**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 one form to collect information to help assess laboratories participating in the Accredited Laboratory program, 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.

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 assess 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 an electronic version (PDF fillable) of the 10,110.2 form. It 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. Two 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, *Notice of Request To Renew an Approved Information Collection (Laboratories)* on November 12, 2021 (86 FR 62770) requesting comments on this information collection renewal. The Agency received one comment that was not relevant in response to the *Federal Register* notice. FSIS also contacted Sara Stull (317) 564-3680 x 7234; Jason Ausmus (229) 336-7216; and Umed Singh (209) 394-6914 x 4137 to request input on the Agency’s burden estimates for the forms. All three individuals agreed with the Agency’s burden estimate of 30 minutes or less to complete the Application for FSIS Accredited Laboratory Program form. Therefore, the Agency is making no change to the estimated time for completion.

**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 1 hour.

*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 ofEstablish-Ment | No. ofRespon-dents | No. of Responses per Respondent | TotalAnnual 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 $55.63 annually. The Agency estimates that it will cost respondents $55.63 an hour, including fringe benefits, to develop and submit applications. Respondents will spend an annual total of 1 hour and $55.63. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2020.

**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 $44.99 annually. The costs arise primarily from the time spent by FSIS staff reviewing submissions. The Agency estimates a cost of $44.99 per hour, including fringe benefits, for the FSIS staff.

**15.** **Reasons for Changes in Burden:**

FSIS is reducing the burden hours for this collection by 12 hours, 12 respondents, and 12 responses because FSIS discontinued the Pasteurized Egg Product Recognized Laboratory Form, PEROL–F–0008.05.

**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.