

## 2009 SUPPORTING STATEMENT

### United States Standards for Livestock and Meat Marketing Claims, Naturally Raised Claim for Livestock and the Meat and Meat Products Derived from such Livestock

OMB No. 0581-NEW

#### A. Justification.

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Agricultural Marketing Service

[Docket No. AMS-LS-07-0131; LS-07-16]

United States Standards for Livestock and Meat Marketing Claims, Naturally Raised Claim for Livestock and the Meat and Meat Products Derived from such Livestock

**AGENCY:** Agricultural Marketing Service, USDA

**ACTION:** Notice and Request for Comments on a NEW Information Collection.

**SUMMARY:** The Agricultural Marketing Service (AMS) is establishing a voluntary standard for a naturally raised marketing claim that livestock producers may request to have verified by the Department of Agriculture (USDA). This standard incorporates revisions made as a result of comments received from an earlier proposed standard. A number of livestock producers make claims associated with production practices in order to distinguish their products in the marketplace and there are a growing number of entities that are capturing value-added opportunities by using alternative production methods to meet the demands of consumers and markets seeking meat and meat products from naturally raised livestock. This voluntary standard will allow livestock producers to utilize AMS' voluntary, third party verification services to provide validity to such naturally raised livestock claims and, in certain cases, access to markets that require AMS verification. AMS verification of this claim would be accomplished through an audit of the production process in accordance with procedures that are contained in Part 62 of

**1. EXPLAIN THE CIRCUMSTANCES THAT MAKE THE COLLECTION OF INFORMATION NECESSARY. IDENTIFY ANY LEGAL OR ADMINISTRATIVE REQUIREMENTS THAT NECESSITATE THE COLLECTION.**

Section 203 (c) of the Agricultural Marketing Act of 1946, as amended (7U.S.C. 1622), directs and authorizes the Secretary of Agriculture “to develop and improve standards of quality, condition, quantity, grade, and packaging, and recommend and demonstrate such standards in

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order to encourage uniformity and consistency in commercial practices.” Utilization of this voluntary standard would be accomplished through an audit of the production process in accordance with procedures that are contained in Part 62 of Title 7 of the Code of Federal Regulations (7 CFR Part 62).

The Quality Systems Verification Programs (QSVP) are a collection of voluntary, audit-based, user-fee funded programs that allow applicants to have program documentation and program processes assessed by Agricultural Marketing Service (AMS) auditor(s) and other USDA officials. The QSVP are user-fees based on the approved hourly rate established under 7

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CFR, Part 62. Applicants (individual or business with financial interest in the product) may request services through the submission of Form LS-313 “Application for Service.”

Congress did not specifically authorize this information collection, but as a user-fee branch, completion and submission of Form LS-313 serve as a legal agreement and assures payment for services provided.

**2. INDICATE HOW, BY WHOM, AND FOR WHAT PURPOSE THE INFORMATION IS TO BE USED. EXCEPT FOR A NEW COLLECTION,**

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**INDICATE THE ACTUAL USE THE AGENCY HAS MADE OF THE INFORMATION RECEIVED FROM THE CURRENT COLLECTION.**

(a). Application for Service, QSVP Services 62.202. Applicants requesting the Audit, Review, and Compliance (ARC) Branch services for QSVP shall submit Form LS-313 available on the Internet at <http://eforms.ams.usda.gov/#CustomersLS>. Under noncommitment services, the applicant is charged only for the hours actually required to perform the services requested.

A signed and approved application (Form LS-313) constitutes authorization for the

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Department to enter the establishment for the purpose of performing official functions under the regulations. It also serves as the legal agreement between the Department and the applicant, wherein the applicant agrees to abide by the applicable regulations and to pay for the services rendered at the hourly rates, as listed in section 62.300. In approving the applications, the Department agrees to provide requested services under the regulations. All approved applications remain in effect indefinitely for those establishments, who regularly use QSVP services.

