Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 246

RIN 0584–AD47

Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Discretionary WIC Vendor Provisions in the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108–265

AGENCY: Food and Nutrition Service, USDA.

ACTION: Proposed rule.

SUMMARY: This rule proposes to amend regulations for the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) by adding three requirements mandated by the Child Nutrition and WIC Reauthorization Act of 2004 concerning retail vendors authorized by WIC State agencies to provide supplemental food to WIC participants in exchange for WIC food instruments. This rulemaking would require 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. In addition, State agencies would be required to maintain a list of State-licensed wholesalers, distributors, and retailers, and infant formula manufacturers registered with the Food and Drug Administration, and would require WIC-authorized retail vendors to purchase infant formula only from sources on the list. Further, State agencies would be required to 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. The intent of these provisions is to, respectively, enhance due process for vendors; prevent defective infant formula from being consumed by infant WIC participants; and 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 proposes to adjust the vendor civil money penalty (CMP) levels to reflect inflation.

DATES: To be assured of consideration, comments on this proposed rule must be received by the Food and Nutrition Service on or before October 2, 2006.

ADDRESSES: The Food and Nutrition Service invites interested persons to submit comments on this proposed rule. Comments may be submitted by any of the following methods:

- Mail: Send comments to Patricia N. Daniels, Director, Supplemental Food Programs Division, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 528, Alexandria, Virginia, 22302, (703) 305–2746.
- Web Site: Go to *http://www.fns.usda.gov/wic.* Follow the online instructions for submitting comments through the link at the Supplemental Food Programs Division Web site.
- E-Mail: Send comments to *wichq-sfpd@fns.usda.gov.* Include Docket ID Number 0584–AD47, Discretionary WIC Vendor Provisions Proposed Rule in the subject line of the message.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identities of the individuals or entities submitting the comments will be subject to public disclosure. All written submissions will be available for public inspection at the address above during regular business hours (8:30 a.m. to 5 p.m.) Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Debra Whitford, Chief, Policy and Program Development Branch, Supplemental Food Programs Division, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 528, Alexandria, Virginia, 22302, (703) 305–2746, OR *Debbie.Whitford@fns.usda.gov.*

SUPPLEMENTARY INFORMATION:

I. Procedural Matters

Executive Order 12866

This proposed rule has been determined to be significant and was reviewed by the Office of Management and Budget (OMB) in conformance with Executive Order 12866.

Regulatory Impact Analysis

The following summarizes the conclusions of the regulatory impact analysis.

Need for Action

This rule proposes to amend the Federal WIC Regulations by adding three requirements mandated by the Child Nutrition and WIC Reauthorization Act of 2004 concerning WIC-authorized retail vendors. This rulemaking would require 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. In addition, State agencies would be required to maintain a list of State-licensed wholesalers, distributors, and retailers, and infant formula manufacturers registered with the FDA, and would require WIC-authorized retail vendors to purchase infant formula only from sources on the list. Further, State agencies would be required to prohibit the authorization of or payments to 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. Finally, this rule also proposes a process for the periodic 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.

Benefits

The notification of vendors of an initial incidence of a violation provides the vendor with an opportunity to correct a violation. Thus, State agencies may spend less time and resources on sanction cases and ultimately program operations would be improved and program costs would decrease.

Requiring vendors to obtain infant formula only from suppliers registered with FDA or licensed under State law will help to prevent the sale of adulterated stolen infant formula for use by infant WIC participants, thus safeguarding their health.

Requiring above-50-percent vendors to restrict the costs of their participant incentive items to nominal value would protect the WIC program from paying excess money for WIC foods.

Making the inflation adjustment consistent for all CMP levels would benefit WIC Program administration by making all CMP calculations uniform.

Costs

Although this proposed rule has been designated as significant, the costs associated with implementing the proposed changes are not expected to significantly add to current program costs.

Little time will be needed to issue a notice of violations to a vendor, which presumably will entail a standardized format with space for the vendor's name and address and for listing the violations. Likewise, little time will be needed to document in the vendor file the reason(s) such notice would compromise an investigation and thus would not be sent.

The State agency is required to provide the list of registered or licensed infant formula suppliers to vendors on an annual basis, which a State agency could satisfy by linking its Web site to the list of licensed suppliers on the Web site of the State's licensing agency.

FNS currently estimates that only about 2,000 of the approximately 50,000 authorized vendors will be subject to incentive items restrictions. Little time will be needed by the State agency to approve/disapprove incentive items, since this process only involves comparison of the vendor's price documentation with the less-than-$2 nominal value limit. Indeed, the State agency may provide above-50-percent vendors with a list of allowable incentive items, and the vendor would indicate on the list which of these incentive items it wishes to use and return the list to the State agency.

The proposed process for the periodic adjustment of WIC vendor CMP amounts to reflect inflation would not increase administrative costs because the CMP calculation process would be the same for all vendor violations. Under the current regulations, the CMP levels for some but not all vendor violations have previously been adjusted for inflation. Under the proposed process, all vendor CMP levels would be periodically 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.

Regulatory Flexibility Act

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act (RFA) of 1980, (5 U.S.C. 601–612). Pursuant to that review, Eric M. Bost, Under Secretary, Food, Nutrition, and Consumer Services, has certified that this rule would not have a significant impact on a substantial number of small entities. However, in fulfilling the intent of the Child Nutrition and WIC Reauthorization Act of 2004, the rule may have a significant economic impact on the small number of above-50-percent vendors that have been authorized to participate in the WIC Program. These vendors tend to be smaller grocery stores that serve WIC participants exclusively or predominantly, have a large volume of WIC transactions, and may not be subject to the retail market forces that keep food prices at competitive levels. In accordance with the law, the proposed rule would require that State agencies implement restrictions on the incentive items provided to program participants by above-50-percent vendors in order to prevent the cost of the incentive items from increasing the food prices charged to the WIC Program by these vendors. Currently FNS estimates that about 2,000 of the approximately 50,000 authorized vendors will be subject to incentive items restrictions. FNS does not expect that the rule will result in an overall reduction in the number of authorized vendors, but rather in lower food prices charged to the WIC Program by above-50-percent vendors.

FNS also does not expect the other three provisions of the proposed rule to have a significant economic impact on small entities. One of these provisions requires State agencies to provide WIC retail vendors with a list of State-licensed infant formula wholesalers, distributors, retailers, and FDA-registered manufacturers; vendors may obtain infant formula for sale to WIC participants only from the entities on the list. FNS believes that a large majority of WIC vendors currently obtain infant formula from legitimate sources which will appear on the lists provided by the State agencies. Thus the requirement for the list will impact a very small minority of WIC vendors.

One of the other provisions requires the State agency to notify a vendor of a violation in writing before documenting a subsequent violation which could result in sanctions based on a pattern of violations, unless such notification would compromise an investigation. This provision will help vendors to comply with their responsibilities and thus prevent sanctions. FNS estimates that only 5 percent of WIC-authorized vendors would be impacted by this provision. Moreover, this impact would be economically beneficial for these vendors since such notification would help them to prevent the loss of business resulting from disqualification, or CMP payments imposed in lieu of disqualification, and related legal costs.

The remaining provision would periodically increase the CMP amounts to reflect inflation for those CMP's which had not previously been adjusted for inflation. Under the current regulations, the CMP levels for some but not all vendor violations have previously been adjusted for inflation. Initially, the proposed process 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. FNS estimates that only 3 percent of WIC-authorized vendors would be impacted by this provision. Moreover, this provision would only increase maximum CMP amounts on a periodic basis to reflect inflation; the underlying formula for calculating CMP amounts, based on a percentage of a vendor's average redemptions and the number of violations as set forth in

§ 246.12(l)(1)(x), would not be altered by this provision.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments and the private sector. Under section 202 of the UMRA, the Department generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local or tribal governments, in the aggregate, or the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, Section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the most cost effective or least burdensome alternative that achieves the objectives of the rule.

This proposed rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local and tribal governments or the private sector of $100 million or more in any one year. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 12372

The WIC Program is listed in the Catalog of Federal Domestic Assistance Programs under 10.557. For the reasons set forth in the final rule in 7 CFR part 3015, subpart V, and related Notice (48 FR 29115, June 24, 1983), this program is included in the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Federalism Summary Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under Section (6)(b)(2)(B) of Executive Order 13121.

Prior Consultation With State Officials

Prior to drafting this proposed rule, we received input from State agencies regarding issues and concerns with implementation of the three legislative provisions contained in this rulemaking. FNS regional offices have formal and informal discussions with WIC State agency officials on an ongoing basis regarding program and policy issues. 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.

