

Estimate of the Information Collection Burden for the Special Supplemental Nutrition Program for Women, Infants and Children (OMB #0584-0043)

This document explains the calculation of the information collection burden for the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) under OMB #0584-0043, as revised to include the reporting and recordkeeping requirements contained in the final rule “Discretionary WIC Vendor Provisions in the Child Nutrition and WIC Reauthorization Act of 2004, P.L. 108-265,” which is currently in clearance. Some of the new provisions added to the WIC Regulations by this proposed rule would increase the reporting and recordkeeping burdens, as highlighted below in bold. The discussion of these changes in the information collection burden due to program changes, as well as adjustments to the information collection burden since the previous submission, is highlighted in bold below. The resulting recalculations are also reflected in the attached spreadsheet.

Five comments addressed the information collection burden of the 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. The discussion of these comments is also highlighted in bold below. Some of these comments addressed the information collection burden of more than one provision of the proposed rule and thus are referred to more than once.

Also, adjustments were necessary for several reasons:

- For the first time, burden hours have been calculated under OMB #0584-0043 for applicants for program benefits, resulting in 292,983 burden hours; see below under “Affected Public: Applicants for Program Benefits.”
- Also, the total number of respondents has decreased from 15,595,000 to 1,990,457. Although the applicants for program benefits have been added as respondents, the previous number of respondents had been greatly overstated.
- The existing information collection burden approved under OMB #0584-0043 needs to be adjusted to reflect that a new WIC State agency was added during Fiscal Year 2006 (the Commonwealth of the Northern Mariana Islands), resulting in a total of 90 WIC State agencies.
- FNS now estimates that there are 47,000 WIC-authorized retail vendors instead of the 45,000 vendors previously estimated.

AFFECTED PUBLIC: STATE AND LOCAL AGENCIES

REPORTING REQUIREMENTS

1. Section 246.4 requires that by August 15 of each year, as a prerequisite for the receipt of funds from the Food and Nutrition Service (FNS), the State agency must submit all substantive changes to its State Plan to FNS for approval. The State plan sets forth the State agency's policies and procedures for operating the program. The proposed rule included two new State Plan provisions. Previously, FNS had estimated that each State agency needs 117.33 burden hours annually to update its entire State Plan, resulting in 10,442 total burden hours per year (89 State agencies x 117.33 burden hours).

This final rule adds the two proposed State plan provisions. The first of these two provisions, §246.4(a)(14)(iii), concerns 1) the notification of 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, 2) the approval of incentive items which above-50-percent vendors may provide to WIC participants and other customers. The second provision, §246.4(a)(14)(xvii), concerns the annual 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 Food and Drug Administration (FDA).

There were no comments on the information collection burden of these two provisions. Accordingly, the one reporting burden hour per response set forth in the proposed rule for each these two provisions is requested for this final rule.

Thus 2 hours are added to the previous 117.33 hours per response, increasing to 119.33 hours per response. This results in the addition of 298 burden hours to the previous 10,442 total annual burden hours for the entire State Plan, increasing to 10,740 total annual burden hours for the entire State Plan (119.33 x 90 State agencies = 10,740). 180 of these hours are based on the program change of adding the new requirements for the State Plan, and 118 of these hours are based on the adjustment of adding a new State agency (117.33 x 90 = 10,560; 10,560 - 10,442 = 118 hours based on the adjustment; 119.33 x 90 = 10,740; 10,740 - 10,560 = 180 hours based on the program change; 180 + 118 = 298.

2. Section 246.5(b) requires each organization interested in being authorized as a local agency to submit an application to the State agency. The average local agency agreement is for two years; there are 1870 local agencies; therefore, FNS estimates each year that half (935) local agencies submit applications. Each application requires 2 burden hours to complete. Thus, (935 local agencies x 2 burden hours per application total 1,870 annual burden hours for this provision) which has not changed since the last submission.
3. Section 246.6 requires the State agency to enter into a signed agreement with each local agency, health and human service agency, and private physician that performs WIC functions. The average local agency agreement is for two years; therefore, FNS estimates

each year that half which is 935 local agencies sign agreements with the State agency. Each agreement requires 1.5 burden hours to complete. **Thus FNS estimates 1,403 annual burden hours for this provision (935 local agencies x 1.5 burden hours per agreement) which has changed since the last submission's estimate of 1,247 which contained a mathematical error.**

4. Section 246.7(f)(2)(iii)(A) allows the State agency to extend the 10-day period of notification of eligibility for special nutritional risk applicants to 15 days when the local agency provides written justification of the need for such an extension. Currently, all State agencies have developed policies under which such an extension may be provided. FNS estimates that each year one-sixth or 312 of all local agencies make written requests for such extensions. Each request for an extension requires 0.25 burden hours to complete. FNS estimates 78 annual burden hours for this provision (312 local agencies x 0.25 burden hours per request) which has not changed since the last submission.
5. Sections 246.7(i) and 246.10(d)(1) (formerly 10(c)(1)(v)) require that 1) in §246.7(i), pertinent certification data be collected and recorded by the local agency on a form (or forms) provided by the State agency (usually in the form of computer software) and that participants be notified of their rights and responsibilities, including notification of termination for failure to pick up food instruments, notification of disqualification and notification of expiration of each certification period; and 2) in §246.10(d)(1), that medical documentation must be obtained in order to provide participants with infant formula not covered by the State agency's infant formula rebate contract. (The former §246.10(c)(1)(v) was designated as §246.10(d)(1) by the Food Packages Interim Rule, 72 FR 68966, December 6, 2007.)