Form LS-313 is used by the Department to identify the responsible authorities in

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establishments requesting services and to initiate billing and collection accounts. Without a properly signed and approved Form LS-313, Department officials would not have the authority to enter the premises to provide grading and/or certification services nor would users of the services be legally obligated to abide by the regulations or to remit payment for services rendered.

(b). Request for Service (62.204). 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. A request for QSVP services is made when an applicant contacts the ARC Office, as applicable.

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Usually, these requests are received verbally. Utilizing verbal requests for ARC services has proved least burdensome to the public providing effective and timely service.

(c). Withdrawal of Application for Service (62.203). 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. Although this is an acceptable option for an applicant the

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process is not often used, therefore, AMS does not anticipate withdrawal services during the initiation of the program.

(d). Denial, suspension, or cancellation of service (62.210). 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

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auditor or other USDA official, or (4) allow access to facilities and records within the scope of the program. Because this is voluntary non-commitment service minimal denials, suspensions, or cancellations are expected.

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

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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.

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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.

(e). Request for Appeal Service (62.211). Appeals of adverse decisions under this part, may be made in writing to the Livestock and Seed Program Deputy Administrator at STOP 0249, Room

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2092-South, 1400 Independence Avenue, SW., Washington, D.C. 20250–0249. Appeals must be made within 30 days of receipt of adverse decision.

Actions 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. Because this is voluntary non-commitment services minimal appeal services are expected.

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**3. DESCRIBE WHETHER, AND TO WHAT EXTENT, THE COLLECTION OF INFORMATION INVOLVES THE USE OF AUTOMATED, ELECTRONIC, MECHANICAL, OR OTHER TECHNOLOGICAL COLLECTION TECHNIQUES OR OTHER FORMS OF INFORMATION TECHNOLOGY, E.G. PERMITTING ELECTRONIC SUBMISSION OF RESPONSES, AND THE BASIS FOR THE DECISION FOR ADOPTING THIS MEANS OF COLLECTION. ALSO DESCRIBE ANY CONSIDERATION OF USING INFORMATION TECHNOLOGY TO REDUCE BURDEN.**

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To facilitate providing service, AMS will allow applicants to facsimile transmit completed and signed application forms into field offices. Once the completed forms are received, services may be provided. However, due to the legal requirements associated with the forms, it is still necessary to have copies with original signatures. Therefore, applicants must follow-up the facsimile transmission by mailing the original application to the field office.

AMS is committed to complying with the e-Government Act, which requires Government agencies, in general, to provide the public the option of submitting information or transacting

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business electronically to the maximum extent possible. AMS is working to meet the legal requirements for accepting digital signatures. When those requirements are met the AMS will accept electronic application forms. The forms are available in a pdf fillable/printable version and accessible through the Internet website <http://www.ams.usda.gov/AMSV1.0/#CustomerLS>.

**4. DESCRIBE EFFORTS TO IDENTIFY DUPLICATION. SHOW SPECIFICALLY WHY ANY SIMILAR INFORMATION ALREADY AVAILABLE CANNOT BE USED OR MODIFIED FOR USE FOR THE PURPOSE(S) DESCRIBED IN ITEM 2 ABOVE.**

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To decrease burden on the applicant the existing Form LS-313 authorized by 7 CFR Part 54.61 and Part 62.202 currently approved under in OMB No. 0581-0124, 7 CFR Part 54 – Meats, Prepared Meats, and Meat Products (Grading, Certification, and Standards) and 7 CFR Part 62 – Quality Systems Verification Program (QSVP), will be used to collect applicant name, and specific plant information. The signed Form LS-313 serves as a legal agreement between USDA and users of the service. Additionally, the signed form constitutes authorization for Department employees to enter establishments for the purpose of providing requested services under the regulations, eliminating the need for other forms or modifications of requests. Upon

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approval we will submit a request to merge this collection into the currently approved OMB 0581-0124, January 8, 2008.

