UNITED STATES FOOD AND DRUG ADMINISTRATION

Certification of Identity for
Freedom of Information and Privacy Act Requests

OMB Control No. 0910-0832

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. 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. 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. In processing certain requests under the FOIA and the Privacy Act, the agency must confirm that the individual making the request is the same person to whom the records pertain and will be released.

   To assist respondents to this collection of information, we developed Form FDA 3975 entitled, "*Certification of Identity*." Accordingly, we are requesting extension of OMB approval of the information collection and associated form.

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. Other information pertaining to requesting information under the FOIA is available from our website, including instruction on making a FOIA request by mail, fax, or online using our FOIA submission portal at http://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

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.

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

   In accordance with 5 CFR 1320.8(d), we published a 60 day notice for public comment in the Federal Register of November 22, 2019 (84 FR 64539). One comment was received expressing concern for fraudulent requests. The comment also suggested that our burden estimate might be high, however no alternative estimate was provided.

   With regard to the protection of personal information FDA will remain vigilant in its adherence to the protection of information pertaining to individuals under the Privacy Act and any additional and applicable laws protecting the release of private information. We will also consider lowering our burden estimate in the future, however we note this is a relatively new information collection and our evaluation is ongoing.

9. Explanation of Any Payment or Gift to Respondents

   No payment or gift is provided for this 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

Act Requests and Appeals. Individuals will complete Form FDA 3975 via the webpage where a notice is displayed on the form.

11. Justification for Sensitive Questions

Although the information collection solicits personal information, providing the information is voluntary and requests are generated by respondents. The information is maintained in the AIMS FOIA database, which stores and tracks FDA FOIA requests. AIMS FOIA users have passwords for accessing the database, and only the agency FOIA headquarters (Division of Freedom of Information) and the agency component(s) processing the FOIA request would have access to any particular FOIA request and its relevant documents, such as the certification of identify.

12. Estimates of Annualized Burden Hours and Costs

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.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
3975; Certification of Identity	50	1	50	.17 (10 mins.)	8.5

12b. Annualized Cost Burden Estimate

There are no annualized costs to respondents for the burden hours for this collection of information.

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

There are no expected annualized costs to the Federal Government.

15. Explanation for Program Changes or Adjustments

Based on agency data, we have received no more than 50 submissions since establishing the collection in 2017. We have therefore adjusted the number of respondents resulting in a decrease to the collection.

16. Plans for Tabulation and Publication and Project Time Schedule

We have no plans to tabulate and publish information from this information collection.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.