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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 54 and 62

[No. LS-02-10]

RIN 0581-AC12

Quality Systems Verification Programs

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The Agricultural Marketing Service (AMS) is establishing a separate user-fee schedule for the Quality Systems Verification Programs (QSVP) and expanding the scope of the QSVP to include all agricultural products and services within the responsibility of the Livestock and Seed (LS) Program. A new part 62 is established for QSVP services. QSVP are a collection of voluntary, audit-based, user-fee programs authorized under the Agricultural Marketing Act of 1946. QSVP facilitate the global marketing and trade of agricultural products; provide consumers the opportunity to distinguish specific characteristics involved in the production and processing of agricultural products; and ensure that product consistently meets program requirements.

DATES: Effective October 25, 2005.

FOR FURTHER INFORMATION CONTACT: James L. Riva, Chief, Audit, Review, and Compliance (ARC) Branch, telephone 202-720-1124, or e-mail James.Riva@usda.gov.

SUPPLEMENTARY INFORMATION:

Background and Discussion

The Agricultural Marketing Act of 1946 (AMA), as amended, (7 U.S.C. 1621, *et seq.*), gives AMS the authority to provide services so that agricultural products may be marketed to their best advantage, that trade may be facilitated,

and that consumers may be able to ascertain characteristics involved in the production and processing of products and obtain the quality of product they desire. AMA also provides for the collection of fees from users of these services that are reasonable and cover the cost of providing services.

The QSVP were developed in 1995 and have since grown to include several value-added marketing programs. The QSVP have grown steadily over the past few years, with auditors conducting 385 assessments in fiscal year (FY) 2001, 562 assessments in FY 2002, and 715 assessments in FY 2003, and 915 assessments in FY 2004. Presently, 14 full-time auditors conduct assessments for the LS Program.

QSVP are voluntary, audit-based, user-fee funded programs developed and conducted at the request of industry and others as a cost-effective alternative to conventional product certification. QSVP use International Organization for Standardization's (ISO) Guidelines and standards as a format for evaluating program documentation to ensure consistent assessment practices and promote international recognition of assessment results.

QSVP user-fees were previously based on the approved hourly rate established for meat grading and certification services provided by the Meat Grading and Certification (MGC) Branch pursuant to 7 CFR part 54. Following the initial program development period, LS Program management conducted a detailed cost analysis of QSVP services and determined that the existing hourly rate established for meat grading and certification services did not sufficiently cover the cost of providing QSVP services. Due to the complexity of planning, performing and interpreting the results of assessments, auditor positions are classified at the GS-11/12 pay grade, in contrast to the GS-5/7/9 pay grade classifications of most MGC Branch full-time positions.

Upon considering all QSVP operational expenses, the LS Program determined that the actual cost of QSVP services, excluding travel costs, to be \$108 per hour. LS Program management considered employee salaries and benefits; Agency and LS Program overhead; total revenue hours available to the ARC Branch; and included other anticipated costs such as, federally mandated pay raises through FY 2005,

rent, communications, utilities, contractual services, supplies, and equipment in their analysis.

The LS Program considered alternatives to creating a separate user-fee for QSVP services, but found that none were sufficient. Maintaining the same user-fee for QSVP services currently used for conventional meat grading and certification services would not sufficiently cover the cost of providing QSVP services. Another option was to terminate all QSVP services, which would adversely affect producers, businesses, and consumers who desire QSVP services and those entities with already-established programs.

The QSVP were administered through the LS Program's MGC Branch pursuant to 7 CFR part 54 using the user-fee schedule established for meat grading and certification services. In 2001, the administration of QSVP was moved by the LS Program to the Audit, Review, and Compliance (ARC) Branch. This rule establishes a separate user-fee of \$108 per hour for QSVP services under a new part 62. Additionally, this rule expands the scope of QSVP services to include all agricultural products or services within the responsibility of the LS Program, such as livestock, meat, meat products, seed, feedstuffs, as well as processes involving the production of these products, agricultural product data storage, product traceability and identification. A new part 62 is established for QSVP services.

Executive Order 12866

This rule has been determined to be not significant for purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect and would not preempt or supersede any State or local laws, regulations, or policies, unless they present an irreconcilable conflict. There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this rule.

