SUPPORTING STATEMENT JUSTIFICATION FOR RECORDS TO BE KEPT BY OFFICIAL ESTABLISHMENTS AND RETAIL STORES THAT GRIND RAW BEEF PRODUCTS

1. Circumstances Making Collection Of Information Necessary:

This information collection requests a new information collection of burden hours for records to be kept by official establishments and retail stores grinding or chopping raw beef products.

The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, et seq.). These statutes mandate that FSIS protect the public by verifying that meat and meat products are safe, wholesome, not adulterated, and properly labeled and packaged.

Under this rule, FSIS is amending its recordkeeping regulations to clarify that all grinders or choppers of raw beef products, beef manufacturing trimmings, or trimmings fabricated at retail intended for use in raw ground or chopped beef products, including retail facilities, are persons required by FMIA to keep records which will fully and correctly disclose all transactions involved in their business subject to the Act. If not doing so already, these businesses must maintain records that disclose the identity and supplier of all materials used in the preparation of each lot of raw ground or chopped beef product.

In addition, FSIS is requiring that specific information be kept in the required records and that retail stores maintain store-designed systems that allow them to link individual packages of raw ground or chopped beef products prepared and sold by them to the required records.

2. How, By Whom and Purpose Information Is To Be Used:

The following is a discussion of the required information collection and recordkeeping activities.

<u>Recordkeeping</u>

All official establishments and retail stores that grind or chop beef products are required to keep these records. These records provide critical information about how, when, and where raw ground or chopped beef product was prepared, shipped, received, stored, and handled, and which are essential to illness outbreak investigations, recalls, and other agency public health activities conducted by FSIS.

In addition, FSIS is requiring that specific information be kept in the required records and that retail stores maintain store-designed systems that allow them to link individual packages of raw ground or chopped beef products prepared and sold by them to the required records. The required records must include the following information:

- 1. Name, point of contact (name, title, e-mail, and facsimile number) telephone number, and establishment number of the Federal, State, or foreign establishment supplying the raw source material;
 - 2. Supplier lot numbers and production dates for each raw source material used; and,
 - 3. The names of the supplied materials.

There are a total of 3,317,301 burden hours for the information collection requests relating to establishment responses.

3. Use Of Improved Information Technology:

Establishments and retail stores may make use of electronic recordkeeping.

4. Efforts To Identify Duplication:

FSIS has determined that these information collections will not duplicate any other information collections. The required records and reports are not available from other sources, either within government or from non-government sources. There is no similar information that can be used or modified.

5. Methods To Minimize Burden On Small Business Entities:

Data collected from small businesses are the same as from large ones. FSIS estimates that 51,962 small firms will be affected.

6. Consequences If Information Were Collected Less Frequently:

To conduct the information collections less frequently would reduce the effectiveness of the meat inspection program.

7. Circumstances That Would Cause The Information Collection To Be Conducted In A Manner:

- requiring respondents to report information to the agency more often than quarterly;
- 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;
- requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three 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;
- 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 statute or regulation, that is not supported by disclosure and data 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 procedures to protect the information's confidentiality to the extent permitted by law.

There are no special circumstances that require the collection of information to be inconsistent with the guidelines listed above.

8. Consultation With Persons Outside The Agency:

FSIS embedded its 60 day notice in the proposed rule that was published in <u>Federal Register</u> (79 FR 42464) on July 22, 2014. In response to comments, FSIS removed requirements for entities covered by this rule to provide names, points of contact, and phone numbers for official establishments. Also in response to comments, the Agency eliminated the requirement that the weight of each source component used in a lot of ground beef be kept. However, in response to other public comments, FSIS increased the time estimates for recordkeeping activities, the frequency of recordkeeping tasks, and the number of active grinding days per week. FSIS also increased the number of retail stores that will be affected by the rule.

Additionally, the burden hours in the proposed rule only accounted for the additional recordkeeping burden that would be placed on the establishments, but the information collection package seeks approval for all the recordkeeping which includes the development of production records as well as the overall recordkeeping requirements.

9. Payment Or Gifts To Respondents:

Respondents do not receive gifts or payments.

10. Confidentiality Provided To Respondents:

No assurances other than routine protection provided under the Freedom of Information Act have been provided to respondents.

11. Questions Of A Sensitive Nature:

The applicants are not asked to furnish any information of a sensitive nature.

12. Estimate Of Burden:

The total estimated burden for this information collection is 3,317,301 burden hours.

FSIS estimates that 65,911 official establishments and retail stores will take an average of 50

minutes to file records 312 times a year for large firms and 312 times a year for small firms for a total of 65,911 responses and 3,317,301 hours.

RECORDKEEPING—PRODUCTION RECORDS (9 CFR 320.1)

Type of Establish- Ment	No. of Respon- dents	No. of Responses per Responde nt	Total Annual Responses	Annual Time in Respons e (Hours)	Total Annual Time in Hours
Large retail facilities and ests.	18,956	312	5,914,272	50	954,055
Small retail facilities and ests.	46,955	312	14,649,960	50	2,363,245
Total	65,911				3,317,301

The cost to the respondents is estimated at \$126,057,438 annually. The Agency estimates that it will cost respondents \$38 an hour in fulfilling these paperwork requirements. Respondents will spend an annual total of 3,317,301 hours and \$126,057,438.

13. Capital, Start-up Cost, And Subsequent Maintenance

There are no capital or start-up costs related to this information collection activity.

14. Annual Cost To The Federal Government:

The cost to the Federal Government for this information collection is \$184,834 annually. The Agency estimates a cost of \$38 per hour for the time of its personnel.

15. Reasons For Changes In Burden:

This is a new information collection of 3,317,301 hours. Based on comments received from the public, the burden hours changed from what was in the proposed rule.

16. Tabulation, Analyses And Publication Plans:

There are no plans to publish the data for statistical use.

17. OMB Approval Number Display:

18. Exceptions To The Certification:

There are no exceptions to the certification. This information collection accords with the certification in item 19 of the OMB 83-I.