Nature of Concerns and the Need To Issue This Rule

State agencies are primarily concerned with the potential administrative burdens involved with implementing the new legislative requirements in this proposed rule. However, as previously noted, this proposed rule is based mainly on three new requirements mandated by the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108–265. First, the statute requires State agencies to notify WIC-authorized retail vendors in writing of an initial violation, for violations requiring a pattern of occurrences in order to impose a sanction, before documenting a subsequent violation unless notification would compromise an investigation; this requirement was intended to enhance the due process afforded to vendors facing disqualification or civil money penalties. Second, the statute requires State agencies to maintain a list of State-licensed wholesalers, distributors, and retailers, and infant formula manufacturers registered with the Food and Drug Administration, and requires that WIC-authorized retail vendors purchase infant formula only from sources on the list; this requirement was intended to prevent defective infant formula from being consumed by infant WIC participants. Third, the statute requires State agencies to prohibit the authorization of or payments to 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; this requirement was intended 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.

The proposed rule would also provide a process for periodically adjusting WIC vendor CMP levels for inflation in a manner consistent with the process for adjusting other WIC CMP levels for inflation set forth in the final rule ''Department of Agriculture Civil Monetary Penalties Adjustment,'' 70 FR 29573, May 24, 2005. Under that final rule, the CMP levels for some but not all vendor violations have previously been adjusted for inflation. Initially, the proposed process 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.

Extent to Which We Meet Those Concerns

FNS has considered the impact of this proposed rule on WIC State and local agencies. Through the rule-making process, FNS has attempted to balance the need for State agencies to meet the new requirements against the administrative challenges that State agencies are likely to encounter in meeting them. These challenges include the commitment of adequate resources to compile the list of acceptable entities from which infant formula must be purchased; determine when notification of violations would compromise an investigation; and, develop and enforce the incentive items provisions.

The proposed rule would allow State agencies discretion to determine if providing notification of violations to vendors before documenting additional violations would compromise the investigation.

In addition, under the proposed rule, State agencies could use their Web sites as the primary means for providing their vendors with lists of infant formula manufacturers registered with the FDA and infant formula wholesalers, distributors, and retailers licensed under State law. FNS will also provide the State agencies with the FDA list of manufacturers, and State licensing and tax authorities could provide the WIC State agencies with lists or Web site links on the other entities. Also, State legislation or rulemaking could be used to limit the kind of entities to be included on the lists provided to the vendors.

Further, State agencies would not be required to permit above-50-percent vendors to provide incentive items. If a State agency decides not to permit such promotions at all, then there would be no administrative burden to the State agency to approve such items to ensure compliance with the statutory requirement.

Finally, State agencies would need to amend their schedules of sanctions to reflect the inflation adjustments for CMP levels in the proposed rule and to notify their vendors of this change. FNS does not expect this to involve a significant expenditure of resources.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule is intended to have preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full and timely implementation. This rule is not intended to have retroactive effect unless so specified in the **EFFECTIVE DATES** section of the final rule. Prior to any judicial challenge to the provisions of the final rule, all applicable administrative procedures must be exhausted. This rule concerns WIC vendors. In the WIC Program, the administrative procedures which must be exhausted by WIC vendors are as follows. First, State agency hearing procedures pursuant to § 246.18(a)(1) must be exhausted for vendors concerning denial of authorization, termination of agreement, disqualification, civil money penalty or fine. Second, the State agency process for providing the vendor an opportunity to justify or correct the food instrument pursuant to § 246.12(k)(3) must be exhausted for vendors concerning delaying payment for a food instrument or a claim. Third, administrative appeal to the extent required by § 3016.36 must be exhausted for vendors concerning procurement decisions of State agencies.

Civil Rights Impact Analysis

FNS has reviewed this proposed rule in accordance with the Department Regulation 4300–4, ''Civil Rights Impact Analysis,'' to identify and address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities. After a careful review of the rule's intent and provisions, FNS has determined that there is no way to soften the effect on any of the protected classes regarding those provisions of the rule concerning notice of violations and restrictions on incentive items. However, the rule explicitly forbids discrimination against a protected class recognized by the WIC Program (race, color, national origin, age, sex, or disability) regarding the inclusion of businesses on the list which State agencies must provide to vendors of infant formula manufacturers registered with the FDA, and State-licensed infant formula wholesalers, distributors, or retailers. All data available to FNS indicate that protected classes have the same opportunity to participate in the WIC Program as non-protected classes. FNS specifically prohibits the State and local government agencies that administer the WIC Program from engaging in actions that discriminate based on race, color, national origin, age, sex, or disability in accordance with § 246.8 of the WIC Regulations. Where State agencies have options and they choose to implement a certain provision, they must implement it in such a way that it complies with the regulations at § 246.8.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35; see 5 CFR part 1320) requires that OMB approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. This proposed rule contains information collections that are subject to review and approval by OMB; therefore, FNS has submitted an information collection under OMB#0584–0043, which contains the changes in burden from adoption of the proposals in the rule, for OMB's review and approval.

Comments on the information collection in this proposed rule must be received by October 2, 2006.

Send comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for FNS, Washington, DC 20503. Please also send a copy of your comments to Patricia N. Daniels, Director, Supplemental Food Programs Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 528, Alexandria, Virginia 22302. For further information, or for copies of the information collection requirements, please contact Debra Whitford at the address indicated above. Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the Agency's functions, including whether the information will have practical utility; (2) the accuracy of the Agency's estimate of the proposed information collection burden, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this request for comments will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Title: Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Discretionary WIC Vendor Provisions in the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108–265.

OMB Number: 0584–0043.

Expiration Date: March 31, 2007.

Type of Request: Revision of a currently approved collection.

Abstract: Pursuant to the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108–265, this rule proposes three new requirements and one administrative change for WIC State agencies regarding vendors authorized to provide supplemental food to WIC participants in exchange for WIC food instruments. First, State agencies would be required to notify a vendor 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 such notification would compromise an investigation. Second, State agencies would be required to provide the vendors with a list of State-licensed infant formula wholesalers, distributors, and retailers, and FDA-registered infant formula manufacturers, and would require the vendors to purchase infant formula only from the sources on the list. Third, State agencies would be required to implement restrictions on incentive items provided to WIC participants by above-50-percent vendors, with limited exceptions subject to State agency discretion.

The administrative change concerns § 246.12(l)(1)(x)(C) and (l)(2)(i), which this rule proposes to amend by adding a process for periodically adjusting the WIC vendor CMP levels for inflation in a manner consistent with the process for adjusting other WIC CMP levels for inflation set forth in the final rule ''Department of Agriculture Civil Monetary Penalties Adjustment,'' 70 FR 29573, May 24, 2005. Under that final rule, the CMP levels for some but not all vendor violations have previously been 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. This would only require WIC

State agencies to change the maximum CMP amount per violation and the maximum CMP amount per total investigation in the CMP calculation process set forth in each State agency's schedule of sanctions, which is part of the vendor agreement. The CMP calculation process may be set forth only once in the sanctions schedule since the same CMP calculation process may be applied to all violations and investigations. Thus no measurable reporting or recordkeeping burden would result.

The respondents are the 89 WIC State agencies which administer the WIC Program under Federal-State agreements executed annually with FNS. The average burden per response and the annual burden hours are explained below and summarized in the chart which follows.

Respondents for this Proposed Rule: State agencies.

Estimated Number of Respondents for this Proposed Rule: 405.

Estimated Number of Responses per Respondent for this Proposed Rule: 3,303.

Estimated Total Annual Burden on Respondents for this Proposed Rule: 1,095 Hours.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Section of regulations	Annual number of respondents	Annual frequency	Average burden per response	Annual burden hours
Reporting Burden:				
§246.4(a)(14)(iii)	90	1	1.0	90
§246.4(a)(14)(xvii)	90	1	1.0	90
Total Reporting Burden in the Proposed Rule	180	2		180
Recordkeeping Burden:				
§246.12(g)(10)	90	1	1.0	90
§246.12(h)(8)	45	1,000	0.25	250
§246.12 (l)(3)	90	2,300	0.25	575
Total Recordkeeping Burden in the Proposed Rule	225	3,301		915
Total Reporting and Recordkeeping Burden in the Proposed Rule	405	3,303		1,095
Total Current WIC Reporting and Recordkeeping Burden Hours Approved by OMB for Information Collection #0584–0043	16,325,125	28,280,366		3,051,075
Grand Total Proposed WIC Reporting and Recordkeeping Burden Hours Resulting from the Proposed Rule	16,325,530	28,283,669		3,052,170

1. Reporting

Section 246.4(a)(14)(iii)

Section 246.4(a)(14)(iii), as amended by this proposed rule, would require WIC State agencies to set forth policies and procedures in their WIC State Plans for 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. FNS estimates that this would require one burden hour per State agency per year.

Section 246.4(a)(14)(xvii)

Section 246.4(a)(14)(xvii), as proposed to be added by this rule, would require 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 Food and Drug Administration (FDA). FNS estimates that this would require one burden hour per State agency per year.