Regulatory Flexibility Act and Paperwork Reduction Act

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA)(5 U.S.C. 601 *et seq.*), AMS has considered the economic effect of this action on small entities and has determined that this rule will not have a significant economic impact on a substantial number of small entities. The purpose of RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly burdened.

AMS, through the LS Program's ARC Branch, provides voluntary assessment services to approximately 415 businesses, including 152 livestock slaughterers, 72 meat processors, 46 livestock producers feeders, 135 organic certifying companies, 4 trade associations, and 4 State and Federal entities. Seventy-five percent (*i.e.*, 346) of these businesses are classified as small entities and generate approximately 65 percent of the ARC Branch's revenue. AMS anticipates that many new applicants for QSVP will be classified as small entities. The Small Business Administration (13 CFR 121.201) defines small agricultural producers as those having annual receipts of less than \$750,000; small agricultural service firms as those whose annual receipts are less than \$6 million; and small meat packers as those that have less than 500 employees. No entity, small or large, is obligated to use voluntary QSVP services provided under the authority of AMA.

AMS regularly reviews its user-fee-financed programs to determine if the fees are adequate to cover the cost of the services provided. The most recent review determined that the hourly rate previously charged by the ARC Branch for QSVP services did not generate sufficient revenues to recover operating costs for current and near-term periods while maintaining a 4-month operating reserve of \$275,000. In FY 2004, the ARC Branch incurred a \$330,000 operating loss. Losses have depleted the ARC Branch's operating reserve and placed the ARC Branch in an unstable financial position that could adversely affect its ability to provide QSVP services.

While existing automated information management systems for data collection, retrieval, dissemination, applicant billing, and disbursement of employee entitlements, were utilized, the ARC Branch continued to lose revenue due to the cost of providing QSVP services utilizing auditors classified at the GS-11/12 pay grade while charging a user-

fee that is based on a lower GS-5/7/9 pay grade classification.

The ARC Branch operating costs increased as a result of higher salaries associated with higher grade employees; congressionally mandated salary increases for all Federal Government employees; ongoing information system technology upgrades necessary to remain compatible with customer and Agency systems; inflation of non-salary operating expenses; and office maintenance expenses. AMS estimates that this action will provide the ARC Branch with an additional \$576,000 for FY 2006, offsetting the FY 2005 operating losses of \$558,000. This fee increase will help create a 4-month operating reserve as required by AMS.

The new part 62 includes sections on definitions; sections related to providing services, including availability and how to apply for services; and suspension, denial, or cancellation of service and other sections relating to fees. These sections are similar to, or the same as, provisions that currently apply to Quality Systems Verification Programs.

The information collection requirements that appear in this final rule have been approved by OMB and assigned OMB Control Number 0581-0124. Under this rule, applicants are required to submit a cover letter and a complete copy of the applicant's program documentation when a request for service is made. This is a one-time requirement per service request. The QSVP also requires applicants to retain records and documents necessary to support the requested service for the period of at least one calendar year following the year the record was created and long enough to assess conformance of the product through the applicant's quality management system. Additionally, applicants must ensure that such records and documents are readily available and easily accessible.

AMS' estimate for recordkeeping burden reflects the amount of time needed to prepare, store, and maintain documents. Based on its experience with QSVP, AMS understands that applicants develop and maintain complete documentation of their programs as a normal business practice. AMS believes the cost burden associated with submission of complete program documentation to be limited to the time needed for the applicant to review the documentation for completeness and accuracy. AMS estimates this time to average 24 hours per applicant at \$20.00 per hour for a total one-time burden per applicant of \$480.00. AMS estimates the total one-time burden if 50 applicants applied under this rule to be \$24,000.

Based on its experience, AMS also believes that the documents and records required to be retained are normally retained by applicants as part of their normal business practices. However, if record keepers were compensated for their time, AMS estimates that the time required for each applicant to retain these records and documents in a manner required in the rule to average 6 hours per year at \$20.00 per hour for a total annual burden of \$120.00 per applicant. Assuming that 50 applicants are retained under this rule, the total annual burden is estimated to be \$6,000.

