United States Food and Drug Administration

Certification of Identity for Freedom of Information and Privacy Act Requests

OMB Control No. 0910-0832 - Extension

SUPPORTING STATEMENT

**Part A: Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection supports laws pertaining to the Freedom of Information Act (5 USC 552 (FOIA) and the Privacy Act (5 USC 552a), as well as applicable FDA regulations at 21 CFR Part 20 and Part 21. Regulations in 21 CFR Part 20 apply to requests made under the FOIA. Regulations in 21 CFR Part 21 apply to records about individuals that are maintained, collected, used, or disclosed by the Food and Drug Administration and contained in Privacy Act Record Systems. Under the FOIA and the Privacy Act, certain records about an individual are only releasable to that individual. Information regarding personnel, medical, and other protected files, the release of which would constitute an unwarranted invasion of personal privacy, can only be released to the individual identified in those records.

This information collection also supports Form FDA 3975 entitled "Certification of Identity," which is used by FDA to identify an individual requesting a particular record under the Freedom of Information Act (FOIA) and the Privacy Act. The form is required only if an individual makes a FOIA request or Privacy Act request for their own records but has not provided sufficient assurance of identity in the incoming request.

The FOIA grants the public a right to access Federal records not normally prepared for public distribution. The Privacy Act grants a right of access to members of the public who seek access to one's own records that are maintained in an Agency's system of records (i.e., the records are retrieved by that individual's name or other personal identifier). The statutes overlap, and individuals who request their own records are processed under both statutes. The Agency may need to confirm that the individual making the FOIA or Privacy Act request is indeed the same person named in the Agency records. Respondents to the information collection are asked for certain information including name, citizenship status, social security number, address, date of birth, place of birth, signature, and date of signature.

Accordingly, we are requesting extension of OMB approval of the information collection and associated form, as described in this Supporting Statement.

2. Purpose and Use of the Information Collection

The information collected is used to verify the identity of the individual requesting information under the FOIA and Privacy Act. In this way we can ensure that the individual requesting the information is legally entitled to receive the records. Respondents to the information collection are private individuals.

3. Use of Improved Information Technology and Burden Reduction

We estimate that 70% of the respondents will use electronic means to make a request for records. The form is available on our website (at https://www.fda.gov/media/107210/download); although if an individual requests one, we will send it by mail or email. Other information pertaining to requesting information under the FOIA is available from our website (at https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request), including instruction on making a FOIA request by mail or fax.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

Respondents to the collection are private individuals. We are unaware of any undue burden preventing respondents from making requests as desired.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is driven by respondents. Procedures for this collection, and the subsequent responses to such requests by FDA, are prescribed by 21 CFR Part 21 Subpart D; a reduction in frequency could constitute a failure by the Agency to comply with that subpart.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

FDA published a 60-day notice for public comment in the *Federal Register* of July 11, 2025 (90 FR 30944). FDA received two comments that were Paperwork Reduction Act (PRA) related. The commenters questioned the practical utility of the information collection, asserting that the information requested is unnecessary. FDA has determined that the information collection has practical utility because the information requested is necessary to process requests submitted to the Agency.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate handling of information collected. While this ICR collects personally identifiable information (PII) or other data of a personal nature, we have minimized these elements as much as possible. The PII submitted for Form FDA 3975, (Certification of Identity) includes name, citizenship status, Social Security Number (SSN), address, Date of Birth, and Place of Birth. The collection instrument (FDA Form 3975) is maintained in a Privacy Act system of records as described in

HHS/FDA System of Records Notice (SORN) 09-90-0058 for FDA's Tracking Records and Case Files for FOIA and Privacy 3 Act Requests and Appeals.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

Table 1 -- Estimated Annual Reporting Burden

| FDA Form | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|
| Certification of Identity; Form FDA 3975 | 24 | 1 | 24 | 0.50 (30 minutes) | 12 |

12b. Annualized Cost Burden Estimate

The estimated hourly wage rate for civilian workers is $49.32 (March 2026 Bureau of Labor and Statistics data, https://www.bls.gov/news.release/pdf/ecec.pdf) then doubled to account for benefits and overhead, and rounded to the nearest dollar.

Table 2 -- Annualized Cost Burden Estimate

| FDA Form | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| Certification of Identity; Form FDA 3975 | 12 | $93 | $1,118 |
| Total | | | $1,118 |

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital costs or operating and maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

Due to the nature of these submissions, we consider our processing of and responses to them to be a de minimus addition to the workloads of otherwise fully encumbered employees.

Table 3 -- Annualized Cost to the Federal Government[1]

| Government Personnel | Time Commitment | Estimated Annual Salary | Total Costs |
|---|---|---|---|
| GS-13 (1) | 1% | $121,785 | $1,217.85 |
| Total | | | $1,217.85 |

[1] U.S. Office of Personnel Management, 2026; Washington, D.C. Metro Area GS Pay Table: OPM.gov

15. Explanation for Program Changes or Adjustments

There are no changes to the information collection. ROCIS reflects an increase in burden hours; however, this increase does not represent a programmatic change. During the previous renewal, the estimated burden per response was inadvertently reported as 0.17 hours instead of 0.5 hours. This submission corrects that error and the resulting increase in total annual burden hours is solely attributable to the correction of the previously reported burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There is no reason that display of the OMB Expiration Date would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.