2. Recordkeeping

Section 246.12(g)(10)

Section 246.12(g)(10) would require WIC State agencies to provide to authorized WIC retail vendors a list, on an annual basis, of infant formula wholesalers, distributors, and retailers licensed in the State in accordance with State law (including regulations), and infant formula manufacturers registered with FDA that provide infant formula. FNS has provided the State agencies with the list of the infant formula manufacturers registered with FDA. 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 estimates that this would require one burden hour per State agency per year.

Section 246.12(h)(8)

Section 246.12(h)(8) would require WIC State agencies to establish a process for approval or disapproval of requests from above-50-percent vendors for permission to provide incentive items to WIC participants or other customers. As previously mentioned, FNS currently estimates that about 2,000 of the approximately 50,000 authorized vendors will be subject to incentive items restrictions. A State agency could decide not to allow any incentive items at all, in which case an approval process would not be necessary. FNS has received inquiries from several WIC State agencies indicating an interest in not allowing such incentive items at all.

Accordingly, we assume 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 assume 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 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. Thus FNS estimates that State

agencies will approve/disapprove incentive items for 1,000 above-50-percent vendors, and that each approval/disapproval will require 15 minutes, resulting in 250 total annual burden hours.

Section 246.12(l)(3)

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 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. Approximately 2,300 vendors investigated annually commit violations involving a pattern. We assume that little time will be needed to issue the notice, which presumably will entail a standardized format with space for the vendor's name and address and for listing the violations. We also assume that little time will be needed to document in the vendor file the reason(s) such notice would compromise an investigation and thus would not be sent. Thus FNS estimates that 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, resulting in 575 total annual burden hours.

E-Government Act Compliance

The Food and Nutrition Service is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

II. Background

As previously noted, this proposed rule would amend the WIC Program regulations by adding three requirements mandated by the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108–265, concerning retail vendors authorized by WIC State agencies to provide supplemental food to WIC participants in exchange for WIC food instruments. This rulemaking would reflect the statutory requirement that WIC State agencies notify WIC-authorized 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. In addition, the State agency would be required to maintain a list of State-licensed wholesalers, distributors, and retailers, and FDA-registered manufacturers, and WIC-authorized vendors would be required to purchase infant formula only from sources on the list. Further, State agencies would be required to 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 other customers unless the vendor provides the State agency with proof that the vendor obtained the incentive items or merchandise at no cost.

October 1, 2004 was the effective date of Public Law 108–265 for all of these requirements. In December 2004 and April 2005, FNS issued policy and guidance to WIC State agencies on implementation of these requirements. This proposed rule reflects the policy and guidance provided to State agencies.

Additionally, this proposed rule would add a process for periodically adjusting the WIC vendor CMP levels for inflation in a manner consistent with the process for adjusting other CMP levels for inflation set forth in the final rule ''Department of Agriculture Civil Monetary Penalties Adjustment,'' 70 FR 29573, May 24, 2005. Under that final rule, the CMP levels for some but not all vendor violations have previously been adjusted for inflation. Initially, this proposed provision 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.

1. Notice of Violation

a. Introduction

Section 203(c)(5) of Public Law 108–265 amended section 17(f) of the Child Nutrition Act of 1966, 42 U.S.C. 1786 (CNA), by adding a new paragraph (26) to require the State agency to notify the vendor in writing of the initial violation, for violations requiring a pattern of occurrences in order to impose a sanction, prior to documenting another violation, unless the State agency determines that notifying the vendor would compromise an investigation.

This requirement was effective for violations committed under investigations beginning on or after October 1, 2004, superseding § 246.12(l)(3) of the current WIC regulations, which provides that the State agency is not required to warn a vendor that violations had been detected before imposing a sanction. (All references to regulatory sections in this preamble are to Title 7 of the CFR unless otherwise indicated.) In December 2004, State agencies were advised that their vendor agreements and sanction schedules must be reviewed and amended as appropriate to reflect this new requirement.

b. Provisions in the Proposed Rule (§§ 246.4(a)(14)(iii), 246.12(h)(3)(xviii), 246.12(l)(3))

The proposed revision of § 246.12(l)(3) would require the State agency, prior to imposing a sanction for a pattern of violations, to either notify the vendor in writing of the initial violation, or document in the vendor file the reason(s) for determining that such notification would compromise an investigation.

Also, as proposed in § 246.12(l)(3)(ii), the State agency may use the same method of notification which the State agency uses to provide a vendor with adequate advance notice of the time and place of an administrative review per § 246.18(b)(3) of the WIC regulations. We recommend that State agencies use a method of notification which provides evidence of delivery of the notification. Finally, as proposed in § 246.12(l)(3)(iii), the State agency may conduct another compliance buy visit after the notification of violation is received by the vendor, or presumed to be received by the vendor consistent with the State agency's procedures for providing such notification. During a compliance buy visit, an investigative agent of the State or local agency transacts WIC food instruments with a vendor while posing as a participant.

Further, the proposed amendment of § 246.12(h)(3)(xviii) would remove the reference to the current requirement that the State agency does not have to provide a vendor with a prior warning about violations, and would add the notification requirement as set forth in Public Law 108–265.

Section 246.4(a)(14)(iii) currently provides that the State Plan must include a copy of the vendor agreement, including a copy of the sanction schedule, which may be incorporated as an attachment, or, if the sanction schedule is in the State agency's

regulations, through citation to those regulations. This proposed rule amends § 246.4(a)(14)(iii) by including the notice of violations process so that, like the schedule of sanctions, the notice of violations process may be incorporated as an attachment or, if it is in the State agency's regulations, through citation to those regulations.

c. Types of Violations Subject to the Notification Requirement

The State agency must 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 that notifying the vendor would compromise an investigation. This includes violations for a pattern of overcharging; receiving, transacting and/or redeeming food instruments outside of authorized channels, including the use of an unauthorized vendor and/or an unauthorized person; charging for supplemental food not received by the participant; providing credit or non-food items, other than alcohol, alcoholic beverages, tobacco products, cash, firearms, ammunition, explosives, or controlled substances as defined in 21 U.S.C. 802, in exchange for food instruments; or providing unauthorized food items in exchange for food instruments, including charging for supplemental foods provided in excess of those listed on the food instrument. This notice requirement also applies to any violations for which a pattern of violations must be established in order to impose a State agency vendor sanction in accordance with § 246.12(l)(2) of the WIC regulations.

Notification is not required for violations involving a vendor's redemptions exceeding its inventories, since there are no initial violations in such instances; such violations are determined during one audit of inventory, not separate compliance buy visits. Additionally, such notification is not required for WIC vendor disqualifications or civil money penalties based on Food Stamp Program sanctions. Neither is notification required for violations that only require one incidence before a sanction is imposed.

d. Impact of the Notice Requirement on Documenting a Pattern of Violations

Several State agencies have requested clarification as to whether a State agency may sanction a vendor based on violations detected in the initial compliance buy visit if those violations fulfill the State agency's pattern requirement, even though a notice of violations has not been provided to the vendor. We have also been asked several related questions.

For investigations beginning on or after October 1, 2004, a pattern may not be established based solely on violations occurring during one compliance buy visit, even if violations on several food instruments occur during that one compliance buy visit. This is true regardless of whether the State agency determines that notifying the vendor would compromise the investigation. For example, if a State agency requires three violations as the pattern for overcharging, and the vendor initially commits this violation by overcharging on three food instruments during one compliance buy visit, the State agency may not sanction the vendor without two additional overcharging violations detected during one or more subsequent compliance buy visits. The intent of the notification provision is that a vendor be notified in writing that a violation had occurred prior to documenting another violation, unless such notification would compromise an investigation. As such, to allow a pattern to be identified during one compliance buy visit would be contrary to the intent of the law. Instead, the State agency must treat all of the violations of one type occurring during the first compliance buy visit as one occurrence in the pattern determination.

Also, if multiple violations occur during a compliance buy visit, the State agency must cite in the notification all of the types of violations which require a pattern of violative incidences in order to impose a sanction (with the exception of redemptions exceeding inventory, as previously discussed). For example, if a vendor transacts food instruments for unauthorized food items and also overcharges during the same compliance visit, then the vendor has committed two separate types of violations; both types must be cited in a notification of violation, unless such notification would compromise an investigation on either type of violation.

Likewise, if a vendor commits one type of violation in one compliance buy visit, followed by a notification, and then commits another type of violation in a subsequent compliance visit, then another notification must be provided to the vendor concerning this second type of violation. Further, we also encourage State agencies to attach a copy of the sanctions schedule to any notification of violations, to provide greater assurance that a vendor is on notice of all sanctionable violations prior to a subsequent compliance buy visit.

e. Determination of Whether the Notice Would Compromise an Investigation

As noted above, the State agency is not required to notify the vendor after the initial violation if the State agency determines that such notice would compromise an investigation. The notice could compromise an investigation if the investigation is covert, such as a compliance buy investigation, which involves an investigative agent posing as a WIC participant and transacting WIC food instruments. In such circumstances, the notice would reveal the existence of an investigation which had been previously unknown to the vendor.