Comments concerning small business consideration and the information collection burden or discussed in the next section of this document.

Comments

AMS published a proposed rule in the April 7, 2005, **Federal Register** [66 FR 17611] for public comment. The comment period ended on May 9, 2005. The comment period regarding the information collection requirements that would result from this proposal ended on June 6, 2005. The comments have been posted on AMS' Web site at <http://www.ams.usda.gov/lsg/arc/rule.htm>.

Discussion of Comments

USDA received 3 comments from interested persons, which included two seed trade organizations and one interested party. While one of the seed organizations did not oppose the proposed rule, the second recommended an alternative program that would delegate certification activities to existing organizations. The comment from the interested party opposed the QSVP as a new program that would enhance the federal deficit. The commenters raised a number of concerns including establishing duplicative or conflicting service for the seed industry and questioning the fee analysis itself.

The QSVP is an established program that began providing service in 1995, as a voluntary, user-fee funded program, under the authority of the Agricultural Marketing Act of 1946. As such, expanding the scope of the QSVP to include all agricultural products and services within the responsibility of the LS Program will not enhance the federal deficit. Further, with regard to expanding program service to the seed industry, the QSVP will facilitate the global marketing and trade of not only seeds and seed products, but all agricultural products and services under the LS Program. With regard to the concerns raised about duplicative and conflicting service for the seed industry,

we believe that the QSVP has and will provide a valuable resource for those businesses and industries that wish to use a USDA shield or statement. One commenter noted that some facilities are already ISO certified and that this should be taken into account in the QSVP procedure. To the extent appropriate, ISO certification will be taken into account under QSVP.

One commenter suggested that the QSVP programs be changed to a program that would delegate certification activities to existing organizations. Also, another commenter was concerned about the QSVP adding a layer of complexity in connection with marketing of seed both domestically and internationally. The existing QSVP provides services to primarily the livestock and meat industries. This final rule will provide the same services in the expanded program format, which includes the seed industry. As such, this does not represent a significant program change. Further, individual entities are free to request QSVP services or not, as the program is voluntary.

Concerns were raised about certain aspects of the fee analysis. Two commenters were of the view that the \$20.00 per hour used to estimate the costs for the applicant was too low. As part of the Paperwork Reduction Act burden estimate, a \$20.00 per hour cost was based upon our experience with QSVP and is reasonable for purposes of information collection burden estimates. The \$20.00 cost is separate and distinct from the \$108.00 per hour fee. The commenters also noted that the methodology concerning the \$108.00 per hour fee is sound, but that non-salary expenses were three times the expense for salaries. The charge of \$108.00 per hour reflects the rate necessary to recover the costs of administering the QSVP. AMS considered numerous factors in developing the rate to charge to provide services. AMS and LS Program management considered employee salaries and benefits; Agency and LS Program overhead; total revenue hours available to the ARC Branch; and included other anticipated costs, such as federally mandated pay raises, rent, communications, utilities, contractual services, supplies, and equipment in their analysis.

Finally, one commenter questioned the salaries of the employees used in the program. This commenter also disagreed that the rule will not have a significant economic impact on small companies. AMS estimates that this action will provide an additional \$420,000 for FY 2005. Of the \$420,000, small businesses would pay an average of \$878.00 more

per year per applicant. A similar result is expected for new applicants who would be considered small businesses. Further, no entity, small or large, is obligated to use voluntary QSVP services provided under the authority of the AMA. Accordingly, we disagree with this comment.

Another commenter questioned the size of businesses with 5,000 employees, noting that such entities should be considered large businesses. Under Small Business Administration criteria, certain entities with less than 500 employees are considered small businesses.

No changes to the regulation will be made as a result of the comments received. However, AMS will continue to work with the existing trade organizations and their respective industries regarding implementation of this and any future rulemakings.

Pursuant to 5 U.S.C. 533, it is found and determined that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register**. The fees should be implemented as soon as possible to avoid further financial losses for the program. Given the current status of this program, our effective date of two weeks after publication in the **Federal Register** is reasonable.

List of Subjects

7 CFR Part 54

Meats, Prepared Meats, and Meat Products.

