e)(13) of P.L. 108-265, which amended section 17(h) (14) of the CNA, State agencies are required to prohibit the authorization of or payments to vendors that derive more than 50 percent of their annual food sales revenue from WIC food instruments (“above-50-percent vendors”) 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. The intent of this provision is to ensure that the WIC Program does not pay the cost of incentive items provided by above-50-percent vendors in the form of high food prices.

Finally, this rule also establishes a process for the adjustment at least once every four years of all vendor civil money penalty (CMP) levels to reflect inflation; under the current regulations, the CMP levels for some but not all vendor violations have been previously adjusted for inflation. Initially, this would have the effect of raising the maximum CMP level from \$10,000 to \$11,000 per violation, and raising the CMP level from \$40,000 to \$44,000 as the maximum amount for all violations occurring during a single investigation, for those WIC CMP levels which have not previously been adjusted for inflation. Imposing CMP’s does not involve an information collection burden since the State agency uses information already in its possession - the vendor’s average redemption level and the length of the disqualification which otherwise would have been imposed for the same offense - to determine CMP amounts; only the maximum levels for these amounts will change as a result of the discretionary vendor final rule. (See §246.12(l)(1)(x) for the formula which is required for calculating CMP amounts.)

The attached “Estimate of the Information Collection Burden” describes the comments on the proposed rule related to the information collection burden, and sets forth the program changes and adjustments in detail, as well as describing in detail all of the information collections included under OMB #0584-0043.

2. Purpose and use of the information.

The entire information collection involves 36 regulatory provisions. One of these provisions, §246.4 providing the State Plan requirements, consists of 27 paragraphs. The attached “Estimate of the Collection of Information Burden” and “WIC State Plan Information Collection Burden Hours” describes all of these provisions in detail.

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

The information collections for these provisions mostly 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. The information collections related to the discretionary vendor final rule include three reporting requirements and three

recordkeeping requirements:

Reporting

1) Section 246.4(a)(14)(iii) requires WIC State agencies to set forth policies and procedures in their WIC State Plans for a) notifying a retail vendor in writing when an investigation reveals an initial violation for which a pattern of violations must be imposed in order to impose a sanction, unless the State agency determines that the notice would compromise an investigation, and for b) incentive items approved by the State agency for above-50-percent vendors to provide to WIC participants or other customers.

2) Section 246.4(a)(14)(xvii) requires WIC State agencies to set forth policies and procedures in their WIC State Plans for annually compiling and distributing to authorized WIC retail vendors a list of infant formula wholesalers, distributors, and retailers licensed under State law, and infant formula manufacturers registered with the FDA.

3) Section 246.12(h)(8) would require above-50-percent vendors to request approval from their WIC State agencies for incentive items which these vendors may provide to WIC participants or other customers.

There were no comments on the information collection burden of these provisions.

Recordkeeping

1) Section 246.12(g)(11), formerly 246.12(g)(10) in the proposed rule, requires WIC State agencies to create a list which must be made available to authorized WIC retail vendors on at least an annual basis, such as on a State agency web site, of infant formula wholesalers, distributors, and retailers licensed in the State in accordance with State law (including State regulations), and infant formula manufacturers registered with FDA.

2) Section 246.12(h)(8) requires WIC State agencies to establish a process for approving or designating incentive items which above-50-percent vendors may provide to WIC participants or other customers. Vendors will need to request approval if the State agency does not designate which incentive items may be used.

3) Section 246.12(l)(3) requires the State agency to notify a vendor in writing when an investigation reveals an initial violation for which a pattern of violations must be established in order to impose a sanction before another such violation is documented, unless the State agency determines, in its discretion on a case-by-case basis, that notifying the vendor would compromise an investigation. Prior to imposing a sanction for a pattern of violations, the State agency would either provide such notice to the vendor, or document in the vendor file the reason(s) for determining that such notice would compromise an investigation.