Monthly WIC participation is 5,940,588 women and children participants (1,949,149 women + 3,991,439 children) and 2,035,817 infants (7,976,404 total participants). Women and children participants are certified twice per year and infants are certified once per year. FNS estimates that the collection of certification data and the provision of appropriate notifications require ten minutes (0.17 burden hours) per participant and further estimates that 1 percent (0.01) of all infant certifications require an additional two minutes (0.03 burden hours) for the documentation required to issue an infant formula that is not covered by the State agency's infant formula rebate contract.

Thus FNS estimates 2,019,800 total annual burden hours for the certification of women and children under § 246.7(i) ($5,940,488 \times 2 = 11,881,976 \div 1,870$ local agencies = 6,354 per local agency x 0.17 burden hours per response = 2,019,800); 346,089 total annual burden hours for the certification of infants under § 246.7(i) ($2,035,817 \div 1,870 = 1,088.67 \times 1,870 = 2,035,816.8$ rounded up to 2,035,817 x 0.17 = 346,088.89 rounded up to 346,089); and 611 total annual burden hours for the medical documentation needed for infants to receive non-rebate infant formula under § 246.10(d)(1) ($20,358$ infants $\div 1,870 = 10.88$ rounded up to 11 x 1870 = 20,357.99, rounded up to 20,358 x 0.03 = 610.73 rounded up to 611).

6. Section 246.7 (j)(9) requires that when the State agency must suspend or terminate the program benefits of any participant during the participant's certification period due to shortages in program funds, the State agency must issue an advance notice to all affected participants. The State agency is also required to notify FNS prior to taking such action. FNS estimates that 4 State agencies may need to take such action per year. FNS further estimates that providing this notice to FNS would require 0.09 burden hours. Thus FNS estimates the total annual burden for this notice to FNS to be 0.36 burden hours (4 State agencies per year x 0.09 burden hours per notice). This has not changed since the last submission.
7. Section 246.7(k) requires the State agency to ensure that Verification of Certification (VOC) cards are issued to participating migrants and to other participants who are likely to relocate during the certification period. FNS further estimates that issuing these cards to 7,976,404 participants would require 0.09 burden hours. FNS estimates the total annual burden for this provision to be 15,004 burden hours (7,976,404 participants x 0.0209 = 166,706.84 needing VOC cards, rounded up to 166,707 ÷ 1,870 = 89.14 participants provided VOC cards per local agency x 1,870 = 166,706.99 rounded up to 166,707 x .09 = 15,003.63 rounded up to 15,004).
8. Section 246.10(b)(1) requires State agencies to identify foods that are acceptable for use in the Program in accordance with program regulations. This includes identifying which foods, substitutions, brands and packaging the State will authorize for use in the Program. State agencies conduct such food reviews and submit food lists as part of their annual State Plan. FNS estimates that 40 burden hours are needed for each State agency to comply with this provision. Previously, FNS estimated 3,560 total annual burden hours based on 89 State agencies (89 State agencies x 40 burden hours per State agency). **However, one new State agency has been added, so that FNS now estimates 3,600 total annual burden hours for this provision (90 State agencies x 40 burden hours per State agency).**
9. Section 246.11(d)(2) requires each local agency to develop and submit an annual nutrition education plan to the State agency. FNS estimates that 40 burden hours are needed for each local agency to comply with this provision. FNS estimates 74,800 total annual burden hours for this provision (1,870 local agencies x 40 burden hours per local agency). This has not changed since the last submission.
10. Section 246.12(g)(4)(i) of the Vendor Cost Containment Interim Rule, 70 FR 71708, November 29, 2005, requires a State agency to annually collect information needed to determine whether currently authorized vendors and new vendor applicants derive or may be expected to derive more than 50 percent of their annual food sales revenue from WIC food instruments. FNS estimates that each State agency will need 2 burden hours to collect the information required to assess a vendor's status. As previously noted, there are now 90 WIC State agencies.

Further, FNS annually provides each State agency with a report comparing the WIC redemptions to the redemptions of the Supplemental Nutrition Assistance Program

(SNAP, formerly the Food Stamp Program) for each of its vendors which is authorized by SNAP; most WIC-authorized retail vendors are also authorized by SNAP. If a vendor's SNAP redemptions exceed its WIC redemptions, that vendor is considered to be a regular vendor, not an above-50-percent vendor. Thus far, this report has shown that 88 percent of the WIC-authorized vendors have more redemptions than WIC redemptions, thus eliminating the need for State agencies to obtain further documentation from these vendors. As a result, the need for further documentation only concerns 12 percent of the authorized vendors - 5,640 vendors (12 percent x 47,000 = 5,640).

Regarding the 5,640 authorized vendors whose above-50-percent status must be documented, there are about 62.66 such vendors per each State agency ($5,640 \div 90 = 62.66$). Thus FNS now estimates 11,280 burden hours for State agencies ($90 \times 62.66 \times 2 \text{ hours} = 11,280$) for this provision.