7 CFR Part 62

Food grades and standards, Food labeling, Meat and meat products.

■ For the reasons set forth in the preamble, chapter 1 of title 7 of the Code of Federal Regulations is amended by amending part 54 and adding part 62 to read as follows:

PART 54—[AMENDED]

■ 1. The authority citation for part 54 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

§ 54.4 [Amended]

- 2. In § 54.4, paragraph (5) is removed.
- 3. Part 62 is added to read as follows:

PART 62—LIVESTOCK, MEAT, AND OTHER AGRICULTURAL COMMODITIES (QUALITY SYSTEMS VERIFICATION PROGRAMS)

Subpart A—Quality Systems Verification Programs Definitions

Sec.

62.000 Meaning of terms.

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62.100 Administrator.

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Miscellaneous

OMB Control Number

62.400 OMB control number assigned pursuant to the Paperwork Reduction Act.

Authority: 7 U.S.C. Sec. 1621–1627.

Subpart A—Quality Systems Verification Programs Definitions

§ 62.000 Meaning of terms.

Words used in this subpart in the singular form shall be deemed to impart the plural, and vice versa, as the case may demand. For the purposes of such regulations, unless the context otherwise requires, the following terms shall be construed, respectively, to mean:

Administrator. The Administrator of the Agricultural Marketing Service (AMS), or any officer or employee of AMS to whom authority has heretofore been delegated or to whom authority may hereafter be delegated, to act in the Administrator's stead.

Agricultural Marketing Service. The Agricultural Marketing Service of the U.S. Department of Agriculture.

Applicant. Any individual or business with financial interest in QSVP services who has applied for service under this part.

Assessment. A systematic review of the adequacy of program or system documentation, or the review of the completeness of implementation of a documented program or system.

Auditor. Person authorized by the Livestock and Seed Program to conduct official assessments.

Branch. The Audit, Review, and Compliance Branch of the Livestock and Seed Program.

Chief. The Chief of the ARC Branch, or any officer or employee of the Branch

to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in the Chief's stead.

Conformance. A user's quality manual and supporting documentation.

Deputy Administrator. The Deputy Administrator of the Livestock and Seed Program, or any officer or employee of the Livestock and Seed Program to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in the Deputy Administrator's stead.

Financially interested person. Any individual, partnership, corporation, other legal entity, or Government agency having a financial interest in the involved product or service.

Livestock. Bovine, ovine, porcine, caprine, bison or class of Osteichthyes.

Official mark. Official mark or other official identification means any form of mark or other identification, used under the regulations to show the conformance of products with applicable program requirements, or to maintain the identity of products for which service is provided under the regulations.

Official memoranda or assessment reports. Official memorandum means any assessment report of initial or final record of findings made by an authorized person of services performed pursuant to the regulations.

Products. Includes all agricultural commodities and services within the scope of the Livestock and Seed Program This includes livestock, meat, meat products, seed, feedstuffs, as well as processes involving the production of these products, agricultural product data storage, product traceability and identification.

QSVP Procedures. Audit rules and guidelines set forth by the Agricultural Marketing Service regarding the development, documentation, and implementation of QSVP.

Quality Manual. A collection of documents that describe the applicant's quality management system, as it applies to the requested service.

Quality Systems Verification Programs (QSVP). A collection of voluntary, audit-based, user-fee programs that allow applicants to have program documentation and program processes assessed by AMS auditor(s) and other USDA officials under this part.

Regulations. The regulations in this part.

USDA. The U.S. Department of Agriculture.

Administration

§ 62.100 Administrator.

The LS Program Deputy Administrator is charged with the administration of official assessments conducted according to the regulations in this part and approved LS Program QSVP procedures.

Service

§ 62.200 Services.

QSVP, under this regulation, provide applicants, the ability to have USDA assess documented processes or systems.

(a) Assessment services provided under the regulations shall consist of:

(1) A review of the adequacy of an applicant's quality manual against LS Program QSVP procedures, internationally recognized guidelines, or other requirements as approved by the LS Program;

(2) An onsite assessment of the applicant's program to ensure implementation of provisions within the quality manual and the applicant's conformance with applicable program requirements and LS Program QSVP procedures; and

(3) A reassessment of the applicant's program to ensure continued implementation of provisions within the quality manual and the applicant's conformance with program requirements and applicable LS Program QSVP procedures;

(b) Developmental assistance in the form of training to explain LS Program QSVP procedures is available upon request.