**5. IF THE COLLECTION OF INFORMATION IMPACTS SMALL BUSINESSES OR OTHER SMALL ENTITIES (ITEM 5 OF THE OMB FORM 83-I), DESCRIBE THE METHODS USED TO MINIMIZE BURDEN.**

Approved applications remain in effect until the legal status of the applicant(s) changes. Therefore, the information is collected as infrequently as possible. Only essential information,

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which cannot be gathered from other sources, is collected. The Small Business Administration defines, in 13 CFR Part 121, small agricultural producers as those having annual receipts of no more than \$750,000 and small agricultural service firms (first handlers and importers) as those having annual receipts of no more than \$6.5 million. The procedures for collecting this information were designed to minimize the burden on the public and requiring the same reporting requirements for all applicants does not disadvantage any applicant that is smaller than industry average.

Under these definitions, we estimate that out of the 20 total respondents for this

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collection, approximately 19 are considered small business.

**6. DESCRIBE THE CONSEQUENCE TO FEDERAL PROGRAM OR POLICY ACTIVITIES IF THE COLLECTION IS NOT CONDUCTED OR IS CONDUCTED LESS FREQUENTLY, AS WELL AS ANY TECHNICAL OR LEGAL OBSTACLES TO REDUCING BURDEN.**

The information requested under 7 CFR Part 62 for the Quality Systems Verification Program are essential to the efficient operation of these programs. The information is collected

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only when an application initially requests program services.

**7. EXPLAIN ANY SPECIAL CIRCUMSTANCES THAT WOULD CAUSE AN INFORMATION COLLECTION TO BE CONDUCTED IN A MANNER:**

- **REQUIRING RESPONDENTS TO REPORT INFORMATION TO THE AGENCY MORE OFTEN THAN QUARTERLY;**

DEPARTMENT OF AGRICULTURE 21

Agricultural Marketing Service

[Docket No. AMS-LS-07-0131; LS-07-16]

United States Standards for Livestock and Meat Marketing Claims, Naturally Raised Claim for Livestock and the Meat and Meat Products Derived from such Livestock

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- **REQUIRING RESPONDENTS TO PREPARE A WRITTEN RESPONSE TO A COLLECTION OF INFORMATION IN FEWER THAN 30 DAYS AFTER RECEIPT OF IT;**
- **REQUIRING RESPONDENTS TO SUBMIT MORE THAN AN ORIGINAL AND TWO COPIES OF ANY DOCUMENT;**

We do not require applicant to retain records for more than 3 years.

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Agricultural Marketing Service

[Docket No. AMS-LS-07-0131; LS-07-16]

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- **REQUIRING RESPONDENTS TO RETAIN RECORDS, OTHER THAN HEALTH, MEDICAL, GOVERNMENT CONTRACT, GRANT-IN-AID, OR TAX RECORDS FOR MORE THAN 3 YEARS;**
- **IN CONNECTION WITH A STATISTICAL SURVEY, THAT IS NOT DESIGNED TO PRODUCE VALID AND RELIABLE RESULTS THAT CAN BE GENERALIZED TO THE UNIVERSE OF STUDY;**

DEPARTMENT OF AGRICULTURE      23

Agricultural Marketing Service

[Docket No. AMS-LS-07-0131; LS-07-16]

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- **REQUIRING THE USE OF A STATISTICAL DATA CLASSIFICATION THAT HAS NOT BEEN REVIEWED AND APPROVED BY OMB;**
- **THAT INCLUDES A PLEDGE OF CONFIDENTIALITY THAT IS NOT SUPPORTED BY AUTHORITY ESTABLISHED IN STATUE OR REGULATION, THAT IS NOT SUPPORTED BY DISCLOSURE AND DATA**

DEPARTMENT OF AGRICULTURE      24

Agricultural Marketing Service

[Docket No. AMS-LS-07-0131; LS-07-16]

United States Standards for Livestock and Meat Marketing Claims, Naturally Raised Claim for Livestock and the Meat and Meat Products Derived from such Livestock

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**SECURITY POLICIES THAT ARE CONSISTENT WITH THE PLEDGE, OR WHICH UNNECESSARILY IMPEDES SHARING OF DATA WITH OTHER AGENCIES FOR COMPATIBLE CONFIDENTIAL USE; OR**