Several State agencies commented on the information collection burden of these recordkeeping provisions. The attached "Estimate of the Information Collection Burden" describes these comments and responds to them.

b. From whom will the information be collected?

The respondents for the information collection in all provisions are State agencies, local agencies, applicants for program benefits, and retail vendors; for the discretionary vendor final rule, the respondents are State agencies and retail vendors.

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

The information collections for all 36 provisions mostly 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 discretionary vendor final rule requires the State agency to set forth policies and procedures in their WIC State Plan regarding the notification of violations provided to vendors; the list of infant formula suppliers from whom vendors may obtain infant formula; and, the designation of incentive items which above-50-percent vendors may provide to customers. The State Plan must be submitted to FNS annually; this is a reporting burden for the State agency. FNS uses the State Plan to determine whether the State agency has policies and procedures in place to comply with FNS regulations. FNS approval of the State Plan is a prerequisite for FNS approval of the Federal-State Agreement providing the State agency with federal WIC grant funds to operate the program for another fiscal year.

The discretionary vendor final rule also requires the State agency to notify a vendor of a violation found during a compliance investigation before documenting an additional violation which would result in sanctions. The State agency must either provide the notification to the vendor, which would be documented in the vendor file, or make a determination that the notification would compromise an investigation, which would also be documented in the vendor file. Thus this is a recordkeeping requirement for the State agency. The purpose of this requirement is to provide vendors with an opportunity to correct violations before the number of violations reaches the threshold for imposing sanctions.

The discretionary vendor final rule also requires the State agency to create a list of State-licensed suppliers of infant formula and infant formula manufacturers registered with FDA; this is a recordkeeping burden for the State agency. The State agency must make this list available to vendors, such as on a State agency web site, on at least an annual basis. The purpose of this list is to provide vendors with the identification of suppliers or manufacturers from whom the vendors are allowed to purchase infant formula.

Finally, the discretionary vendor final rule also requires the State agency to restrict the incentive items which above-50-percent vendors may provide to WIC participants or other customers. The State agency may either require its vendors to seek approval for incentive items or provide a list of pre-approved incentive items to vendors as part of the vendor agreement. The purpose of this requirement is to prevent the costs of these incentive items from increasing the food prices charged to WIC.

d. How will the information be collected?

At least half of the State agencies submit their State Plans to FNS in an electronic format. State agencies have developed forms for local agencies to submit certification and financial data to the State agencies; although State agency practices vary, these forms are often submitted electronically, either directly or via email attachments or by facsimile. Most of the 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. The information will be collected using various forms developed by FNS for State agency use approved by OMB:

OMB #0584-0045: Expiration date 9/30/2011, FNS-798 & FNS 798A, WIC Monthly Financial Management and Participation Report and Addendum (Section 246.25(b)(1)).

OMB #0584-0332: Expiration date 10/31/2009, Federal/State Agreements (Section 246.3 (c)).

OMB #0584-0401: Expiration date 1/31/2009, The Integrity Profile (TIP) Report (Section 246.12(i)(3)).

OMB #0584-0431: Expiration date 7/31/2011, WIC Local Agency Directory (Section 246.25(c)).

e. How frequently will the information be collected?

The certification and financial information is reported monthly. The State Plan, the vendor infant formula list, and the vendor incentive item requests for approval are collected annually, and each retail State agency provides a notification of violations on average to 27 vendors per year, or documents the reason for not doing so.

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 and other Congressional offices. The information may also be made available to private contractors conducting research for FNS. The information may also be made public when the reports drafted by the contractors are issued. To protect the confidentiality of participants and vendors, this 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?

Collections have increased more for food delivery system requirements (vendor management and the processing of food instruments) than for any other program area during the current decade, reflecting the increased concern of the Administration and Congress for holding down program food costs and protecting

program integrity. However, despite this substantial increase, the resulting total of all burden hours for food delivery systems is only 12 percent of the total of all burden hours for OMB No. 0584-0043.