§ 62.201 Availability of service.

QSVP services under these regulations are available to international and domestic government agencies, private agricultural businesses and any financially interested person.

§ 62.202 How to apply for service.

Applicants may apply for QSVP services by submitting the following information to the ARC Branch headquarters office at USDA, AMS, LSP, ARC Branch, 1400 Independence Avenue, SW., STOP 0294, Room 2627-S, Washington, DC 20250-0294; by fax to: (202) 690-1038, or e-mail to: ARCBranch@usda.gov.

(a) The original completed form LS-313, Application for Service;

(b) A letter requesting QSVP services; and

(c) A complete copy of the applicant's program documentation, as described in the LS Program QSVP procedures.

§ 62.203 How to withdraw service.

Service may be withdrawn by the applicant at any time; provided that, the applicant notifies the ARC Branch in writing of his/her desire to withdraw the application for service and pays any expenses the Department has incurred in connection with such application.

§ 62.204 Authority to request service.

Any person requesting service may be required to prove his/her financial interest in the product or service at the discretion of the Deputy Administrator.

§ 62.205 Conflict of interest.

No USDA official shall review any program documentation or determine conformance of any documented process or system in which the USDA official has financial holdings.

§ 62.206 Access to program documents and activities.

(a) The applicant shall make its products and program documentation available and easily accessible for assessment, with respect to the requested service. Auditors and other USDA officials responsible for maintaining uniformity and accuracy of service under the regulations shall have access to all parts of facilities covered by approved applications for service under the regulations, during normal business hours or during periods of production, for the purpose of evaluating products or processes. This includes products in facilities which have been or are to be examined for program conformance or which bear any official marks of conformance. This further includes any facilities or operation that is part of an approved program.

(b) Documentation and records relating to an applicant's program must be retained for at least one calendar year following the calendar year during which the record was created.

§ 62.207 Official assessment.

Official assessment of an applicant's program shall include:

(a) *Documentation assessment.* Auditors and other USDA officials shall review the applicant's program documentation and issue finding of the review to the applicant.

(b) *Program assessment.* Auditors and USDA officials shall conduct an onsite assessment of the applicant's program to ensure provisions of the applicant's program documentation have been implemented and conform to LS Program QSVP procedures.

(c) *Program Determination.* Applicant's determined to meet or not meet LS Program QSVP procedures or

the applicant's program requirements shall be notified of their program's approval or disapproval.

(d) *Corrective and/or preventative actions.* Applicants may be required to implement corrective and/or preventative actions upon completion of assessment. After implementation of corrective and/or preventative actions, the applicant may request another assessment.

§ 62.208 Publication of QSVP assessment status.

Approved programs shall be posted for public reference on the ARC Branch Web site: <http://www.ams.usda.gov/lsg/arc/audit.htm>. Such postings shall include:

- (a) Program name and contact information,
- (b) Products or services covered under the scope of approval,
- (c) Effective dates of approval, and
- (d) Control numbers of official assessments, as appropriate, and
- (e) Any other information deemed necessary by the Branch Chief.

§ 62.209 Reassessment.

Approved programs are subject to periodic reassessments to ensure ongoing conformance with the LS Program QSVP procedures covered under the scope of approval. The frequency of reassessments shall be based on the LS Program QSVP procedures, or as determined by the Deputy Administrator.

§ 62.210 Denial, suspension, or cancellation of service.

(a) QSVP services may be denied if an applicant fails to meet its program requirements, or conform to LS Program QSVP procedures, such as:

- (1) Adequately address any program requirement resulting in a major non-conformance or an accumulation of minor non-conformances that result in the assignment of a major non-conformance for the program.
- (2) Demonstrate capability to meet any program requirement resulting in a major non-conformance.

(3) Present truthful and accurate information to any auditor or other USDA official; or

(4) Allow access to facilities and records within the scope of the program.