- **REQUIRING RESPONDENTS TO SUBMIT PROPRIETARY TRADE SECRET, OR OTHER CONFIDENTIAL INFORMATION UNLESS THE AGENCY CAN DEMONSTRATE THAT IT HAS INSTITUTED**

DEPARTMENT OF AGRICULTURE 25

Agricultural Marketing Service

[Docket No. AMS-LS-07-0131; LS-07-16]

United States Standards for Livestock and Meat Marketing Claims, Naturally Raised Claim for Livestock and the Meat and Meat Products Derived from such Livestock

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**PROCEDURES TO PROTECT THE INFORMATION'S  
CONFIDENTIALITY TO THE EXTENT PERMITTED BY  
LAW.**

There are no special circumstances. The collection of information is consistent with the guidelines in 5 CFR 1320.6.

**8. IF APPLICABLE, PROVIDE A COPY AND IDENTIFY THE DATE AND PAGE  
NUMBER OF PUBLICATION IN THE FEDERAL REGISTER OF THE**

**DEPARTMENT OF AGRICULTURE      26**

Agricultural Marketing Service

[Docket No. AMS-LS-07-0131; LS-07-16]

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**AGENCY'S NOTICE, REQUIRED BY 5 CFR 1320.8(d), SOLICITING COMMENTS ON THE INFORMATION COLLECTION PRIOR TO SUBMISSION TO OMB. SUMMARIZE PUBLIC COMMENTS RECEIVED IN RESPONSE TO THAT NOTICE AND DESCRIBE ACTIONS TAKEN BY THE AGENCY IN RESPONSE TO THESE COMMENTS. SPECIFICALLY ADDRESS COMMENTS RECEIVED ON COST AND HOUR BURDEN.**

The 60-day Notice was published in the *Federal Register* on March 11, 2009, Vol. 74, No. 46, page 10528-10529. We received three comments in response to the Notice; however, the

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Agricultural Marketing Service

[Docket No. AMS-LS-07-0131; LS-07-16]

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comments were outside the scope of the Notice as the comments pertained to the naturally raised standard or the definition of natural which did not address the cost and hour burden of the collection of information. No actions were taken in response to the comments submitted.

**DESCRIBE EFFORTS TO CONSULT WITH PERSONS OUTSIDE THE AGENCY TO OBTAIN THEIR VIEWS ON THE AVAILABILITY OF DATA, FREQUENCY OF COLLECTION, THE CLARITY OF INSTRUCTIONS AND RECORDKEEPING, DISCLOSURE, OR**

DEPARTMENT OF AGRICULTURE 28

Agricultural Marketing Service

[Docket No. AMS-LS-07-0131; LS-07-16]

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**REPORTING FORMAT (IF ANY), AND ON THE DATA ELEMENTS TO BE RECORDED, DISCLOSED, OR REPORTED.**

**CONSULTATION WITH REPRESENTATIVES OF THOSE FROM WHOM INFORMATION IS TO BE OBTAINED OR THOSE WHO MUST COMPILE RECORDS SHOULD OCCUR AT LEAST ONCE EVERY 3 YEARS -- EVEN IF THE COLLECTION OF INFORMATION ACTIVITY IS THE SAME AS IN PRIOR PERIODS. THERE MAY BE CIRCUMSTANCES THAT MAY PRECLUDE CONSULTATION IN A**

DEPARTMENT OF AGRICULTURE      29

Agricultural Marketing Service

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**SPECIFIC SITUATION. THESE CIRCUMSTANCES SHOULD BE EXPLAINED.**

No problems were noted by individuals that completed the LS-313 below.

**AgInfoLink USA**  
Carrie Lewis, Verified  
Services Manager

**Maverick Ranch Natural Meats**  
Clayton Parker, Quality

**PM Beef Holdings LLC**  
Lisa C. Hernandez

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Longmont, CO 80501  
Phone: 303-682-9898

Control Manager  
Denver CO 80216  
Phone: (303) 294-0146 Ext.  
177

Windom, MN 56101  
Phone: (507) 831-6233

**9. EXPLAIN ANY DECISION TO PROVIDE ANY PAYMENT OR GIFT TO RESPONDENTS, OTHER THAN REMUNERATION OF CONTRACTORS OR GRANTEES.**

DEPARTMENT OF AGRICULTURE      31

Agricultural Marketing Service

[Docket No. AMS-LS-07-0131; LS-07-16]

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AMS does not provide any payment or gift to respondents.