The notice could also compromise covert investigations of the vendor being conducted by the Food Stamp Program, the USDA Office of Inspector General, the State Police, or other authorities, as well as the WIC investigation being conducted by the State agency; the term ''investigation'' does not exclusively refer to WIC investigations. Ideally, these other authorities should coordinate with the WIC State agency to prevent several investigations of the same vendor from being conducted at the same time. However, sometimes the WIC State agency may not learn about the existence of another investigation until after the WIC investigation has already begun.

A State agency may determine that any notification based on a different violation occurring during a subsequent compliance buy visit would compromise the investigation, even though the State agency had not determined that the notification following the previous compliance buy visit would compromise the investigation. The State agency may choose not to notify the vendor regarding a different violation identified in a subsequent compliance buy visit.

The statute provides the State agency with the discretion to determine whether notifying the vendor will compromise an investigation and to use its judgment to determine whether a notice should be sent to the vendor. Such determinations must be made on a case-by-case basis. In making this determination, there are a number of factors which the State agency may wish to review—for example, the severity of the initial violation, the compliance history of the vendor, or whether the vendor has been determined to be high risk consistent with § 246.12(j)(3) of the WIC regulations. The State agency has the discretion to determine which factors to consider and how much weight should be assigned to each factor. If the State agency decides not to

send the notice, the basis for this decision must be documented in the vendor file since the matter may be raised on appeal of any adverse actions taken as a result of the investigative activity.

2. List of Infant Formula Manufacturers, Wholesalers, Distributors, and Retailers

a. Introduction (§ 246.12(g)(10))

Section 203(e)(8) of the Public Law 108–265 amends section 17(h)(8)(A) of the CNA by requiring that each State agency maintain a list of infant formula wholesalers, distributors, and retailers licensed in the State in accordance with State law (including regulations), and infant formula manufacturers registered with FDA that provide infant formula. This statute requires authorized vendors to only purchase infant formula from sources on the above-described list. In December 2004, State agencies were notified of the requirement and when to amend their State Plans, vendor agreements, vendor manuals, and vendor training plans and materials as appropriate to reflect this new requirement.

This provision is intended to prevent stolen infant formula from being purchased with WIC food instruments. Such formula may constitute a health hazard for a variety of reasons, including direct tampering with formula before it is sold to unsuspecting retailers, falsification of labeling to change expiration dates, counterfeiting, or improper storage.

This proposed rule would add a new § 246.12(g)(10) which requires the State agency to provide the above-noted list of infant formula sources to the vendors on at least an annual basis, and to provide that the list must include the addresses as well as the names of the businesses; this is intended to make it easier for vendors to locate a nearby business and also to avoid inadvertently contacting an unlicensed business with a similar name.

The proposed § 246.12(g)(10)(i) would require a State agency to notify vendors that they must purchase infant formula only from the sources set forth on the State agency's list, although the State agency may, at its option, permit vendors to obtain infant formula from sources on another State agency's list.

The proposed § 246.12(g)(10)(i) also clarifies that the infant formula list requirement would only pertain to ''infant formula,'' contract and non-contract brand, as defined in § 246.2, and infant formula covered by a waiver granted under § 246.16a(e), but not to ''exempt infant formula'' or ''WIC-eligible medical foods'' as defined in § 246.2. These terms are used in the same manner in the CNA and Public Law 108–265.

b. State Licenses for Wholesalers, Distributors, and Retailers (§ 246.12(g)(10)(ii) and (g)(10)(iii))

The proposed § 246.12(g)(10) would require the State agency to compile its list in accordance with its State licensing laws and regulations. As previously noted, Public Law 108–265 requires State agencies to maintain a list of infant formula wholesalers, distributors, and retailers licensed in the State in accordance with State law (including regulations), and infant formula manufacturers registered with FDA that provide infant formula. Congress recognized that licensing requirements and types may vary significantly among States, noting, for example, that some States may have health licensing requirements while other States have business licensing requirements. (House Committee on Education and the Workforce, Report No. 108–445, 3/23/04, p. 58) Consistent with this recognition, the statute does not require that the license must specifically cover infant formula; many States/Indian Tribal Organizations (ITOs) may not have such licensing.

For example, a State agency has asked whether tax registration would be considered a State/ITO ''license'' within the meaning of the statutory provision. If a State/ITO has no other kind of health or business licensing, then tax registration or some other form of official State recognition of a business would suffice.

Moreover, the statute does not require that a State agency use all of the licenses which might apply to one of the State-licensed categories (wholesaler, distributor, retailer). For example, a State might have health licensing and business licensing for retailers. Thus, the proposed § 246.12(g)(10)(ii) would permit a State agency to choose which license to use for compiling the list; the State agency would not be required to use both kinds of licenses.

Further, the statute does not address the question as to whether a State agency could restrict the sources of infant formula available to authorized vendors. Absent guidance in statute, this proposed rule has been drafted to permit a State agency to exclude an entity from the list only for two specific reasons. First, the proposed § 246.12(g)(10)(iii)(A) would permit the State agency to exclude a State-licensed entity when specifically required by State law or regulations; State agencies would need to consult with their legal counsel to determine the correct process for implementing any restrictions on its list of infant formula sources. Second, the proposed § 246.12(g)(10)(iii)(B) would permit a State agency to exclude an entity from the list if the entity does not sell infant formula.

Also, the statute did not provide a basis for a licensed entity to exclude itself from the list. Accordingly, there is no basis in the proposed rule for a wholesaler, distributor, or retailer to exclude itself from the list, except as permitted by State law or regulations.

The State agency must be mindful of its responsibility to abide by all applicable Civil Rights laws and regulations. The State agency may not exclude any business from the list in a discriminatory manner against any protected class, or in a manner which would have a disparate impact on a protected class. Likewise, State agencies are encouraged to consider the impact on small businesses of their decisions on how to construct their lists.

c. Methods for Providing the List to Vendors (§ 246.12(g)(10))

Under this proposed provision, the State agency may provide a hard copy list to each vendor. However, the list may also be provided by ''other effective means.'' This refers to such means as providing vendors with a telephone number or e-mail address to inquire about the license status of a source. Alternatively, the list could be made available to the general public on-line, including an on-line list maintained by a State licensing agency. Such on-line lists may provide a search function for the license status of a business, instead of an actual list; this is acceptable. These are only examples; other methods may also be acceptable, depending on whether these other methods are effective.

Of course, some vendors may not have access to the Internet and will need a hard copy provided by the State agency, or some other means to determine if a business is licensed, such as contacting the State agency by telephone, in writing, or by electronic facsimile transmission.

d. Selection Criterion (§ 246.12(g)(3)(i), 246.4(a)(14)(xvii))

The proposed rule would require the State agency to adopt a new vendor selection criterion requiring vendors to obtain infant formula from the listed sources as a condition of authorization. The current § 246.12(g)(3)(i) requires minimum variety and quantity of supplemental foods as a vendor selection criterion. This proposed rule would add a sentence to this existing selection criterion which would make

infant formula from a supplier on the State agency's list part of the requirement for a minimum variety and quantity of supplemental foods. This proposed rule would add § 246.4(a)(14)(xvii) to require that the State agency describe its policies and procedures in the State Plan regarding compiling and distributing the infant formula list, and requiring vendors to purchase infant formula only from that list. Also, State agencies have the discretion under § 246.12(l)(2) to establish sanctions for vendors obtaining infant formula from unlicensed sources.

For the selection criterion to be effective, as well as any sanctions which a State agency may choose to establish, vendors must be required to maintain invoices or receipts showing the source of their infant formula purchases to enable the State agency to monitor vendor compliance. State agencies currently have the authority to require vendors to maintain such documentation under § 246.12(h)(3)(xv). State agencies should ensure that their vendor agreements require maintenance of this documentation by the vendors.

e. Training (§ 246.12(i)(2))

Section 246.12(i)(2) of the current WIC regulations, would be revised by the proposed rule to ensure that vendors are aware of their responsibilities regarding use of the list of infant formula sources provided to them by State agencies. Section 246.12(i)(2) of the current WIC regulations sets forth the content of the training which State agencies are required to provide to their vendors. This proposed rule would revise § 246.12(i)(2) to add the State agency infant formula list requirement to the subjects which State agencies must include in their training for vendors.