(b) QSVP services may be suspended if the applicant fails to meet its program requirements, or conform to LS Program QSVP procedures; such as failure to:

- (1) Adequately address any program requirement resulting in a major non-conformance;
- (2) Demonstrate capability to meet any program requirement resulting in a major non-conformance;

(3) Follow and maintain its approved program or QSVP procedures;

(4) Provide corrective actions and correction as applicable in the timeframe specified;

(5) Submit significant changes to and seek approval from the Chief prior to implementation of significant changes to an approved program;

(6) Allow access to facilities and records within the scope of the approved program;

(7) Accurately represent the eligibility of agricultural products or services distributed under an approved program;

(8) Remit payment for QSVP services;

(9) Abstain from any fraudulent or deceptive practice in connection with any application or request for service under the rule; or

(10) Allow any auditor or other USDA official to perform their duties under the regulations of this part.

(c) QSVP services maybe be cancelled, an application may be rejected, or program assessment may be terminated if the Deputy Administrator or his designee determines that a nonconformance has remained uncorrected beyond a reasonable amount of time.

§ 62.211 Appeals.

Appeals of adverse decisions under this part, may be made in writing to the Livestock and Seed Program Deputy Administrator at STOP 0249, Room 2092-South, 1400 Independence Avenue, SW., Washington, D.C. 20250-0249. Appeals must be made within 30 days of receipt of adverse decision.

(a) *Procedure for Appeals.* Actions under this subparagraph concerning decision of appeals of the Deputy Administrator shall be conducted in accordance with the Rule of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes set forth at 7 CFR § 1.130 through § 1.151 and the Supplemental Rules of Practice in 7 CFR part 50.

(b) [Reserved]

§ 62.212 Official assessment reports.

Official QSVP assessment reports shall be generated by the auditor at the conclusion of each assessment and a copy shall be provided to the applicant.

§ 62.213 Official identification.

The following, as shown in figure 1, constitutes official identification to show product or services produced under an approved USDA, Process Verified Program (PVP):

Figure 1.



(a) Products or services produced under an approved USDA, PVP may use the "USDA Process Verified" statement and the "USDA Process Verified" shield, so long as, both the statement and shield are used in direct association with a clear description of the process verified points that have been approved by the Branch.

(b) Use of the "USDA Process Verified" statement and the "USDA Process Verified" shield shall be approved in writing by Chief prior to use by an applicant.

Charges for Service

§ 62.300 Fees and other costs for service.

Fees and other charges will be levied based on the following provisions:

(a) *Fees for service.* Fees for QSVP services shall be based on the time required to provide service calculated to the nearest quarter hour period, including, but not limited to, official assessment time, travel time, and time required to prepare assessment reports. The hourly fee rate shall be \$108 per hour.

(b) *Transportation costs.* Applicants are responsible for paying actual travel costs incurred to provide QSVP services including but not limited to: Mileage charges for use of privately owned vehicles, rental vehicles and gas, parking, tolls, and public transportation costs such as airfare, train, and taxi service.

(c) *Per diem costs.* The applicant is responsible for paying per diem costs incurred to provide QSVP services away from the auditor's or USDA officials' official duty station(s). Per diem costs shall be calculated in accordance with existing travel regulations (41 CFR, subtitle F—Federal Travel Regulation System, chapter 301).

(d) *Other costs.* When costs, other than those costs specified in paragraphs (a), (b), and (c) of this section, are involved in providing the QSVP services, the applicant shall be responsible for these costs. The amount of these costs shall be determined administratively by the Chief. However, the applicant will be notified of these costs before the service is rendered.

§ 62.301 Payment of fees and other charges.

Fees and other charges for QSVP services shall be paid in accordance with the following provisions. Upon receipt of billing for fees and other charges, the applicant shall remit payment within 10 business days by check, electronic funds transfer, draft, or money order made payable to USDA, AMS, in accordance with directions on the billing. Fees and charges shall be paid in advance if required by the auditor or other authorized USDA official.

Miscellaneous**OMB Control Number****§ 62.400 OMB control number assigned pursuant to the Paperwork Reduction Act.**

The information collection and recordkeeping requirements of this part have been approved by OMB under 44 U.S.C. Chapter 35 and have been assigned OMB Control Number 0581-0124.