**10. DESCRIBE ANY ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS AND THE BASIS FOR THE ASSURANCE IN STATUTE, REGULATION, OR AGENCY POLICY.**

Most of the information collected on Form LS-313 is protected under the Freedom of Information Act (FOIA), and such information is not made available to the public.

DEPARTMENT OF AGRICULTURE      32

Agricultural Marketing Service

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**11. PROVIDE ADDITIONAL JUSTIFICATION FOR ANY QUESTIONS OF A SENSITIVE NATURE, SUCH AS SEXUAL BEHAVIOR AND ATTITUDES, RELIGIOUS BELIEFS, AND OTHER MATTERS THAT ARE COMMONLY CONSIDERED PRIVATE. THIS JUSTIFICATION SHOULD INCLUDE THE REASONS WHY THE AGENCY CONSIDERS THE QUESTIONS NECESSARY, THE SPECIFIC USES TO BE MADE OF THE INFORMATION, THE EXPLANATION TO BE GIVEN TO PERSONS FROM WHOM THE INFORMATION IS REQUESTED, AND ANY STEPS TO BE TAKEN TO**

DEPARTMENT OF AGRICULTURE      33

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**OBTAIN THEIR CONSENT.**

Information of a sensitive nature is not collected.

**12. PROVIDE ESTIMATES OF THE HOUR BURDEN OF THE COLLECTION OF INFORMATION. THE STATEMENT SHOULD:**

- **INDICATE THE NUMBER OF RESPONDENTS, FREQUENCY OF RESPONSE, ANNUAL HOUR BURDEN, AND AN EXPLANATION**

DEPARTMENT OF AGRICULTURE      34

Agricultural Marketing Service

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**OF HOW THE BURDEN WAS ESTIMATED. UNLESS DIRECTED TO DO SO, AGENCIES SHOULD NOT CONDUCT SPECIAL SURVEYS TO OBTAIN INFORMATION ON WHICH TO BASE HOUR BURDEN ESTIMATES. CONSULTATION WITH A SAMPLE (FEWER THAN 10) OF POTENTIAL RESPONDENTS IS DESIRABLE. IF THE HOUR BURDEN ON RESPONDENTS IS EXPECTED TO VARY WIDELY BECAUSE OF DIFFERENCE IN ACTIVITY, SIZE, OR COMPLEXITY, SHOW THE RANGE OF ESTIMATED HOUR BURDEN, AND EXPLAIN THE REASONS**

DEPARTMENT OF AGRICULTURE 35

Agricultural Marketing Service

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**FOR THE VARIANCE. GENERALLY, ESTIMATES SHOULD NOT INCLUDE BURDEN HOURS FOR CUSTOMARY AND USUAL BUSINESS PRACTICES.**

- **IF THIS REQUEST FOR APPROVAL COVERS MORE THAN ONE FORM, PROVIDE SEPARATE HOUR BURDEN ESTIMATES FOR EACH FORM AND AGGREGATE THE HOUR BURDENS IN ITEM 13 OF OMB FORM 83-I.**

DEPARTMENT OF AGRICULTURE      36

Agricultural Marketing Service

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- **PROVIDE ESTIMATES OF ANNUALIZED COST TO RESPONDENTS FOR THE HOUR BURDENS FOR COLLECTIONS OF INFORMATION, IDENTIFYING AND USING APPROPRIATE WAGE RATE CATEGORIES.**

The respondents' estimated annual cost of providing information to the AMS (7 CFR Part 62) is \$9,868. This total has been estimated by multiplying the 483 (burden hours) by \$20.43 which is the average hourly rate of farmers and ranchers according to the U.S. Department of Labor.