3. Incentive Items

a. Introduction (§ 246.12(g)(3)(iv))

Section 203(e)(13) of Public Law 108–265 amends section 17(h)(14) of the CNA by prohibiting a State agency from authorizing or making payments to above-50-percent vendors which provide incentive items or other free merchandise to program participants, with only two exceptions. One exception includes food or merchandise of nominal value as determined by the Secretary; USDA advised the State agencies in December 2004 that the nominal value is less than $2. The other exception includes incentive items or other merchandise for which the vendor provides proof to the State agency showing that the vendor had obtained the incentive items or other merchandise at no cost. Above-50-percent vendors are for-profit vendors that derive more than 50 percent of their annual food revenue from the transaction of WIC food instruments or for-profit vendor applicants expected to derive more than 50 percent of annual food revenue from the transaction of WIC food instruments. The above-50-percent vendor category includes vendors which have often been referred to as ''WIC-only stores.'' In December 2004, State agencies were advised to amend their vendor selection criteria and sanction schedules to reflect this new requirement.

Data indicate that WIC food expenditures increasingly include payments to WIC-only stores whose prices are not governed by the market forces that affect most retail grocers. As a result, the prices charged by these vendors tend to be higher than the prices charged by other WIC-authorized retail vendors. WIC-only stores have provided a wide array of incentive items to WIC participants—including diapers, strollers, bicycles, small kitchen appliances, other household products, food, sales or ''specials,'' services such as transportation, and cash incentives to WIC shoppers for bringing new customers to these stores. Because WIC-only vendors serve WIC shoppers exclusively or primarily, this provision is intended to ensure that the WIC Program does not pay the cost of incentive items in the form of high food prices.

Under § 246.12(h)(3)(ii) of the current Federal WIC Regulations, a WIC food instrument may only be used to purchase the supplemental foods listed on that food instrument, and directly adding the cost of an incentive item to a WIC food instrument is a vendor violation subject to sanctions under § 246.12(l)(1)(iii)(F). However, these regulatory provisions do not address the increased prices charged by above-50-percent vendors for WIC supplemental foods to reflect the costs of the incentive items.

As discussed more fully below, the proposed rule would add a new vendor selection criterion to the WIC regulations which would make compliance with the State agency's incentive items policies a condition of vendor authorization for above-50-percent vendors. This proposed provision, § 246.12(g)(3)(iv), also describes allowable and prohibited incentive items. Further, the proposed regulations include a requirement for a mandatory sanction for incentive items violations committed by above-50-percent vendors. The proposed regulations also require training for vendors on the policies and procedures concerning incentive items. Finally, this rule proposes to require the State agency to include in its vendor agreement with the above-50-percent vendor, or in another document provided to the above-50-percent vendor and cross-referenced in the vendor agreement, the policies and procedures regarding the provision of incentive items to customers.

Also, § 246.12(h)(3)(iii) of the current WIC regulations requires the vendor to provide program participants the same courtesies offered to other customers. Thus, an above-50-percent vendor must not treat non-WIC customers more favorably than WIC customers regarding incentive items. In addition, such vendors would not have a reliable means to distinguish between WIC customers and non-WIC customers when a WIC food instrument is not transacted. Consequently, the only way to ensure that WIC participants are not provided with incentive items which exceed nominal value would be to apply the same restrictions on incentive items provided to all customers.

b. Allowable and Prohibited Incentive Items (§ 246.12(g)(3)(iv))

i. Allowable Incentive Items

Although Public Law 108–265 prohibits the authorization of above-50-percent vendors that provide most incentive items, it does not require State agencies to permit the use of any incentive items. State agencies currently have broad discretion to establish vendor selection criteria that meet their needs for effective program administration. Moreover, since State agencies have authority to exclude all above-50-percent vendors, they may establish more restrictive limits on incentive items for such vendors as a condition of authorization. Thus allowable incentive items could be disallowed by a State agency under the proposed rule.

As proposed by this rule, the first allowable incentive item would include food or merchandise obtained at no cost to the above-50-percent vendor, and provided to customers without charge or sold to customers at or above cost, subject to documentation. As proposed by this rule, the second allowable incentive item would include food or merchandise of nominal value; that is, having a per item cost of less than $2, including food or merchandise of nominal value involved with a raffle or similar promotion.

As proposed by this rule, the third allowable incentive item would include

food sales and ''specials'' if there is no cost or only a nominal cost to the above-50-percent vendor (less than $2) regarding the food items involved and they do not result in a charge to a WIC food instrument for foods in excess of the foods listed on the food instrument. Sales and specials include reduced prices for a period of time; buy one, get one free; buy one, get one at a reduced price; free amounts added to an item by a manufacturer; manufacturer coupons; and, store loyalty shopping cards.

As an example of no cost or nominal cost to the above-50-percent vendor, regarding buy one, get one free, the free food item would be acceptable if it had been obtained by the vendor at no cost or for less than $2, or if the vendor would be compensated for the second item, e.g., upon presentation of a manufacturer's coupon to the manufacturer. However, if the vendor had purchased the food item for $2 or more, then the free item would not be acceptable.

Regarding buy one, get one at a reduced price promotions, the reduced price may not be charged to the WIC food instrument if the second product is not covered by the food instrument; the WIC customer must pay this amount with his/her own money. Otherwise, this incentive item would be purchased with Federal funds, which is prohibited by statute. Also, use of the food instrument to purchase a second product not covered by the food instrument would constitute a violation of § 246.12(l)(1)(iv) of the WIC regulations, which mandates a one-year disqualification of the vendor for providing foods in excess of those listed on the food instrument.

As proposed by this rule, the fourth allowable incentive item would include for-profit services which would not otherwise be prohibited, and which the participant would purchase at a fair market value. As discussed below, services which constitute a conflict of interest or the appearance of such conflict, such as assistance with applying for benefits, would be prohibited. However, other services, such as transportation, would be allowable if the participant purchases such services at a fair market value for comparable services.

As previously noted, the only exceptions to the statute's prohibition on incentive items of above-50-percent vendors are food or merchandise of nominal value and incentive items or other merchandise which the above-50-percent vendor had obtained at no cost. This implies that all services are prohibited since services are not food or merchandise. However, the legislative history of the statute does not indicate an intention to prohibit for-profit business enterprises or minimal customary courtesies of the retail food trade.

For example, as proposed by this rule, an above-50-percent vendor would be allowed to provide customers with transportation by automobile if the fare charged to customers for this service would be equal to the taxi cab fare for the same distance. The fare charged by the above-50-percent vendor could be based on a bus or van fare for the same distance if the above-50-percent vendor provides participants with transportation by bus or van, and the comparable bus or van fare is not publicly subsidized. The transportation fare charged by the above-50-percent vendor could not be based on a fare which is subsidized with tax funds, as often occurs with bus fares, since such fares do not compensate for all of the related costs and provide all of the profit. A service not otherwise prohibited would be allowable if it is provided only for profit. This would ensure that none of the costs of the transportation would be reflected in the prices charged for WIC supplemental food.

The legislative history of the statute also does not indicate an intention to prohibit the minimal customary courtesies of the retail food trade, such as helping the customer to obtain an item from a shelf or from behind the counter, bagging purchased items for the customer, and assisting the customer with loading the purchased items into his/her automobile. Such services are an integral part of customer service in a retail food store. As proposed by this rule, the fifth allowable incentive item includes the minimal customary courtesies of the retail food trade.

ii. Prohibited Incentive Items

First, as proposed by this rule, services which would constitute a conflict of interest, or which would have the appearance of such conflict, would be prohibited. For example, assistance with applying for WIC benefits would be prohibited because the above-50-percent vendor would benefit financially if the applicant is certified.

Second, as previously discussed, the State agency would have the discretion to prohibit incentive items which this rule proposes to allow.

Third, lottery and raffle tickets provided to WIC shoppers at no charge or below face value would be prohibited incentive items. The perceived value of a lottery or raffle ticket is far greater than its face value, since the perceived value is based on potential winnings. The legislative history of Public Law 108–265 supports the prohibition of lottery tickets as incentives, 150 Cong. Rec. S7244–01., June 23, 2004.

Fourth, cash gifts in any amount for any reason would be prohibited incentive items. Cash is neither food nor merchandise, and thus would not fall under the exceptions.

Fifth, anything made available in a public area as a complimentary gift which a customer may consume or take without charge would be a prohibited incentive item. This applies to give-away food, soft drinks, or other items which are placed on a counter top, shelf, or display rack, for customers to take as they please. As a result, there is no control on the amount of such items which a customer may take. Thus there is no assurance that a customer would be limited to less than $2 worth of such items.

Sixth, an allowable incentive item of nominal value would be a prohibited incentive item if it is provided more than once per customer per shopping visit, regardless of the number of participants, the amount of food, or the number of food instruments involved. Without this restriction, the less-than-$2 limit would be undermined. However, this restriction does not apply if the less-than-$2 limit would not be exceeded. For example, the less-than-$2 limit would not be exceeded if the incentive items had been obtained by the vendor at no cost. Likewise, the less than $2 limit would also not be exceeded for an incentive item with a nominal value of less than $2, which, if multiplied, would not exceed the less-than-$2 limit; for example, the vendor would be allowed to provide two incentive items during one shopping visit if the per item cost of the incentive item was 99 cents.

