SUPPORTING STATEMENT JUSTIFICATION FOR LABORATORIES INFORMATION COLLECTION

1. Circumstances Making Collection of Information Necessary:

This information collection requests a new information collection related to the collection of information 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 will use these two forms to collect information to help assess laboratories, to ensure they meet required standards, participating in the pasteurized egg product or the Accredited Lab programs.

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 will use 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 will use the data collected in the desk audit of existing labs or in the appraisal of a new applicant. Previously, FSIS performed on-site reviews of laboratories in the PERPLab program. But the Agency has moved to conducting desk audits of these laboratories and, therefore, has a greater need for information to be submitted by the laboratories.

Any non-Federal laboratory that is applying for the FSIS Accredited Laboratory program will need 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 will use the information collected by the form to help access the laboratory applying for admission to the FSIS Accredited Laboratory program. FSIS has been using the Accredited Laboratory Program form for some

time but without OMB approval. The Agency is including the form in this information collection to obtain OMB approval.

3. Use of Improved Information Technology:

Under the E-Gov Act, firms may submit the forms electronically.

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. 20 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 April 24, 2012 (77 FR 24455) requesting comments regarding this information collection request. The Agency received one comment in response to the Federal Register notice, but the notice was not directly related to the information collection.

FSIS requested comments from three knowledgeable people on the Application for FSIS Acrredited 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).

The Agency also 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. One person thought it would take about an hour a first time, but later only 20 to 30 minutes. Another person said it would take 2 to 2½ hours to complete initially, but after that it would take about 1 hour. And finally, a third person said that it will take about an hour to complete.

FSIS has determined that it will retain its estimate of 1 hour for completing the form.

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 24 hours.

PERPLab

The Agency estimates that 23 labs will once a year spend 60 minutes to complete the self-assessment audit checklist for a grand total of 23 responses and 23 burden hours.

(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	23	1	23	60	23

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 1hour 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 $888 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 24 hours and $888.

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 $370 annually. The costs arise primarily from the time spent by FSIS staff reviewing protocols and data. The Agency estimates a cost of $37 per hour.

15. Reasons for Changes in Burden:

This is a new information collection consisting of a total of 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 forms. Being required to put the expiration date on the forms 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.