11. Section 246.12(g)(4)(ii)(B) of the Vendor Cost Containment Interim Rule requires State agencies to collect the shelf prices for WIC-approved foods from authorized retail vendors twice annually. FNS previously estimated that twice annually each State agency would need 1 burden hour to collect vendors' shelf prices, resulting in 178 burden hours for this provision for State agencies (89 State agencies x 2 collections x 1 burden hour). However, as previously noted, there are now 90 State agencies. Also, the previous estimate did not take into account the number of vendors from whom each State agency would need to collect the shelf prices.

Thus FNS now estimates 94,000 annual burden hours for the State agencies. On average, each State agency must collect the shelf prices from 522.22546.51 vendors twice annually ($47,000 \div 90 = 522.22$; $522.22 \times 2 = 1,044.44$). Thus $1044.44 \times 90 = 93,999.6$ hours, rounded to 94,000.

12. Section 246.12(i)(1) requires the State agency to conduct annual retail vendor training to assure that retail vendors have knowledge of program rules and procedures. FNS estimates that developing the content of retail vendor training materials requires 8 burden hours per State agency. FNS further estimates that it takes 2 burden hours to provide training to each vendor. FNS previously estimated 90,712 annual burden hours for this provision (89 State agencies x 8 burden hours) + (45,000 vendors' x 2 burden hours). **FNS now estimates 720 hours for developing the training (90 State agencies x 8 burden hours = 720) and 94,000 annual burden hours for conducting the training (47,000 vendors $\div 90 = 522.22 \times 90 = 46,999.99$ rounded up to 47,000 x 2 burden hours = 94,000).**

13. Section 246.12(j)(4) requires that each year the State agency conduct compliance investigations of five percent or 2,350 retail vendors. State agencies use a variety of resources to conduct compliance investigations, including State agency staff, contractor staff, local agency staff, law enforcement staff and staff of other WIC State agencies. For each compliance investigation, the State agency is required to conduct either two compliance buys or one inventory audit per retail vendor. FNS estimates that it takes 1 burden hour to conduct a compliance buy and 2 burden hours to conduct an inventory

audit, which results in a total of 2 burden hours per compliance investigation (either 2 compliance buys x 1 burden hour or 1 inventory audit x 2 burden hours). In the previous submission, FNS estimated that the total annual burden for this provision to be 4,500 burden hours (45,000 retail vendors x 0.05 annual compliance investigation requirement x 2 burden hours per compliance investigation). **FNS now estimates 4,700 annual burden hours for this provision (47,000 retail vendors x .05 = 2,350 ÷ 90 = 26.11 x 90 = 2,349.99 rounded up to 2,350 x 2 burden hours per compliance investigation = 4,700).**

14. Section 246.12(o) requires the State agency to develop and implement procedures to document the handling of complaints by participants and vendors. FNS estimates that 10,000 complaints are received a year from participants and vendors nationwide. FNS further estimates it takes 1 burden hour to process each complaint. The total annual burden estimated for this provision is 10,000 burden hours (10,000 complaints ÷ 90 = 111.11 x 90 = 10,000 x 1 burden hour per complaint = 10,000) which has not changed since the previous submission.
15. Section 246.12(q) requires the State agency to identify the disposition of all food instruments as either issued or voided and as either redeemed or unredeemed. Many State agencies currently track their food instrument inventories and disposition through their management information systems. FNS previously estimated that the State agency spends 40 burden hours a year to account for the disposition of its food instruments; the total annual burden estimated for this provision was 3,560 burden hours (89 State agencies x 40 burden hours). **The total annual burden now estimated for this provision is 3,600 burden hours (90 State agencies x 40 burden hours).**
16. Section 246.14(d)(1) requires the State agency to seek FNS approval of costs for automated data processing systems, capital expenditures over \$25,000 and management studies performed by outside agencies, departments and consultants. FNS estimates that each year it receives an average of 15 requests for such approvals and that each request requires 160 burden hours for the State agency to document and submit. The total annual burden estimated for this provision is 2,400 annual burden hours (15 requests per year x 160 burden hours per request) which has not changed since the previous submission.
17. Section 246.16(d) requires the State agency to allocate WIC funds to local agencies based on claims submitted at least quarterly by the local agency. FNS estimates that State agencies distribute funds to 1,870 local agencies 4 times per year each distribution of funds requires 2 burden hours to complete. FNS estimates the total annual burden for this provision to be 14,960 annual burden hours (1,870 x 4 x 2 = 14,960) which has not changed since the last submission.
18. Section 246.17(c)(1) requires FNS to provide written notification of disqualification to all 90 State agencies that fail to comply with program requirements. This provision also requires the State agency to provide written notification to local agencies that it determines have failed to comply with program requirements.

FNS estimates that 10 local agencies will be disqualified per year. FNS further estimates that preparing and providing a written notice of disqualification requires 8 burden hours per notice. FNS estimates the total annual burden for this provision to be 80 burden hours (10 local agency disqualifications per year \div 90 = 0.1111, therefore; 9.99×8 burden hours per notice = 79.9 rounded up to 80) which has not changed since the previous submission.