Seventh, food or merchandise of greater than nominal value would be a prohibited incentive item, as required by the statute. As previously noted, the statute provided USDA with the authority to determine the nominal value amount, which USDA has advised State agencies to be less than $2.

Eighth, food or merchandise provided to customers for more than $1.99 that is below cost would be prohibited incentive items, since the $1.99 nominal value requirement would otherwise be circumvented, and services provided for a fee of less than fair market value would be prohibited incentive items, to ensure that the costs of the transportation would not be reflected in the prices charged for WIC supplemental food, as intended by the statute.

Ninth, any kind of incentive item which incurs a liability for the WIC Program would be prohibited. For example, if an accident occurs when an above-50-percent vendor provides transportation services to customers, resulting in personal injury or property damage, the WIC Program would not be liable for such personal injury or property damage.

Tenth, any kind of incentive item would be prohibited if it violates any Federal, State, or local law or regulations. For example, this prohibition would be intended to prevent an above-50-percent vendor from providing transportation services without the permits required by State and local laws for such services.

We are specifically soliciting comments on whether there are circumstances in which a legitimately market-competitive above-50-percent vendor could be disadvantaged by the prohibition on providing incentives to non-WIC customers.

c. The Authorization Process (§ 246.12(g)(3)(iv))

As previously noted, Public Law 108–265 prohibits a State agency from authorizing or making payments to an above-50-percent vendor which provides prohibited incentive items to customers. As discussed below, the vendor agreement would set forth the restrictions on incentive items; the vendor's signature on the agreement would signify the intention to comply with the restrictions. However, other evidence of intent might be revealed at the on-site preauthorization visit, such as advertising prohibited incentive items. Accordingly, the proposed § 246.12(g)(3)(iv) prohibits the authorization of an above-50-percent vendor which engages in such practices or otherwise indicates an intention to provide prohibited incentive items to customers.

d. Sanctions (§ 246.12(l)(iii)(G)) and Training (§ 246.12(i)(2))

A mandatory sanction would be appropriate if an authorized vendor has engaged in a pattern of incentive items violations. As previously indicated, this kind of violation reduces the funds available to provide benefits to needy women, infants and children at nutritional risk. Accordingly, § 246.12(l)(1)(iv)(B) of this proposed rule would provide a one-year disqualification for a pattern of such violations. This sanction must be included in the State agency's schedule of sanctions. To ensure that the above-50-percent vendors are aware of their responsibilities regarding incentive items, this issue has been added to § 246.12(i)(2) in this proposed rule, which lists the subjects which State agencies must include in their training for vendors.

e. Vendor Agreement Provisions on Incentive Items (§ 246.12(h)(8))

Sections 246.4(a)(14)(iii) and 246.12(h)(8) of the proposed rule would require the State agency in its vendor agreement or another document provided to the vendor and cross-referenced in the vendor agreement for above-50-percent vendors to set forth which incentive items are allowable, if any, and the process for obtaining approval before the vendor provides incentive items to customers.

Further, if any incentive items are permitted, the State agency would have to approve all incentive items which above-50-percent vendors intend to provide to customers. Therefore, such vendors would have to submit to State agencies a list of incentive items, the cost of each item, and documentation, such as an invoice or similar document, indicating the cost of each incentive item. The documentation for each item would have to show that it had been obtained for either less than the $2 nominal value limit or that it had been obtained at no cost.

The WIC State agency may need to contact the source stated on the invoice or similar document to verify the information. The invoices must be closely examined to ensure that the sources of the incentive items are not buying services or other arrangements designed to circumvent the law. For example, the vendor provides $30 to a buying service, which purchases a stroller for $30 and then provides it to the vendor at no cost; the vendor then provides it to the customer at no cost. The State agency must ensure that the vendor does not provide this stroller to a customer for less than $30. Otherwise, this kind of arrangement would circumvent the prohibition on using Federal funds to provide incentive items above nominal value to WIC shoppers.

Under this proposed rule, the State agency would be required to notify the vendor in writing of the approval or disapproval of the incentive item; this notification may be electronic, such as electronic mail or facsimile. This approval process may be structured in a number of different ways. The list and its supporting documentation may be submitted when the vendor signs the vendor agreement, either for an initial or subsequent authorization, and returns it to the State agency for approval and cosigning by the State agency. The State agency may include a list of allowable incentive items as part of the vendor agreement format; the vendor would indicate on the list which of these incentive items it wishes to use. Of course, the State agency may only include food or merchandise on the list, and must ensure that these items are not valued above the less-than-$2 nominal value limit per item.

Alternatively, instead of including the incentive items approval process within the authorization process, the State agency may permit the vendor to request approval for use of an incentive item at any time during the period of the agreement, or only at specified times during the period of the agreement.

f. Incentive Item Restrictions for Non-Above-50-Percent Vendors

The statute only addresses incentive items provided by above-50-percent vendors. Thus, restrictions on incentive items for vendors other than above-50-percent vendors must be established in accordance with State/ITO law and/or regulations. State agencies should consult with their legal counsel to determine the correct process for implementing any restrictions on incentive items for vendors other than above-50-percent vendors in accordance with State/ITO law and/or regulations.

4. Administrative Review (§ 246.18(a)(1)(iii)(D) Through (a)(1)(iii)(F))

This proposed rule would add three new exclusions under which a currently authorized vendor would not be entitled to pursue an administrative review of the State agency's WIC policies through the WIC administrative review process. First, a current vendor could not obtain an administrative review of the State agency's determination to include or exclude an infant formula manufacturer, wholesaler, distributor, or retailer from the list which the State agency must provide to vendors. Second, an above-50-percent vendor could not obtain administrative review of the State agency's determination to deny that above-50-percent vendor's request for approval of an allowable incentive item. Third, the State agency's determination whether 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 is not subject to administrative review.

a. State Agency's Exclusion or Inclusion From the Infant Formula Supplier List Not Subject to Administrative Review (§ 246.18(a)(1)(iii)(D))

The State agency's determination to include or exclude an infant formula supplier from the list provided to

vendors is a responsibility of the State agency set forth in the CNA. Section 246.4(a)(14)(xvii) of this proposed rule would require State agencies to describe this determination process in its WIC State Plan. Thus, concerns about this determination process would be properly raised during the public comment phase of State Plan development. Moreover, a vendor would retain the right to seek review of a denial of authorization, termination of the vendor agreement, or imposition of a sanction based on the vendor's alleged non-compliance with the infant formula supplier list policies and procedures.

Further, the exclusion from an administrative review for a State agency's determination to include or exclude an infant formula manufacturer, wholesaler, distributor, or retailer from the infant formula list only applies to WIC-authorized retail vendors. This exclusion would not deny any party aggrieved by such decisions, such as a retailer excluded from the list, from using the legal process administratively or in the courts to pursue an action based on laws or regulations concerning Civil Rights, small business, or other legal rights.

b. The Validity or Appropriateness of the State Agency's Prohibition of Incentive Items and the State Agency's Denial of an Above-50-Percent Vendor's Request To Provide an Incentive Item to Customers Not Subject to Administrative Review (§ 246.18(a)(1)(iii)(E))

The Department's view is that State agencies must have the authority to safeguard WIC food funds. WIC is not an entitlement program. Rather, WIC's funding is discretionary, meaning it is provided as a set amount of funding and can serve only as many customers as this funding allows. As previously noted, the higher prices charged to the WIC Program by above-50-percent vendors reflect the cost of the incentive items which above-50-percent vendors provide to customers. Thus, it is necessary to restrict such incentive items in order to safeguard WIC food funds.

Consistent with this authority, as previously discussed in section 3.b. of this preamble, this proposed rule would provide State agencies with the discretion to prohibit all incentive items.

Administrative review of the State agency's decision to prohibit a particular kind of incentive item or to deny an above-50-percent vendor's request to provide an incentive item to customers would be inconsistent with this discretion of the State agency. However, a vendor would retain the right to seek review of a denial of authorization, termination of the vendor agreement, or imposition of a sanction based on a vendor's alleged non-compliance with restrictions on incentive items.

c. State Agency's Determination To Notify a Vendor of Violations Not Subject to Administrative Review (§ 246.18(a)(1)(iii)(F))

The statute provides the State agency with the discretion to determine whether to notify a vendor in writing after a violation has occurred, based on whether it would compromise an investigation. If the State agency determines that the notification would compromise an investigation, the State agency is not required to provide the notification to the vendor. Thus, administrative review of the absence of such notification would be inconsistent with the discretion provided to the State agency by the statute. Section 246.12(l)(3) of this proposed rule would require the State agency to determine whether notification would compromise an investigation on a case-by-case basis and to document this determination in the vendor file whenever notification is not provided.

