

Certification of Identity for Freedom of Information and Privacy Act Requests

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The collection of information is required under the Freedom of Information Act, 5 USC 552 (FOIA) and the Privacy Act, 5 USC 552a, as well as FDA's regulations at 21 CFR Part 20 and Part 21. Under the FOIA and the Privacy Act, certain records about a person are only releasable to that person. Information in personnel, medical, and similar files release of which would constitute a clearly unwarranted invasion of personal privacy can only be released to the individual at issue in those records. In processing some requests under the FOIA and the Privacy Act, the Agency must confirm that the individual making the request is in fact the same person whose records are being requested.

2. Purpose and Use of the Information Collection

The information collected is used by the FOIA and Privacy Act staff in the Agency to ensure that records that contain information about a person are not releasable to a third party, but are only released to the individual.

The information collected would be used to confirm that the individual requesting records under FOIA or the Privacy Act is legally entitled to receive the records even if the records would not be releasable to a third party.

The information collected would come from individuals.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that 70% of the respondents will use electronic means to fulfill the Agency's requirement or request. At this time, the public can make a FOIA request by mail, fax, or FDA's online FOIA submission portal at <http://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm>. Over 70% of FDA's incoming FOIA requests are made via the online submission form. The online submission form allows the public to upload an attachment, such as the Certification of Identify form. Privacy Act requests are received by mail, fax, or email; there is no online submission portal for Privacy Act requests. FDA receives a very small number of Privacy Act requests (approximately 5 to 10 per year). Under either statute, a fillable, signable, fileable version of the form can be used and submitted by email or, for FOIA, email and online submission portal.

4. Efforts to Identify Duplication and Use of Similar Information

Every agency has its own FOIA and Privacy function because each agency has the responsibility for processing its own records under the FOIA and Privacy Act. Therefore, a requester would need to submit a request directly to FDA if the requester seeks copies of FDA records. If FDA determines that certification of identity is necessary due to the nature of the records requested, FDA contacts the requester. If, for some reason, FDA received the request from another agency such as NIH or CDC because the requester initially sent the request to the wrong agency, and if the other agency had already obtained certification of identity, it would not be necessary for FDA to obtain the information again.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that less than 5% of respondents are small businesses, as the form is only relevant to “individuals” (although that could, hypothetically, be a doctor or a dentist). The form is one page long, and requires six pieces of information, plus the signature and date.

6. Consequences of Collecting the Information Less Frequently

The information on the form is required only if an individual makes an FOIA request or Privacy Act request for records about himself, and has not provided sufficient assurances of identity in the incoming FOIA or Privacy Act request. For any particular FOIA or Privacy Act request that the individual submits, the information would be required one time. If the same requester were to make additional requests for records about herself, another collection would likely not be necessary.

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), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 8/4/2016 (81 FR 51455). No comments were received.

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

The information collected will be kept confidential under the provisions of the Freedom of Information Act. It is well established that home addresses, social security numbers, dates of birth, etc. are considered information contained in personnel, medical, or other records the release of which could cause an unwarranted invasion of personal privacy, and therefore is exempt from public release under Exemption 6 of the FOIA.

The information would be maintained in the AIMS FOIA database, which stores and tracks FDA FOIA requests. The agency’s 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 identity.

11. Justification for Sensitive Questions

Providing your social security number is voluntary. You are asked to provide your social security number only to facilitate the identification of records relating to you. Without your social security number, the agency may be unable to locate any or all records pertaining to you.

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12. Estimates of Annualized Burden Hours and Costs

12 a. 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	60	1	60	.17 (10 minutes)	10

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

This is a new data 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.