19. Section 246.19(a) requires the State agency to develop and submit a corrective action plan in response to an FNS management evaluation report. The FNS goal is to conduct management evaluations on all functional areas of the program for all State agencies within a four-year cycle ($0.25 \times 89 = 22$ State agencies). FNS estimates that each corrective action plan takes approximately 40 burden hours to develop. Thus, in the previous submission, FNS estimated the total annual burden for this provision to be 880 burden hours (22×40). **However, due to the addition of one State agency this has been adjusted to 920 annual burden hours ($0.25 \times 90 = 23$ State agencies \times 40 burden hours per corrective action plan = 920).**
20. Section 246.19(b)(5) requires the State agency to review target areas specified by FNS during local agency reviews. Section 246.19(b)(3) requires the State agency to conduct monitoring reviews of each local agency at least once every two years, which means that each year half (0.5) of all local agencies will be reviewed. FNS estimates that the State agency will be required to address targeted areas during local agency reviews once every four years (0.25). FNS further estimates that it takes 2 burden hours for the State agency to address targeted areas during local agency reviews and report the results of the targeted reviews to FNS. FNS estimates 468 total annual burden hours for this provision ($1,870 \div 90 = 20.77$ local agencies \times 0.5 = 10.39 \times 0.25 = 2.60 \times 2 burden hours = 5.20 \times 90 = 468 annual burden hours) which has not changed since the last submission.
21. Section 246.20(a)(2) requires the State agency to develop and submit a corrective action plan to FNS addressing the findings of USDA Office of the Inspector General (OIG) State or local agency audits. FNS estimates that each year OIG performs 4 audits of WIC State and local agencies. FNS further estimates that each audit response requires 40 burden hours to complete. Thus FNS estimates the total annual burden for this provision to be 160 burden hours (4 audits per year \times 40 burden hours per audit response) which has not changed since the last submission.

RECORDKEEPING REQUIREMENTS

1. **Section 246.12(g)(11), which was proposed as §246.12(g)(10), would require WIC State agencies to annually provide authorized WIC retail vendors a list of State-licensed infant formula wholesalers, distributors and retailers, and FDA-registered infant formula manufacturers. FNS has provided the list of FDA-registered manufacturers to State agencies. A State agency would contact the licensing agency in its State to obtain a list of the other suppliers. A State agency could satisfy this**

requirement by linking its web site to the list of licensed suppliers on the web site of the State's licensing agency. FNS previously estimated that this activity would require one burden hour per State agency per year, resulting in an annual total of 90 burden hours in the proposed rule.

Two comments addressed the information collection burden concerning this requirement; both of the comments are from WIC State agencies. One State agency commenter estimated that 500 hours would be required annually to maintain the list. Another State agency commenter estimated that 120 hours had been required for initial compilation and ongoing maintenance of the list. The experiences and views of these two State agencies may not be representative of the other State agencies. However, FNS took these comments in consideration and increased the burden from 1 hour to 50 hours. Accordingly, the total annual burden hours for the list requirement has been increased from 90 to 4,500 (90 State agencies x 50 burden hours = 4,500 total annual burden hours).

2. Section 246.12(h)(1)(i) requires the State agency to enter into written agreements with retail vendors. State agencies require the vendor to submit a signed vendor agreement with the completed application form. The average retail vendor agreement is for two years; therefore, FNS estimates that each year half of all retail vendors (23,500) will submit applications. FNS further estimates that each application requires 1 burden hour to collect and record in the State agency's recordkeeping system; most State agencies use an electronic management information system for this purpose. In the previous submission, FNS estimated the total annual burden for this provision to be 22,500 annual burden hours for State agencies (45,000 retail vendors' \div 2 = 22,500 x 1 burden hour per each vendor application/agreement). **As noted above, FNS now estimates that there are 47,000 WIC-authorized retail vendors, half of whom (23,500) submit an application/agreement annually. Thus FNS now estimates 23,500 annual burden hours for this provision for State agencies (23,500 retail vendors \div 90 State agencies = 261.11 vendors per State agency; 261.11 vendors x 90 State agencies x 1 burden hour per application/agreement = 23,500 annual burden hours for this provision).**
3. Section 246.12(h)(8) would require WIC State agencies to establish a process for approving incentive items which above-50-percent vendors may provide to WIC participants or other customers. For the proposed rule, FNS estimated that about 2,000 authorized vendors will be subject to incentive items restrictions. Thus far, several State agencies have decided not to allow any incentive items at all; therefore, for those State agencies, an approval process is not necessary.

Accordingly, for the proposed rule, we assumed that half of the WIC State agencies will not allow any incentive items at all and half of the approximate 2,000 above-50-percent vendors nationwide reside in those States. We also assumed that little time will be needed to approve/disapprove a request and record it since this process only involves comparison of the vendor's price documentation with the less-than-\$2 limit established for such items in the rule. The State agency may provide above-50-percent vendors with a list of allowable incentive items, valued above the less-than-

\$2 nominal value limit per item; the vendor would indicate on the list which of these incentive items it wishes to use and return the list to the State agency. FNS estimated that 45 State agencies will approve/disapprove incentive items for 1,000 above-50-percent vendors and each approval/disapproval will require 15 minutes for 250 total annual burden hours.

One commenter addressed the burden of the incentive items restrictions. This commenter asserted that the incentive items restrictions were burdensome, requiring complex internal policies and regulations that will result in additional monitoring and enforcement, as well as more training for vendors.

