

SUPPORTING STATEMENT JUSTIFICATION FOR INFORMATION COLLECTION REQUIREMENTS RELATED TO GENERIC LABEL APPROVAL

1. Circumstances Making Collection of Information Necessary:

This information collection requests a new information collection related to the expansion of generic labeling for meat and poultry 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.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, et seq.). These statutes mandate that FSIS protect the public by ensuring that meat, poultry, and egg products are safe, wholesome, unadulterated, and properly labeled and packaged.

FSIS is amending the meat and poultry products inspection regulations to expand the circumstances in which FSIS will permit the generic approval of the labels of meat and poultry products.

2. How, By Whom and Purpose for Which Information is to be Used:

Labeling

Meat and poultry products establishments must develop product labels (9 CFR 317.4 & 381.115) in accordance with FSIS regulations. To receive approval for such labels, establishments must complete FSIS Form 7234-1. In addition to the form, respondents also submit duplicate copies of the labels. The establishment must maintain a copy of all the labeling used, along with product formulation and processing procedures.

Previously approved labeling that contains certain changes does not need additional FSIS approval (9 CFR 317.5). Establishments must keep a copy of the labeling used, along with the product formulation and processing procedures on file.

3. Use of Improved Information Technology:

Under the Government Paperwork Elimination Act, the Agency is providing electronic versions of FSIS

Form 7234-1. Records may be maintained electronically provided that appropriate controls are implemented to ensure the integrity of the electronic data. The Agency estimates that 80% of the paperwork and recordkeeping is done electronically.

4. Efforts to Identify Duplication:

No USDA agency, or any other Government agency, requires information regarding the marking, labeling, or packaging of meat, poultry, or egg products; or the production of mechanically separated poultry. There is no available 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 for large ones. The information collections must apply to all businesses producing inspected meat and poultry products. However, small businesses usually have fewer and less complex labels than do larger establishments and companies. Approximately, 5,500 small businesses will be affected by this information collection.

6. Consequences if Information Were Collected Less Frequently:

To conduct the information collections less frequently would reduce the effectiveness of the meat, poultry, and egg products 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.

Many establishments will develop, submit, and file more than one label per quarter. None of the other circumstances described above apply to this information collection.

8. Consultation with Persons Outside the Agency:

In accordance with the Paperwork Reduction Act, FSIS embedded a 60-day notice in the proposed rule (76 FR 75809), on December 5, 2011. The Agency received five comments that were related, at least in part, to the information collection. All the comments agreed that the expansion of generic labeling would reduce burden hours and save resources for industry.

9. Payment or Gifts to Respondents:

Respondents will not receive any gifts or payments.

10. Confidentiality Provided to Respondents:

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C.552a.

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 burden estimate for the reporting and recordkeeping requirements associated with this information collection is 86,644 hours.

Labeling

The Agency estimates that, on average, it takes 70 minutes to develop and submit a label application, including 15 minutes to complete FSIS Form 7234-1. FSIS estimates that each year, approximately 8 times per year, 3,000 meat and poultry establishments and 598 foreign establishments will spend 70 minutes to develop, submit to FSIS, and maintain recordkeeping of labels, for a total of 28,784 responses and 33,581 hours.

LABELING DEVELOPMENT AND APPLICATION (9 CFR 317.4 & 381.115/FSIS Form 7234-1)

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Meat/Poultry	3,000	8	24,000	70	28,000
Foreign	598	8	4,784	70	5,581
All Ests.	3,598	8	28,784	70	33,581

The Agency estimates that, on average, it takes 5 minutes to maintain recordkeeping of a label. FSIS estimates that each year, approximately 8 times per year, 3,000 meat and poultry establishments and 598 foreign establishments will spend 5 minutes to maintain recordkeeping of labels, for a total of 28,784 responses and 2,399 hours.

**LABEL RECORDKEEPING
(9 CFR 317.4 & 381.115)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Meat/Poultry	3,000	8	24,000	5	2,000
Foreign	598	8	4,784	5	398
All Ests.	3,598	8	28,784	5	2,399

FSIS estimates that it takes approximately 13 minutes to make changes to and comply with recordkeeping requirements associated with generically approved labeling. The Agency estimates that 5,735 domestic and 598 foreign establishments will annually make 32 generically approved labeling changes for a total of 202,656 responses and 43,908 hours.

**GENERIC LABEL PREPARATION
(9 CFR 317.5)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Meat/Poultry	5,735	32	183,520	13	39.763
Foreign	598	32	19,136	13	4,146
All Ests.	6,333	32	202,656	13	43,909

FSIS estimates that it takes approximately 2 minutes to make changes to and comply with recordkeeping requirements associated with generically approved labeling. The Agency estimates that

5,735 domestic and 598 foreign establishments will annually make 32 generically approved labeling changes for a total of 202,656 responses and 6,755 hours.

**GENERIC LABEL RECORDKEEPING
(9 CFR 317.5)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Meat/Poultry	5,735	32	183,520	2	6,117
Foreign	598	32	19,136	2	638
All Ests.	6,333	32	202,656	2	6,755

Total Cost to Respondents

The cost to the respondents is estimated at \$3,205,828 million annually. The Agency estimates that it will cost respondents \$37 an hour in fulfilling these paperwork and recordkeeping requirements. Respondents will spend an annual total of 86,644 hours and \$3,205,828.

13. Capital and Start-up Cost and Subsequent Maintenance

There are no capital and start-up costs and subsequent maintenance burdens.

14. Annual Cost to Federal Government:

The cost to the Federal Government for these information collection requirements is \$950,000 annually. The costs arise primarily from the inspection review duties necessary to verify that establishments comply with the information collection responsibilities. The Agency estimates a cost of \$37 per hour for its personnel time.

15. Reasons for Changes in Burden:

This is a new information collection associated with the Prior Labeling Approval System—Generic Label Approval proposed rule. The OMB control number that will be assigned to this information collection will be temporary. This information collection, after it is approved by OMB, will be merged with 0583-0092, Marking, Labeling, and Packaging. The merged information collection will result in a net reduction of approximately 34,971 burden hours.

16. Tabulation, Analyses and Publication Plans:

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

17. OMB Approval Number Display:

FSIS will display the OMB approval number on any instructions it publishes relating to recordkeeping activities. The OMB approval number will appear on required FSIS forms. FSIS requests that it not be required to put the expiration date of the information collection of the form. Being required to put the expiration date on the form would place a burden of the Agency because 1) it would require FSIS to print new forms with the expiration date on them and would render the forms unusable in three years; 2) at the end of the approval period FSIS could not print up new forms until OMB gave a new expiration date causing unnecessary delay; and, 3) there is often a time lapse of several months between the date when the expiration expires and the time when OMB will finally give (usually) a three year approval to the extension or revision causing an almost impossible situation of attempting to having forms with the correct expiration date on them.

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.