There were 73,822 burden hours for food delivery systems during the 1990's. Then, the Food Delivery Systems Final Rule, 65 FR 83248, December 29, 2000, added 102,354 burden hours for food delivery systems. FNS further added 136,230 burden hours based on the Vendor Cost Containment Interim Rule, 70 FR page 71708, November 29, 2005. FNS has now submitted a total of 107,082 burden hours to OMB for the discretionary vendor final rule (including adjustments), which, when combined with the other food delivery burden hours, will result in the grand total of 419,488 burden hours for food delivery. The grand total of all burden hours under OMB No. 0584-0043 will be 3,451,206.

3. *Use of information technology and burden reduction.*

FNS makes every effort to comply with the E-Government Act of 2002. FNS encourages its State agency partners to offer electronic submission to local agencies and vendors whenever it is feasible and offers earmarked funding for enhancing State agency Management Information Systems (MIS).

The restrictions on incentive items in the discretionary vendor rule apply to above-50-percent vendors. Thus State agencies must be able to identify these vendors. To assist State agencies in that regard, FNS has developed an automated method for matching a vendor's WIC redemptions with that vendor's Food Stamp Program (FSP) redemptions in order to determine whether that vendor is an above-50-percent or regular vendor; if a vendor's FSP 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 FSP redemptions exceed WIC redemptions for 88 percent of authorized vendors, thus eliminating the need for further documentation for 88 percent of the authorized vendors.

Also, the discretionary vendor rule permits State agencies to provide its list of infant formula suppliers to vendors on a web site instead of a paper format.

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. For example, State agencies are able to prepare and transmit their State Plans using simplified electronic formats developed by FNS. 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 priority within the WIC Program.

4. *Describe efforts to identify duplication and use of similar information.*

There are no similar information collection efforts.

5. *Impacts small businesses or other small entities.*

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. WIC State agencies are authorized by the WIC regulations to collect certain information from all local agencies, retail vendors, and contractors, regardless of size, to ensure the efficient and effective operation of the WIC Program. Furthermore, several provisions of the discretionary vendor rule provide considerable flexibility to all WIC State agencies regarding the manner of implementing its requirements. For example, State agencies may provide above-50-percent vendors with a pre-approved list of incentive items, so that these vendors would not need to request the State agency's approval for incentive items.

6. *Consequences of collecting the information less frequently.*

If the information were collected less frequently, the 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:*

- ***Requiring respondents to report information to the agency more often than quarterly;***

The reporting of WIC participation and expenditure data occurs monthly, rather than quarterly, to enable FNS to meet a statutory requirement to reallocate funds from a State agency not using the funds to a State agency which needs the funds. The ability to promptly reallocate funds is vitally important because WIC is not an entitlement program. A State agency in need of additional funds must cease certifying new participants until more funds are received. Since WIC food benefits are provided to participants on a monthly basis, monthly reporting provides FNS with the most up-to-date information on the level of WIC grant funds remaining with the State agencies. Participation and expenditure data reporting is covered by OMB collection #0584-0045 (expiration date 7/31/2008).

- ***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.

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 and efforts to consult with outside agencies.*

The invitation for comments was set forth on page 43374 of the Discretionary WIC Vendor Provisions Proposed Rule, 71 FR 43371, August 1, 2006, as required by 5 CFR 1320.8(d). Five comments addressed one or more of the proposed provisions.

Also, in December and April 2005, FNS issued policy guidance to WIC State agencies on the implementation of the legislative requirements addressed in this final rule, since those requirements were effective according to the law on October 1, 2004. In response, FNS received a number of questions which resulted in informal discussions with State agency officials and other stakeholders on the implementation of these legislative requirements. Much of the discussion in the preamble of the proposed rule reflected the substance of those consultations.

9. *Explanation of any payment or gift to respondents.*

There are no payments or gifts to respondents.