5. Adjusting Vendor Civil Money Penalty (CMP) Levels for Inflation

The Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), Public Law 101–410, 28 U.S.C 2461, requires periodic adjustment (at least once every four years) of civil money penalty (CMP) levels to reflect inflation. The only WIC vendor-related CMPs established in the CNA pertain to convictions in court for trafficking and illegal sales.

Each Federal Executive agency is responsible for adjusting all CMPs within the agency's jurisdiction. Accordingly, the Department published a final rule to implement inflation adjustments for CMPs of all USDA agencies, ''Department of Agriculture Civil Monetary Penalties Adjustment,'' 70 FR 29573, May 24, 2005, which amended the regulations of individual programs, including WIC (7 CFR part 246), as well as the Departmental regulations on CMPs (Adjusted Civil Money Penalties, 7 CFR 3.91).

Prior to the Department's rule, for all of the mandatory and State agency sanctions, WIC regulations provided that a CMP or fine may not exceed $10,000 per violation or $40,000 for all of the violations investigated as part of a single investigation. The Department's final rule amended § 246.12(l)(1)(x)(C) of the WIC regulations by adding citations to § 3.91(b)(3)(v) and (b)(3)(vi) which provide the amount of the CMP adjusted for inflation for only those vendor sanctions set forth in the CNA. This had the effect of raising the maximum CMP level from $10,000 to $11,000 per violation for convictions for trafficking and illegal sales, and raising the CMP level from $40,000 to $44,000 as the maximum amount for such violations occurring during a single investigation.

As a result, all of the other vendor-related CMPs established in the WIC regulations have not been adjusted for inflation and remain unchanged. This includes CMPs for vendor violations resulting in mandatory sanctions that are handled administratively by the State agency instead of through the courts, and CMPs for State agency sanctions.

The Department believes that the amount of all CMPs should be uniform for all vendor violations. Accordingly, we are proposing to amend § 246.12(l)(1)(x)(C) and (l)(2)(i), to change the amount of the CMPs for the remaining WIC vendor violations to be consistent with the CMP levels set forth in the Department's rule at § 3.91(b)(3)(v).

List of Subjects in 7 CFR Part 246

Food assistance programs, Food donations, Grant programs—Social programs, Indians, Infants and children, Maternal and child health, Nutrition education, Public assistance programs, WIC, Women.

For the reasons set forth in the preamble, 7 CFR part 246 is proposed to be amended as follows:

PART 246—SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS AND CHILDREN

1. The authority citation for part 246 continues to read as follows:

Authority: 42 U.S.C. 1786.

2. In § 246.4, revise the first sentence of paragraph (a)(14)(iii) and add a new paragraph (a)(14)(xvii) to read as follows:

§ 246.4 State plan.

(a) * * *

(14) * * *

(iii) * * * A sample vendor agreement, including the sanction schedule, the process for notification of violations in accordance with § 246.12(l)(3), and the State agency's policies and procedures on incentive items in accordance with § 246.12(g)(3)(iv), which may be incorporated as attachments or, if the sanction schedule, the process for

notification of violations, or policies on incentive items are in the State agency's regulations, through citations to the regulations. * * *

* * * * *

(xvii) *List of infant formula wholesalers, distributors, and retailers.* The policies and procedures for compiling and distributing to authorized WIC retail vendors, on an annual or more frequent basis, as required by § 246.12(g)(10), a list of infant formula wholesalers, distributors, and retailers licensed in the State in accordance with State law (including regulations), and infant formula manufacturers registered with the Food and Drug Administration (FDA) that provide infant formula. The vendor may provide only the authorized infant formula which the vendor has obtained from a source included on the list described in § 246.12(g)(10) to participants in exchange for food instruments specifying infant formula.

* * * * *

3. In § 246.12:

a. Amend paragraph (g)(3)(i) by adding a sentence at the end of the paragraph;

b. Add new paragraphs (g)(3)(iv) and (g)(10);

c. Revise paragraph (h)(3)(ii);

d. Revise the third sentence of paragraph (h)(3)(xviii);

e. Add new paragraph (h)(8);

f. Revise paragraphs (i)(2) and (l)(1)(iv);

g. Amend the third sentence of paragraph (l)(1)(x)(C) by removing the words ''$10,000, except for those violations listed in paragraph (l)(1)(i) of this section, where the civil money penalty must be the maximum amount per violation specified in § 3.91(b)(3)(v) of this title for trafficking violations, or § 3.91(b)(3)(vi) of this title for selling firearms, ammunition, explosives, or controlled substances in exchange for food instruments.'' and adding in their place the words ''a maximum amount specified in §3.91(b)(3)(v) of this title for each violation.'';

h. Amend the fifth sentence of paragraph (l)(1)(x)(C) by removing the words ''$40,000, except for those violations listed in paragraph (l)(1)(i) of this section, where the total amount of civil money penalties may not exceed the maximum amount for violations occurring during a single investigation specified in § 3.91(b)(3)(v) of this title for trafficking violations, or § 3.91(b)(3)(vi) of this title for selling firearms, ammunition, explosives, or controlled substances in exchange for food instruments.'' and adding in their place the words ''an amount specified in § 3.91(b)(3)(v) of this title as the maximum penalty for violations occurring during a single investigation.'';

i. Amend paragraph (l)(2)(i) by removing the words ''$10,000 for each violation.'' in the fourth sentence, and adding in their place the words ''a maximum amount specified in §3.91(b)(3)(v) of this title for each violation.'', and by removing the word ''$40,000.'' in the fifth sentence, and adding in its place the words ''an amount specified in §3.91(b)(3)(v) of this title as the maximum penalty for violations occurring during a single investigation.''; and

j. Revise paragraph (l)(3).

The revisions and additions read as follows:

§ 246.12 Food delivery systems.

* * * * *

(g) * * *

(3) * * *

(i) * * * The State agency may not authorize a vendor applicant unless it determines that the vendor applicant obtains infant formula only from sources included on the State agency's list described in § 246.12(g)(10).

* * * * *

(iv) *Provision of incentive items.* The State agency may not authorize or continue the authorization of an above-50-percent vendor, or make payments to an above-50-percent vendor, which provides or indicates an intention to provide prohibited incentive items to customers. Evidence of such intent includes, but is not necessarily limited to, advertising the availability of prohibited incentive items.

(A) The State agency may approve the following incentive items to be provided by above-50-percent vendors to customers:

(*1*) Food or merchandise obtained at no cost to the vendor, subject to documentation;

(*2*) Food or merchandise of nominal value, i.e., having a per item cost of less than $2, subject to documentation;

(*3*) Food sales and specials which involve no cost or less than $2 in cost to the vendor for the food items involved, subject to documentation, and do not result in a charge to a WIC food instrument for foods in excess of the foods listed on the food instrument;

(*4*) For-profit services which are not otherwise prohibited and are purchased by participants at a fair market value based on comparable for-profit services; and

(*5*) Minimal customary courtesies of the retail food trade, such as helping the customer to obtain an item from a shelf or from behind a counter, bagging food for the customer, and assisting the customer with loading the food into a vehicle.

(B) The following incentive items are prohibited for above-50-percent vendors to provide to customers:

(*1*) Services which result in a conflict of interest or the appearance of such conflict for the above-50-percent vendor, such as assistance with applying for WIC benefits;

(*2*) Incentive items allowed under paragraph (g)(3)(iv)(A) of this section, at the discretion of the State agency;

(*3*) Lottery tickets provided to customers at no charge or below face value;

(*4*) Cash gifts in any amount for any reason;

(*5*) Anything made available in a public area as a complimentary gift which may be consumed or taken without charge;

(*6*) An allowable incentive item provided more than once per customer per shopping visit, regardless of the number of customers or food instruments involved, unless the incentive items had been obtained by the vendor at no cost or the total value of multiple incentive items provided during one shopping visit would not exceed the less-than-$2 nominal value limit;

(*7*) Food, merchandise or services of greater than nominal value provided to the customer;

(*8*) Food, merchandise sold to customers below cost, or services purchased by customers below fair market value;

(*9*) Any kind of incentive item which incurs a liability for the WIC Program; and

(*10*) Any kind of incentive item which violates any Federal, State, or local law or regulations.

* * * * *

(10) *List of infant formula wholesalers, distributors, and retailers licensed under State law or regulations, and infant formula manufacturers registered with the Food and Drug Administration (FDA).* The State agency must provide a list in writing or by other effective means to all authorized WIC retail vendors of the names and addresses of infant formula wholesalers, distributors, and retailers licensed in the State in accordance with State law (including regulations), and infant formula manufacturers registered with the Food and Drug Administration (FDA) that provide infant formula, on at least an annual basis.

(i) *Notification to vendors.* The State agency is required to notify vendors that they must purchase infant formula only

from a source included on the State agency's list, or from a source on another State agency's list if the vendor's State agency permits this, and must only provide such infant formula to participants in exchange for food instruments specifying infant formula. For the purposes of paragraph (g)(10) of this section, ''infant formula'' means infant formula as defined in § 246.2, contract brand and non-contract brand infant formula as defined in § 246.2, and infant formula covered by a waiver granted under § 246.16a(e).

