SUPPORTING STATEMENT JUSTIFICATION FOR
LABORATORIES INFORMATION COLLECTION

1. Circumstances Making Collection of Information Necessary:

This is a request for a renewal of the information collection related to laboratories associated with FSIS regulatory programs.

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.), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 et seq.). These statutes mandate that FSIS protect the public by ensuring that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged.

FSIS uses two forms to collect information to help assess laboratories participating in the pasteurized egg product or the Accredited Laboratory programs, to ensure they meet required standards.

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

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

FSIS uses the PEPRL-F-0008.04 form as a self-assessment audit checklist to collect information related to the quality assurance/quality control procedures in place at in-plant and private laboratories participating in the Pasteurized Egg Product Recognized Laboratory (PEPRLab) program (9 CFR 590.580). FSIS uses the data collected in the desk audit of existing labs or in the appraisal of a new applicant.

Any non-Federal laboratory that is applying for the FSIS Accredited Laboratory program needs to complete an Application for FSIS Accredited Laboratory Program form, 10,110-2, (9 CFR 439). State or private laboratories need only submit the application once for entry into the program. FSIS uses the information collected by the form to help access the laboratory applying for admission to the FSIS Accredited Laboratory program.

3. Use of Improved Information Technology:

Under the Government Paperwork Elimination Act, information may be submitted electronically.

FSIS makes available electronic versions (PDF fillable) of the PEPRL-F-0008.04 and the 10,110.2 forms. They can be filled out on the computer and then either emailed or printed off and submitted to the appropriate office.

4. Efforts to Identify Duplication:

No other Government agency requires this information regarding laboratories. 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. 10 of the laboratories are small entities.

6. Consequences If Information Were Collected Less Frequently:

To conduct the information collections less frequently will reduce the effectiveness of the meat and poultry 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.**

There are no circumstances that would cause the guidelines above not to be met by this information collection.

8. Consultation with Persons Outside the Agency:

In accordance with the Paperwork Reduction Act, FSIS published a 60-day notice in the Federal Register on October 19, 2015 (80 FR 63194) requesting comments regarding this information collection request. The Agency received no comments in response to the Federal Register notice.

FSIS requested comments from three knowledgeable people on the pasteurized laboratory self-assessment audit checklist (Linda Anderson, 712/286-6000; Judy O'Brien, 314-982-2193; Heather Angle-Gardner, 641/673-3486). The commenters agreed that it will take about an hour to complete the form.

FSIS also requested comments from three knowledgeable people on the Application for FSIS Accredited Laboratory Program form. The commenters agreed that it will take 30 minutes are less to complete the form (Dove Mullins, 507-437-5831; Bruce Franta, 507-437-5857; Carrie Abrath, 608-242-2712 x 2966).

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 information collection requirements associated with this information collection is 13 hours.

PERPLab

The Agency estimates that 12 labs will once a year spend 60 minutes to complete the self-assessment audit checklist for a grand total of 12 responses and 12 burden hours.

PERPLab Self-Assessment Audit Checklist (PEROL-F-0008)
(9 CFR 590.580)

Type of Establish-Ment	No. of Respon-dents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Labs	12	1	12	60	12

Accredited Laboratory Program

FSIS estimates that 2 labs will respond once a year, taking 30 minutes per response for a total of 2 responses and 1 hour annually.

Application for Accredited Labs Program Form 10,110-2
(9 CFR 439)

Type of Establish-Ment	No. of Respon-dents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Labs	2	1	2	30	1

The cost to the respondents is estimated at $494 annually. The Agency estimates that it will cost respondents $38 an hour in fulfilling these paperwork and recordkeeping requirements. Respondents will spend an annual total of 13 hours and $494. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data 2014-2015.

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 and Respondents:

The cost to the Federal Government for these information collection requirements is $190 annually. The costs arise primarily from the time spent by FSIS staff reviewing protocols and data. The Agency estimates a cost of $38 per hour.

15. Reasons for Changes in Burden:

FSIS is requesting a reduction in burden hours from 24 hours to 13 hours based on fewer labs completing the forms.

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 and expiration date on the forms.

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.