Another commenter stated that it would be burdensome for State agencies to maintain invoices or similar documentation of the vendor's approved incentive items, showing that the cost of each item is either less than the \$2 nominal value limit or obtained at no cost, as required by §246.12(h)(8)(ii). However, the State agency is required to maintain copies of invoices only if the State agency permits vendors to request approval for incentive items not included on a list of acceptable incentive items provided by the State agency; the State agency is not required to maintain copies of invoices if the State agency provides the vendors with a pre-approved list.

The pre-approved list is part of the vendor agreement. The pre-approved list is returned by the vendor to the State agency at the same time the vendor returns the signed vendor agreement to the State agency during the authorization process. The State agency's information burden for maintaining a copy of the signed agreement is accounted for under §246.12(h)(1)(i), as discussed under #2 above. Thus the State agency's information burden for maintaining a copy of the pre-approved list is already accounted for under §246.12(h)(1)(i). However, some State agencies may not use this approach, preferring instead that vendors request approval for incentive items outside of the vendor agreement process; these State agencies would have an information burden under §246.12(h)(8)(ii). Thus far, FNS knows of one State agency with a large number of above-50-percent vendors which uses the vendor agreement process and another State agency which does not permit incentive items at all.

The commenter addressing the State agency's burden of maintaining copies of the invoices also did not estimate the burden hours needed to comply with this requirement. FNS took these comments into consideration and increased the burden hour estimates per response from 0.25 hour to 1 hour per response for State agencies which require approval for incentive items outside of the vendor agreement process.

Further, it is likely that the number of vendors providing incentive items has decreased significantly since the effective date of the Vendor Cost Containment Interim Rule published November 29, 2005, FR 70 pages 71708 - 71731. This rule requires that the average WIC redemptions per food instrument type for above-50-

percent vendors not exceed the regular vendor average WIC redemptions per food instrument type in each State. This requirement has made it increasingly difficult for above-50-percent vendors to incorporate the cost of incentive items into the cost of the supplemental foods which they exchange with program participants for WIC food instruments. Thus, it is likely that the number of above-50-percent vendors providing incentive items has decreased significantly since the effective date of this interim rule. It is also likely that a significant portion of the above-50-percent vendors reside in States where either incentive items are not allowed or if incentive items are allowed, the agreement process is used.

Under the Vendor Cost Containment Interim Rule, all State agencies which authorize above-50-percent vendors must have their vendor cost containment systems certified by FNS; 32 State agencies obtained this certification. FNS estimates that half of these State agencies (16) will either prohibit incentive items altogether or will provide their above-50-percent vendors with a pre-approved list, so that these State agencies will not have a recordkeeping burden regarding incentive items. Also, current FNS data shows that there are about 1,700 above-50-percent vendors. Since half of the State agencies authorizing these vendors will either prohibit incentive items or provide the pre-approved list, FNS also estimates that half of these vendors (850) will not have a reporting burden regarding incentive items. Accordingly, an estimate of 850 total annual burden hours has been submitted to OMB for the incentive items restrictions in this final rule (850 above-50-percent vendors ÷ 16 State agencies = 53.125 above-50-percent vendors per State agency; 16 x 53.125 x 1 hour per response = 850 total annual burden hours).

4. Section 246.12(i)(4) requires the State agency to document the content of its vendor training and the participation of its vendors in the training. FNS estimates that documenting the content of and participation in vendor training takes the State agency 2 burden hours per year. FNS previously estimated 178 annual burden hours for this provision (89 State agencies x 2 burden hours per year). **However, FNS now estimates 180 annual burden hours for this provision (90 State agencies x 2 burden hours per year).**
5. Section 246.12(j)(6) requires the State agency to document the routine monitoring visits it conducts on its vendors. Section 246.12(j)(2) requires the State agency to conduct routine monitoring visits of five percent (0.05) of its vendors each year. FNS estimates that each routine monitoring visit takes 1 burden hour to document. FNS previously estimated 2,250 burden hours (45,000 vendors x 0.05 annual routine monitoring requirement x 1 burden hour per visit). **However, FNS now estimates 2,350 annual burden hours for this provision (47,000 vendors ÷ 90 = 522.22 x 0.05 = 26.11 annual routine monitoring requirement per State agency x 1 burden hour per visit = 26.11 x 90 = 2,349.99 rounded up to 2,350).**
6. Section 246.12(j)(6) requires the State agency to document the compliance investigations it conducts on its vendors. Section 246.12(j)(4) requires the State agency to conduct compliance investigations of five percent (0.05) of its vendors each year. For each

compliance investigation, the State agency is required to conduct either two compliance buys or one inventory audit per vendor. FNS estimates that it takes 1 burden hour to document a compliance buy and 2 burden hours to document an inventory audit, which results in 2 burden hours per compliance investigation (either 2 compliance buys x 1 burden hour, or 1 inventory audit x 2 burden hours). The total annual burden previously estimated for this provision is 4,500 burden hours (45,000 vendors' x 0.05 annual compliance investigations requirement x 2 burden hours per investigation). **However, FNS now estimates 4,700 annual burden hours for this provision (47,000 vendors ÷ 90 = 522.22 x 0.05 = 26.11 annual investigation requirement per State agency x 2 burden hours per investigation = 522.22 x 90 = 4,699.8 rounded up to 4,700).**

