SUPPORTING STATEMENT JUSTIFICATION FOR INDUSTRY RESPONSES TO NONCOMPLIANCE RECORDS

1. Circumstances Making Collection Of Information Necessary:

This is a request to revise the previously approved information collection for Industry Responses to Noncompliance Records.

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 verifying that meat and poultry products are safe, wholesome, and properly labeled.

If FSIS in-plant personnel discover non-compliances with regulatory requirements they issue Noncompliance Records (NRs). Establishment management has the opportunity to respond in writing.

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

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

Responses to Noncompliance Records

FSIS Form 5400-4 serves as FSIS's official record of noncompliance with one or more regulatory requirements. Inspection program personnel use the forms to document their findings and provide written notification of the establishment's failure to comply with regulatory requirement(s). The establishment

management receives a copy of the form and has an opportunity to respond in writing using the Noncompliance Record form. Response by the establishment's management is voluntary.

There are a total of 13,996 burden hours for the information collection requests relating to establishment responses to receiving a Noncompliance Record.

3. Use Of Improved Information Technology:

Under the E-Gov Act of 2002, individuals may submit the forms electronically. Establishments that wish to submit responses electronically have the option to enroll in the Public Health Information System (PHIS) to submit their responses.

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 for large ones. The number of small businesses in this collection is 2,000.

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.**

There are no special circumstances that require the collection of information to be inconsistent with 5 CFR 1320.6.

8. Consultation With Persons Outside The Agency:

- In accordance with the Paperwork Reduction Act, FSIS published a 60-day notice in the **Federal Register** (90 FR 22683) on May 29, 2025, requesting comments regarding this information collection request. FSIS received no relevant comments. FSIS also contacted three persons regarding the information collection: Plant Superintendent, Yosemite Foods, Inc., (559) 786-1338; FSQA Manager, Pilgrim's Pride Corporation, (936) 631-6268; and Corporate FSQA Manager, Pilgrims**,** 559-352-0574, to request input on the FSIS burden

estimates for the FSIS Form 5400-4. The three individuals agreed that the FSIS burden estimate of 7 minutes to complete the FSIS Form 5400-4 was accurate.

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 13,996 burden hours.

Responses to Noncompliance Reports

FSIS estimates that 7,057 establishments will 17 times a year take an average of 7 minutes to respond to Noncompliance Records on the FSIS Form 5400-4 for a total of 119,969 responses and 13,996 hours.

RESPONSES TO NONCOMPLIANCE RECORDS
(FSIS Forms 5400–4)

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
Ests./I-houses	7,057	17	119,969	7	13,996

The cost to the respondents is estimated at $746,407 annually. The Agency estimates that it will cost respondents $53.33, including fringe benefits, in fulfilling these information collection requirements. Respondents will spend an annual total of 13,996 hours and $746,407. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2024.

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 $987,220 annually. The costs arise primarily for the review of responses to noncompliance records. The Agency estimates a cost of $49.36 per hour, including fringe benefits, for Agency personnel time.

15. Reasons For Changes In Burden:

There is a reduction in the estimated burden for this information collection. FSIS reduced the total estimated burden by 105,973 hours (from 119,969 to 13,996) due to improved electronic capabilities in PHIS, such as the addition of drop-down menus for regulatory citations, which have streamlined the data entry process.

16. Tabulation, Analyses And Publication Plans:

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

17. OMB Approval Number Display:

The form will display the OMB Control Number and date.

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.