10. *Assurance of confidentiality provided to respondents.*

State agencies are required to comply with confidentiality requirements set forth in §246.26(d)(e)(f)(g) and (h) of the WIC regulations. Information obtained from program applicants, participants and vendors, must be 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.*

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

12. *Estimates of hour burden including annualized hourly costs*

The estimated total respondent burden is 10,353,618 burden hours over the 3 year clearance period (3,451,206 annual burden hours x 3). This estimate includes approximately 1,990,457 respondents per year. 0.11 burden hours (6 minutes and 36 seconds) is the estimated average number of burden hours per respondent. The actual respondent burden is dependent upon respondent type. For the details, see ATTACHMENT A: WIC PROGRAM REPORTING AND RECORDKEEPING REQUIREMENTS (OMB #0584-0043)

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	3,034,233	\$24.69	\$74,915,212.77
#0584-0043 Applicants	292,983	\$6.55	\$1,919,038.65
#0584-0043 Vendor staff	123,990	\$21.16	\$2,623,628.40
Totals	3,451,206	---	\$79,457,879.82

These median hourly rates were obtained from the U.S. Department of Labor, Bureau of Labor Statistics, May 2007 National Industry-Specific Occupational Employment and Wage Estimates. The average of the State and local staff average rates is \$24.69, as shown above. The \$6.55 hourly rate for applicants for program benefits is the Federal minimum wage as of July 2008 (U.S. Department of Labor Employment Standards Administration, September 23, 2008, www.dol.gov/esa/minwage/chart.htm). For vendor staff, the hourly rate shown above, \$21.16.

13. Estimates of other total annual cost burden to respondents or record keepers.

There are no capital/start-up or ongoing operation/maintenance costs associated with this information collection.

14. Annualized cost to the Federal government.

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

(1) FNS National Office Staff: 10 Full Time Equivalents (FTEs)
 FNS Regional Staff: 10 FTEs
 20 FTEs
 Subtotal: \$1,535,980*

(2) Overhead cost, travel, office supplies, etc.: \$166,000
 Mailing and telephone: 4,000
 Publication costs: 4,000
 Distribution costs: 2,000
 Subtotal: \$176,000

Federal Rulemaking Costs: \$1,711,980

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

(1) FNS National Office Staff: 16 FTEs

FNS Regional Staff: 40 FTEs
 56 FTEs

Subtotal: \$4,300,744*

* Based on an average \$76,799 annual salary (Average of GS-11, 12, 13 salaries, Step 6, from the U.S. Office of Personnel Management Salary Table 2008-RUS effective January 2008.)

(2) Overhead cost, travel, office supplies, etc.: \$276,000
 Mailing and telephone: \$4,000
 Subtotal: \$280,000

Federal Program Maintenance Costs: \$4,580,744

TOTAL FEDERAL COSTS: \$6,292,724 (\$1,711,980 + \$4,580,744)

15. Explanation for any program changes or adjustments.

FNS is requesting 3,451,206 burden hours for an overall increase of 400,661 (8,680 burden hours due to program changes and 391,981 burden hours due to adjustments). The adjustments are mostly based on the inclusion of the burden hours for applicants for program benefits. The program change increase in burden hours is due to the new statutory requirements which have been introduced into the WIC regulations by the discretionary vendor rule.

Also, the total number of respondents has decreased from 15,595,000 to 1,990,457. The applicants for program benefits have been added as respondents, but the previous number of respondents had been greatly overstated.

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

The public FNS WIC web site is updated monthly with aggregate financial and participation data under "Funding and Program Data" with data from the funding and participation reports provided to FNS by the State agencies. Also, aggregate vendor data based on the annual State agency TIP reports provided to FNS are presented annually on the FNS WIC web site in a document entitled "TIP Report" under "Resources."

17. Reason display of OMB expiration date is inappropriate.

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

18. Exceptions to certification for Paperwork Reduction Act submissions.

There are no exceptions to the certification statement.