- 7. Section 246.12(l)(3) would require 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 violation is documented, unless the State agency determines notifying the vendor would compromise an investigation. Prior to imposing a sanction for a pattern of violations State agency would either provide a notice to the vendor or document in the vendor file the reason(s) that such notice would compromise an investigation. Approximately 2,300 vendors investigated annually commit violations involving a pattern. For the proposed rule, we assumed that little time will be needed to issue or document in a vendor file the notice which presumably will entail a standardized format with space for the vendor's name and address and for listing the violations. Thus, for the proposed rule, FNS estimated that the State agencies will either issue such notices or make such entries in vendor files 2,300 times and that issuing each notice or making such entries will require 15 minutes (0.25 burden hours), resulting in 575 total annual burden hours.**

There were three comments on the information collection burden of this provision. Only one took issue with the number of burden hours estimated in the preamble of the proposed rule. This comment from a State agency stated that it had used approximately 9,180 hours reviewing additional compliance buys and generating notice letters as a result of the notice requirement. This estimate is difficult to substantiate, particularly for one State agency. As previously noted, approximately 2,300 vendors investigated annually by all WIC State agencies are found to be committing types of violations subject to sanctions only if the investigation shows that a pattern of such violations had occurred. Thus, applying the commenter's estimate of 9,180 hours for one State agency to the 2,300 vendors for all State agencies, 4 hours would be required for this activity.

Since a single State agency conducts far fewer than 2,300 such investigations annually, the number of hours needed for a single State agency to issue the notification or document the reason(s) for not doing so would be significantly greater than 4 hours based on this estimate of 9,180 hours. Although this estimate is difficult to grasp, it does indicate that the estimated burden hours in the preamble of the proposed rule may have been too low. Thus the burden for this activity has been increased from 0.25 hours per response to 1 hour per response, for an annual

total for all 90 State agencies of 2,300 burden hours (2,300 vendors ÷ 90 = 25.55 annual notice actions per State agency x 1 burden hour per notice action = 25.55 burden hours per State agency x 90 State agencies = 2,299.5 rounded up to 2,300).

8. Section 246.23(c)(1) requires the State agency to maintain documentation on file regarding the disposition of cases involving improperly obtained or improperly disposed of benefits that result from participant violations. FNS estimates that this recordkeeping requirement takes the State agency 5 burden hours per year. Thus FNS previously estimated that the total annual burden for this provision to be 445 burden hours (89 State agencies x 5 burden hours per year). **However, FNS now estimates 450 annual burden hours for this provision (90 State agencies x 5 burden hours per year).**
9. Section 246.25(a) requires both the State and local agency to maintain full and complete records regarding financial operations and food delivery systems. However, such recordkeeping actually occurs at the State agency level because of the use of centralized MIS systems. FNS estimates that this recordkeeping requirement takes the State or local agency 2 burden hours per month. Previously, FNS estimated 47,016 total annual burden hours for this provision (89 State agencies + 1,870 local agencies = 1,959 x 2 burden hours per month x 12 months per year). **However, FNS now estimates 47,040 total annual burden hours for this provision (90 State agencies + 1,870 local agencies = 1,960 x 2 burden hours per month x 12 months per year).**
10. Section 246.25(a) requires the State and local agency to maintain full and complete records regarding nutrition education. The local agency enters the data into a system hosted at the State agency level. FNS currently estimates annual participation of women and children is 5,940,588 (1,949,149 women + 3,991,439 children) and participation of infants is 2,035,817 (7,976,404 total participants). FNS further estimates that documenting nutrition education contacts takes 1 minute (0.017 burden hours) per participant. Women and children receive nutrition education twice per year (5,940,588 x 2 = 11,881,176 x 0.017 burden hours = 201,979.99 rounded up to 201,980 burden hours) and infants receive nutrition education once per year (2,035,817 infants x 1 x 0.017 burden hours = 34,609 burden hours).

Thus the total annual burden hours currently estimated for women and children nutrition education contacts per year for this provision is 201,980 (1,870 local agencies x 6,354 nutrition education contacts per local agency = 11,881,176 x 0.017 burden hours per contact = 201,980) and the total annual burden hours currently estimated for infant nutrition education contacts is 34,609 which has not changed since the last submission.

11. Section 246.25(a) requires the State and local agency to maintain full and complete records regarding fair hearing procedures. However, such recordkeeping actually occurs at the State agency level because most fair hearings are conducted at the State agency level. FNS estimates that documentation of the fair hearing procedures takes 0.25 burden hours per State or local agency. FNS estimates 490 annual burden hours for this provision (1,870 local agencies + 90 State agencies = 1,960 x 0.25 burden hours per State or local agency) which has not changed from the last submission.

AFFECTED PUBLIC: APPLICANTS FOR PROGRAM BENEFITS

REPORTING REQUIREMENTS

1. Sections 246.7(i) and 246.10(d)(1) require that 1) in §246.7(i) pertinent certification data be collected from women participants or the parents or guardians of infant and child participants (typically a participant herself) and recorded by the local agency on a form(s) provided by the State agency (usually in the form of computer software); and, 2) in §246.10(d)(1) that medical documentation must be obtained from the parents or guardians of infant participants in order for the program to provide these infants participants with infant formula not covered by the State agency's infant formula rebate contract.