(ii) *Type of license.* If more than one type of license applies, the State agency may choose which one to use.

(iii) *Exclusions from list.* The State agency may not exclude a State-licensed entity from the list except when:

(A) Specifically required or authorized by State law or regulations; or

(B) The entity does not carry infant formula.

(h) * * *

(3) * * *

(ii) *No substitutions, cash, credit, refunds, or exchanges.* The vendor may provide only the authorized supplemental foods listed on the food instrument.

(A) The vendor may not provide unauthorized food items, nonfood items, cash, or credit (including rain checks) in exchange for food instruments. The vendor may not provide refunds or permit exchanges for authorized supplemental foods obtained with food instruments, except for exchanges of an identical authorized supplemental food item when the original authorized supplemental food item is defective, spoiled, or has exceeded its ''sell by,'' ''best if used by,'' or other date limiting the sale or use of the food item. An identical authorized supplemental food item means the exact brand and size as the original authorized supplemental food item obtained and returned by the customer.

(B) The vendor may provide only the authorized infant formula which the vendor has obtained from sources included on the list described in § 246.10(g)(10) to participants in exchange for food instruments specifying infant formula.

* * * * *

(xviii) * * * The State agency must notify a vendor in writing when an investigation reveals an initial incidence of a violation for which a pattern of incidences must be established in order to impose a sanction, before another such incidence is documented, unless the State agency determines, in its discretion, on a case-by-case basis, that notifying the vendor would compromise an investigation.

* * * * *

(8) *Allowable and prohibited incentive items for above-50-percent vendors.* The vendor agreement for an above-50-percent vendor, or another document provided to the vendor and cross-referenced in the agreement, must include the State agency's policies and procedures for allowing and prohibiting incentive items to be provided by an above-50-percent vendor to customers, consistent with paragraph (g)(3)(iv) of this section.

(i) The State agency must provide written approval or disapproval (including by electronic means such as electronic mail or facsimile) of requests from above-50-percent vendors for permission to provide allowable incentive items to customers;

(ii) The State agency must maintain documentation for the approval process, including invoices or similar documents showing that the cost of each item is either less than the $2 nominal value limit, or obtained at no cost; and

(iii) The State agency must define unallowed incentive items.

(i) * * *

(2) *Content.* The annual training must include instruction on the purpose of the Program, the supplemental foods authorized by the State agency, the minimum varieties and quantities of authorized supplemental foods that must be stocked by vendors, the requirement that vendors obtain infant formula only from sources included on a list provided by the State agency, the procedures for transacting and redeeming food instruments, the vendor sanction system, the vendor complaint process, the claims procedures, the State agency's policies and procedures regarding the use of incentive items, and any changes to program requirements since the last training.

* * * * *

(l) * * *

(1) * * *

(iv) *One-year disqualification.* The State agency must disqualify a vendor for one year for:

(A) A pattern of providing unauthorized food items in exchange for food instruments, including charging for supplemental foods provided in excess of those listed on the food instrument; or

(B) A pattern of an above-50-percent vendor providing prohibited incentive items to customers as set forth in paragraph (g)(3)(iv) of this section, in accordance with the State agency's policies and procedures required by paragraph (h)(8) of this section.

* * * * *

(3) *Notification of violations.* The State agency must notify a vendor in writing when an investigation reveals an initial incidence of a violation for which a pattern of incidences must be established in order to impose a sanction, before another such incidence is documented, unless the State agency determines, in its discretion, on a case-by-case basis, that notifying the vendor would compromise an investigation. This notification requirement applies to the violations set forth in paragraphs (l)(1)(iii)(C) through (l)(1)(iii)(F), (l)(1)(iv), and (l)(2)(i) of this section.

(i) Prior to imposing a sanction for a pattern of incidences of a violation, the State agency must 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.

(ii) The State agency may use the same method of notification which the State agency uses to provide a vendor with adequate advance notice of the time and place of an administrative review in accordance with § 246.18(b)(3).

(iii) The State agency may conduct another compliance buy visit after the notice of violation is received by the vendor, or presumed to be received by the vendor consistent with the State agency's procedures for providing such notice.

(iv) All of the incidences of a violation occurring during the first compliance buy visit must constitute only one incidence of that violation for the purpose of establishing a pattern of incidences.

* * * * *

4. In § 246.18, redesignate (a)(1)(iii)(D) through (a)(1)(iii)(H) as paragraphs (a)(1)(iii)(G) through (a)(1)(iii)(K) and add new paragraphs (a)(1)(iii)(D), (a)(1)(iii)(E), and (a)(1)(iii)(F), to read as follows:

§ 246.18 Administrative review of State agency actions.

(a) * * *

(1) * * *

(iii) * * *

(D) The State agency's determination to include or exclude an infant formula manufacturer, wholesaler, distributor, or retailer from the list required pursuant to § 246.10(g)(10);

(E) The validity or appropriateness of the State agency's prohibition of incentive items and the State agency's denial of an above-50-percent vendor's request to provide an incentive item to customers pursuant to § 246.12(h)(8);

(F) The State agency's determination whether 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, pursuant to § 246.12(l)(3);

* * * * *

Dated: July 18, 2006.

Eric M. Bost,

Under Secretary, Food, Nutrition, and Consumer Services.

[FR Doc. 06–6596 Filed 7–31–06; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 305, 319, and 352

[Docket No. APHIS–2005–0106]

RIN 0579–AB80

Revision of Fruits and Vegetables Import Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We are reopening the comment period for our proposed rule to revise and reorganize the regulations pertaining to the importation of fruits and vegetables to consolidate requirements of general applicability and eliminate redundant requirements, update terms and remove outdated requirements and references, update the regulations that apply to importations into territories under U.S. administration, and make various editorial and nonsubstantive changes to regulations to make them easier to use. We also proposed to make substantive changes to the regulations, including: Establishing criteria within the regulations that, if met, would allow us to approve certain new fruits and vegetables for importation into the United States and to acknowledge pest-free areas in foreign countries more effectively and expeditiously; doing away with the practice of listing specific commodities that may be imported subject to certain types of phytosanitary measures; and providing for the issuance of special use permits for fruits and vegetables. The proposed changes are intended to simplify and expedite our processes for approving certain new imports and pest-free areas while continuing to allow for public participation in the processes. This action will allow interested persons additional time to prepare and submit comments.

DATES: We will consider all comments that we receive on Docket No. APHIS–2005–0106 on or before August 25, 2006.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and, in the lower ''Search Regulations and Federal Actions'' box, select ''Animal and Plant Health Inspection Service'' from the agency drop-down menu, then click on ''Submit.'' In the Docket ID column, select APHIS–2005–0106 to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.
- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. APHIS–2005–0106, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2005–0106.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Regarding the proposed commodity import request evaluation process, contact Mr. Matthew Rhoads, Planning, Analysis, and Regulatory Coordination, PPQ, APHIS, 4700 River Road Unit 141, Riverdale, MD 20737; (301) 734–8790.

Regarding import conditions for particular commodities, contact Ms. Donna L. West, Senior Import Specialist, Commodity Import Analysis and Operations, PPQ–PRI, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737; (301) 734–8758.

SUPPLEMENTARY INFORMATION: On April 27, 2006, we published in the **Federal Register** (71 FR 25010–25057, Docket No. APHIS–2005–0106) a proposal to revise and reorganize the regulations pertaining to the importation of fruits and vegetables to consolidate requirements of general applicability and eliminate redundant requirements, update terms and remove outdated requirements and references, update the regulations that apply to importations into territories under U.S. administration, and make various editorial and nonsubstantive changes to regulations to make them easier to use. We also proposed to make substantive changes to the regulations, including: (1) Establishing criteria within the regulations that, if met, would allow us to approve certain new fruits and vegetables for importation into the United States and to acknowledge pest-free areas in foreign countries more effectively and expeditiously; (2) doing away with the practice of listing specific commodities that may be imported subject to certain types of phytosanitary measures; and (3) providing for the issuance of special use permits for fruits and vegetables. The proposed changes are intended to simplify and expedite our processes for approving certain new imports and pest-free areas while continuing to allow for public participation in the processes.

Comments on the proposed rule were required to be received on or before July 26, 2006. We are reopening the comment period for Docket No. APHIS–2005–0106 until August 25, 2006, an additional 30 days from the original close of the comment period. This action will allow interested persons additional time to prepare and submit comments. We will also consider all comments received between July 27, 2006 (the day after the close of the original comment period) and the date of this notice.

Done in Washington, DC, this 26th day of July 2006.

W. Ron DeHaven,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E6–12336 Filed 7–31–06; 8:45 am]

BILLING CODE 3410–34–P