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Data for computation of this hourly wage were obtained from the U.S. Department of Labor Statistics' publication, "May 2006 National Occupation Employment and Wage Estimates," published October 24, 2007. This publication can also be found at the following website: [http://www.bls.gov/oes/current/oes\\_nat.htm#b00-0000](http://www.bls.gov/oes/current/oes_nat.htm#b00-0000). Estimates of the burden of collection of information have been summarized on AMS Form 71 enclosed. The number of respondents is based on actual ARC records while the hours per response is a reasonable average of time it takes to complete a response.

**DEPARTMENT OF AGRICULTURE      38**

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**13. PROVIDE AN ESTIMATE OF THE TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORDKEEPERS RESULTING FROM THE COLLECTION OF INFORMATION. (DO NOT INCLUDE THE COST OF ANY HOUR BURDEN SHOWN IN ITEMS 12 AND 14).**

- **THE COST ESTIMATE SHOULD BE SPLIT INTO TWO COMPONENTS: (a) A TOTAL CAPITAL AND START-UP COST COMPONENT (ANNUALIZED OVER ITS EXPECTED USEFUL LIFE); AND (b) A TOTAL OPERATION AND MAINTENANCE**

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Agricultural Marketing Service

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**AND PURCHASE OF SERVICES COMPONENT. THE ESTIMATES SHOULD TAKE INTO ACCOUNT COSTS ASSOCIATED WITH GENERATING, MAINTAINING, AND DISCLOSING OR PROVIDING THE INFORMATION. INCLUDE DESCRIPTIONS OF METHODS USED TO ESTIMATE MAJOR COST FACTORS INCLUDING SYSTEM AND TECHNOLOGY ACQUISITION, EXPECTED USEFUL LIFE OF CAPITAL EQUIPMENT, THE DISCOUNT RATE(S), AND THE TIME PERIOD OVER WHICH COSTS WILL BE INCURRED. CAPITAL**

DEPARTMENT OF AGRICULTURE 40

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**SUMMARY:** The Agricultural Marketing Service (AMS) is establishing a voluntary standard for a naturally raised marketing claim that livestock producers may request to have verified by the Department of Agriculture (USDA). This standard incorporates revisions made as a result of comments received from an earlier proposed standard. A number of livestock producers make claims associated with production practices in order to distinguish their products in the marketplace and there are a growing number of entities that are capturing value-added opportunities by using alternative production methods to meet the demands of consumers and markets seeking meat and meat products from naturally raised livestock. This voluntary standard will allow livestock producers to utilize AMS' voluntary, third party verification services to provide validity to such naturally raised livestock claims and, in certain cases, access to markets that require AMS verification. AMS verification of this claim would be accomplished through an audit of the production process in accordance with procedures that are contained in Part 62 of



**AND START-UP COSTS INCLUDE, AMONG OTHER ITEMS, PREPARATIONS FOR COLLECTING INFORMATION SUCH AS PURCHASING COMPUTERS AND SOFTWARE; MONITORING, SAMPLING, DRILLING AND TESTING EQUIPMENT; AND RECORD STORAGE FACILITIES.**

- **IF COST ESTIMATES ARE EXPECTED TO VARY WIDELY, AGENCIES SHOULD PRESENT RANGES OF COST BURDENS AND EXPLAIN THE REASONS FOR THE VARIANCE. THE**

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[Docket No. AMS-LS-07-0131; LS-07-16]

United States Standards for Livestock and Meat Marketing Claims, Naturally Raised Claim for Livestock and the Meat and Meat Products Derived from such Livestock

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**COST OF PURCHASING OR CONTRACTING OUT INFORMATION COLLECTION SERVICES SHOULD BE A PART OF THIS COST BURDEN ESTIMATE. IN DEVELOPING COST BURDEN ESTIMATES, AGENCIES MAY CONSULT WITH A SAMPLE OF RESPONDENTS (FEWER THAN 10), UTILIZE THE 60-DAY PRE-OMB SUBMISSION PUBLIC COMMENT PROCESS AND USE EXISTING ECONOMIC OR REGULATORY IMPACT ANALYSIS ASSOCIATED WITH THE RULEMAKING CONTAINING THE INFORMATION COLLECTION, AS**