The WIC Program certification process has been designed to avoid duplication. The income eligibility of most participants is established by showing the local agency a benefit or identification card which had been provided to the participant by other programs including Medicaid, SNAP, Temporary Assistance for Needy Families (TANF) and State-administered programs with income criteria similar to WIC's. An applicant is income-eligible for WIC based on participation or other family members' participation in one of those programs. Typically, the mother shares this information with the local agency regarding herself and her children all at one time; a separate process is not needed for obtaining this information regarding each individual participant. Monthly WIC participation is 5,940,588 women and children participants (1,949,149 women + 3,991,439 children) and 2,035,817 infants (7,976,404 total participants). Thus, each of the 1,949,149 women participants provide this information to the local agency one time.

Women and children participants are certified twice per year and infants are certified once per year. FNS estimates that providing certification data to the local agency require three minutes (0.05 burden hours) on average per participant and further estimates that 1 percent (0.01) of all infant certifications require an additional two minutes (0.03 burden hours) for the documentation required to issue an infant formula that is not covered by the State agency's infant formula rebate contract.

To conclude, FNS estimates 292,983 total annual burden hours for applicants under §246.7(i) and §246.10(d)(1), as follows:

- 194,915 total annual burden hours for the application of women and children for program benefits under § 246.7(i): $1,949,149 \times 2 \times 0.05 = 194,915$.
- 97,457 total burden hours for the application of infants for program benefits under § 246.7(i): $1,949,149 \times 0.05 = 97,457$.

- **611 total annual burden hours for providing the medical documentation needed for infants to receive non-rebate infant formula under § 246.10(d)(1):**
 $0.01 \times 2,035,813 = 20,358$; $20,358 \times 0.03 = 611$.

AFFECTED PUBLIC: RETAIL VENDORS

REPORTING REQUIREMENTS

1. Section 246.12(g)(4)(i) of the Vendor Cost Containment Interim Rule requires a State agency to collect information needed to determine whether currently authorized vendors and new vendor applicants derive or may be expected to derive more than 50 percent of their annual food sales revenue from WIC food instruments. FNS previously estimated that each vendor will need 1 hour to provide the required information. The total annual burden previously estimated for this provision was 45,000 burden hours (45,000 vendors x 1 burden hour). As previously noted, there are now 47,000 vendors.

Further, FNS annually provides each State agency with a report comparing the WIC redemptions to the redemptions of the SNAP for each of its vendors which is authorized by SNAP. If a vendor's SNAP redemptions exceed its WIC redemptions, that vendor is considered to be a regular vendor, not an above-50-percent vendor. Thus far, this report has shown that 88 percent of the WIC-authorized vendors have more SNAP redemptions than WIC redemptions, thus eliminating the need for State agencies to obtain further documentation from these vendors. As a result, the need for further documentation only concerns 12 percent of the authorized vendors - 5,640 vendors (12 percent x 47,000 = 5,640 x 1 hour = 5,640 burden hours).

Thus FNS now estimates 5,640 burden hours for vendors for this provision.

2. Section 246.12(g)(4)(ii)(B) of the Vendor Cost Containment Interim Rule requires State agencies to collect the shelf prices for WIC-approved foods from authorized retail vendors twice annually. FNS estimated that twice annually each vendor would need 1 burden hour to report shelf prices. Thus FNS estimated 90,000 burden hours for this provision (45,000 vendors x 2 collections x 1 burden hour). As previously noted, FNS now estimates that there are 47,000 vendors, not 45,000.

Thus FNS estimates 94,000 annual burden hours for the vendors (47,000 vendors x 2 collections x 1 burden hour) for this provision.

3. Section 246.12(g)(11), which was proposed as §246.12(g)(10), would require WIC State agencies to annually provide authorized WIC retail vendors a list of State-licensed infant formula wholesalers, distributors and retailers, and FDA-registered infant formula manufacturers. A vendor may only provide WIC participants with infant formula obtained from entities on the list. A State agency may inspect a vendor's infant formula invoices in order to verify compliance. FNS did not propose any information burden hours for vendors related to this requirement.

However, one commenter stated that this requirement would impose an undue burden on vendors because most vendors deal with dozens if not hundreds of suppliers of products within their stores, including numerous jobbers, sub-jobbers, and other sales persons; it would be impossible, this commenter stated, for the vendor to verify the validity of each source of every purchase or to contact the State agency to ascertain the status of the supplier.

The commenter's concerns are unjustified. The source which must be identified is only the source from whom the vendor purchased the infant formula, not the manufacturer or supplier from whom the vendor's source purchased the infant formula. Also, the infant formula list requirement only pertains to "infant formula" as defined in the WIC regulations, which does not include "exempt infant formula" (formulas requiring a medical prescription), "WIC-eligible medical foods," or any other kind of food.

Further, as recognized by § 246.12(h)(3)(xv), vendors are already required to maintain inventory records used for Federal tax reporting purposes, which would include invoices for infant formula, and to make such records available to the State agency upon request. Thus the infant formula list requirement does not impose any new reporting or recordkeeping burden on vendors. Moreover, attaching a copy of an invoice to a vendor application form, or providing a copy to the State agency at some other time, would involve a negligible amount of time.