Dated: October 4, 2005.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. 05-20310 Filed 10-7-05; 8:45 am]

BILLING CODE 3410-02-P

SMALL BUSINESS ADMINISTRATION**13 CFR Part 126**

RIN 3245-AF31

HUBZone Program; Corrections

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Correcting amendments.

SUMMARY: The U.S. Small Business Administration (SBA) is correcting an improper citation within the interim rule that appeared in the **Federal Register** on August 30, 2005, which amends SBA's HUBZone program regulations.

DATES: Effective October 11, 2005.

FOR FURTHER INFORMATION CONTACT: Michael McHale, Associate Administrator, HUBZone Program, at (202) 205-6731 or by e-mail at: michael.mchale@sba.gov.

SUPPLEMENTARY INFORMATION:**Background**

On August 30, 2005, at 79 FR 51243, the SBA published an interim final rule amending SBA's HUBZone, 8(a) Business Development, Government Contracting and Size Standard regulations. This rule implemented

provisions of the Small Business Act including the Consolidated Appropriations Act, 2005, specifically, Subtitle E of Division K entitled the Small Business Reauthorization and Manufacturing Assistance Act of 2004.

Need for Correction

Since publication, SBA has discovered that this interim rule inadvertently stated SBA's intent to revise § 126.306 (found at 70 FR 51250) when it should have cited specifically to § 126.306(a). SBA intended to revise only subsection (a) leaving the other subsections unchanged.

List of Subjects in 13 CFR Part 126

Administrative practice and procedure, Government procurement, Small businesses.

■ Accordingly, 13 CFR part 126 is corrected by making the following correcting amendments:

PART 126—HUBZONE PROGRAM

■ 1. The authority citation for part 126 continues to read as follows:

Authority: 15 U.S.C. 632(a), 632(j), 632(p) and 657a.

■ 2. Revise the first and last sentences of § 126.306(a) as follows:

§ 126.306 How will SBA process this certification?

(a) The AA/HUB or designee is authorized to approve or decline certifications. * * * The decision of the AA/HUB or designee is the final agency decision.

* * * * *

Dated: September 30, 2005.

Allegra McCullough,

Associate Deputy Administrator/Office of Government Contracting and Business Development.

[FR Doc. 05-20188 Filed 10-7-05; 8:45 am]

BILLING CODE 8025-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 310 and 341**

[Docket No. 2004N-0289]
RIN 0910-AF34

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph for Over-the-Counter Nasal Decongestant Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the final monograph (FM) for over-the-counter (OTC) nasal decongestant drug products (drug products used to relieve nasal congestion due to a cold, hay fever, or other upper respiratory allergies) to remove the indication "for the temporary relief of nasal congestion associated with sinusitis" and to prohibit use of the terms "sinusitis" and "associated with sinusitis" elsewhere on the labeling. This final rule is part of FDA's ongoing review of OTC drug products.

DATES: *Effective Date:* This regulation is effective April 11, 2007.

Compliance Dates: The compliance date for products with annual sales less than \$25,000 is October 11, 2007. The compliance date for all other products is April 11, 2007.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of August 2, 2004 (69 FR 46119), FDA published a proposed rule to amend the FM for OTC nasal decongestant drug products to remove the indication "for the temporary relief of nasal congestion associated with sinusitis" and to prohibit use of the terms "sinusitis" and "associated with sinusitis" elsewhere on the labeling. Recent publications (Refs. 1 and 2) indicate that prospective studies on the role of nasal decongestants in the treatment of sinusitis are lacking, and the data on their use as an adjunct in the treatment of sinusitis are limited and controversial. Despite the lack of evidence for their use, nasal decongestants are recommended or prescribed by health care providers as adjunctive therapy for sinusitis. This treatment occurs within a physician-patient relationship and should not be construed as evidence that consumers should self-diagnose and self-manage sinusitis. In addition, there is preclinical evidence that topical nasal decongestants may have a negative effect on the resolution of sinusitis, as they may increase the degree of sinus inflammation (Ref. 3). Due to the current labeling, FDA is concerned that consumers use OTC nasal decongestant drug products (both oral and topical) to treat symptoms associated with