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**APPROPRIATE.**

- **GENERALLY, ESTIMATES SHOULD NOT INCLUDE PURCHASES OF EQUIPMENT OR SERVICES, OR PORTIONS THEREOF, MADE: (1) PRIOR TO OCTOBER 1, 1995, (2) TO ACHIEVE REGULATORY COMPLIANCE WITH REQUIREMENTS NOT ASSOCIATED WITH THE INFORMATION COLLECTION, (3) FOR REASONS OTHER THAN TO PROVIDE INFORMATION OR KEEPING RECORDS**

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**FOR THE GOVERNMENT, OR (4) AS PART OF CUSTOMARY AND USUAL BUSINESS OR PRIVATE PRACTICES.**

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

**14. PROVIDE ESTIMATES OF ANNUALIZED COST TO THE FEDERAL GOVERNMENT. ALSO, PROVIDE A DESCRIPTION OF THE METHOD USED TO ESTIMATE COST, WHICH SHOULD INCLUDE QUANTIFICATION OF**

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**HOURS, OPERATION EXPENSES (SUCH AS EQUIPMENT, OVERHEAD, PRINTING, AND SUPPORT STAFF), AND ANY OTHER EXPENSE THAT WOULD NOT HAVE BEEN INCURRED WITHOUT THIS COLLECTION OF INFORMATION. AGENCIES ALSO MAY AGGREGATE COST ESTIMATES FROM ITEMS 12, 13, AND 14 IN A SINGLE TABLE.**

The Quality Systems Verification Programs (QSVP) is a collection of voluntary, audit-based, user-fee funded programs. Completion and submission of Form LS-313 serve as a legal agreement and assures payment for service provided. All Federal costs are recovered.

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**15. EXPLAIN THE REASON FOR ANY PROGRAM CHANGES OR ADJUSTMENTS REPORTED IN ITEMS 13 OR 14 OF THE OMB FORM 83-I.**

This is a new collection. Upon approval we will submit a request to merge this collection into the currently approved OMB 0581-0124, January 8, 2008.

**16. FOR COLLECTIONS OF INFORMATION WHOSE RESULTS WILL BE PUBLISHED, OUTLINE PLANS FOR TABULATION, AND PUBLICATION.**

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**ADDRESS ANY COMPLEX ANALYTICAL TECHNIQUES THAT WILL BE USED. PROVIDE THE TIME SCHEDULE FOR THE ENTIRE PROJECT, INCLUDING BEGINNING AND ENDING DATES OF THE COLLECTION OF INFORMATION, COMPLETION OF REPORT, PUBLICATION DATES, AND OTHER ACTIONS.**

Comments will be public on <http://www.regulations.gov/search/index.jsp>, however, cost of burden information collected is not available to the public.

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**17. IF SEEKING APPROVAL TO NOT DISPLAY THE EXPIRATION DATE FOR OMB APPROVAL OF THE INFORMATION COLLECTION, EXPLAIN THE REASONS THAT DISPLAY WOULD BE INAPPROPRIATE.**

The agency is seeking approval to not display the OMB expiration date on the forms associated with this information collection as requested for OMB Number 0581-0124. The type of information collected on the LS-313 form remains in effect until the legal status of the applicant(s) changes. The actual information collected could be considered standard information that rarely changes and can still be current after 20 years since the initial collection. To have an

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expiration date for OMB Approval would create a drastic increase in burden hours on respondents and/or recordkeepers. It would also create duplication of information since all forms would have to be updated after the expiration date even though the information is the same.

**18. EXPLAIN EACH EXCEPTION TO THE CERTIFICATION STATEMENT IDENTIFIED IN ITEM 19, "CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS," OF OMB FORM 83-I.**

The agency is able to certify compliance with all provisions under Item 19 of OMB Form

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83-I.

**B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS**

The collection of information does not employ statistical methods.

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