4. **Section 246.12(h)** requires the State agency to enter into written agreements with retail vendors. State agencies require the vendor to submit a signed vendor agreement with the completed application form. The average retail vendor agreement is for two years; therefore, FNS estimates that each year half (0.5) of all retail vendors will submit application/agreement forms. FNS further estimates that each application/agreement form requires 1 burden hour for the vendor to complete. In the previous submission, FNS only estimated annual burden hours for State agencies for this provision. Thus FNS now estimates 23,500 burden hours for this provision for vendors (47,000 retail vendors x 0.5 of all retail vendors per year x 1 burden hour per application).
5. **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. Much of the discussion above under #3 of the State/local agency recordkeeping burden hours has been repeated here to establish the context for the vendor burden hours regarding this requirement.

For the proposed rule, FNS estimated that about 2,000 authorized vendors will be subject to incentive items restrictions. Thus far, one State agency with a significant number of above-50-percent vendors has decided not to allow any incentive items at all; the approval process is not necessary for this State agency and others which may decide to operate in the same manner.

Accordingly, for the proposed rule, we assumed that half of the WIC State agencies will not allow any incentive items at all and that half of the approximate 2,000 above-50-percent vendors nationwide reside in those States. We also assumed that little time will be needed to approve/disapprove a request and record it, since this process only involves comparison of the vendor's price documentation with the less-than-\$2 limit established for such items in the rule. Indeed, the State agency may provide above-50-percent vendors with a list of allowable incentive items valued at or below the less-than-\$2 nominal value limit per item; the vendor would indicate on the list which of these incentive items it wishes to use and return the list to the State agency. Thus, for the proposed rule, FNS estimated that 45 State agencies will approve/disapprove incentive items for 1,000 above-50-percent vendors, and that each approval/disapproval will require 15 minutes for a total of 250 annual burden hours.

Two comments addressed the burden of the State agencies involved with this requirement. These comments have implications for the burden of the vendors as well.

One comment addressed the burden of the incentive items restrictions but not the number of burden hours.

Another commenter stated that it would be burdensome for State agencies to maintain invoices or similar documentation of the vendor's approved incentive items, showing that the cost of each item is either less than the \$2 nominal value limit or obtained at no cost, as required by §246.12(h)(8)(ii). However, the State agency is required to maintain copies of invoices only if the State agency permits vendors to request approval for incentive items not included on a list of acceptable incentive items provided by the State agency; the State agency is not required to maintain copies of invoices if the State agency provides the vendors with a pre-approved list. If the State agency does not provide a pre-approved list, the vendors would need to provide the State agencies with copies of the invoices. This would involve a reporting burden for the vendors.

The pre-approved list is part of the vendor agreement. The pre-approved list is returned by the vendor to the State agency at the same time the vendor returns the signed vendor agreement to the State agency during the authorization process. The State agency's information burden for maintaining a copy of the signed agreement is accounted for under §246.12(h)(1)(i), as discussed under #2 above. Thus the State agency's information burden for maintaining a copy of the pre-approved list is already accounted for under §246.12(h)(1)(i). However, some State agencies may not use this approach, preferring instead that vendors request approval for incentive items outside of the vendor agreement process; these State agencies would have an information burden under §246.12(h)(8)(ii). Thus far, FNS knows of one State agency with a large number of above-50-percent vendors which uses the vendor agreement process and another State agency which does not permit incentive items at all.

FNS took these comments in consideration and re-estimated the burden hours per response for this activity and increased the burden hour from 0.25 hour to 1 hour per response for State agencies which requires approval for incentive items outside of the vendor agreement process.

As previously discussed, it is likely that the number of vendors providing incentive items has decreased since the effective date of the Vendor Cost Containment Interim Rule in December 2005. It is also likely that a many of the above-50-percent vendors reside in States where either incentive items are not allowed or if incentive items are allowed, the agreement process is used.

Under the Vendor Cost Containment Interim Rule, all State agencies which authorize above-50-percent vendors must have their vendor cost containment systems certified by FNS; 32 State agencies obtained this certification. FNS estimates that half of these State agencies (16) will either prohibit incentive items altogether or will provide their above-50-percent vendors with a pre-approved list. Also, current FNS data shows that there are about 1,700 above-50-percent vendors. Since half of the State agencies authorizing these vendors will either prohibit incentive items or provide the pre-approved list, FNS also estimates that half of these vendors (850) will not have a reporting burden regarding incentive items. FNS estimates that there are currently 1,700 above-50-percent vendors.

Thus FNS estimates that half of these vendors (850) will have a reporting burden. Also, as previously mentioned 32 State agencies authorized above-50-percent vendors and thus need FNS certification of their vendor cost containment systems. As a result, 850 total annual burden hours for State agencies is required in this final rule (850 above-50-percent vendors ÷ 16 State agencies = 53.125 above-50-percent vendors per State agency; 16 x 53.125 x 1 hour per response = 850 total annual burden hours).

The proposed rule did not provide any recordkeeping burden hours for vendors to comply with the incentive item approval requirement. However, as recognized by §246.12(h)(3)(xv) of the WIC regulations, vendors are already required to maintain inventory records used for Federal tax reporting purposes, which would include invoices for incentive items. Thus the incentive items requirements do not impose any new recordkeeping burden on vendors.