



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2066]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Certification of Identity for Freedom of Information Act and Privacy Act Requests

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0832. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Certification of Identity; Form FDA 3975

OMB Control Number 0910-0832--Extension

This information collection 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 available from our website at: <https://www.fda.gov/RegulatoryInformation/FOI/default.htm>, although if an individual requests one, we will send it by mail or email. 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.

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.

In the *Federal Register* of November 22, 2019 (84 FR 64539), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received stating it was important that FDA retain the information collection to help protect against potential identity fraud. The comment also suggested that the associated burden for completing and submitting Form FDA 3975 may be lower than estimated, but did not provide alternative figures for us to consider. We therefore retain our burden estimate, which is as follows:

Table 1.--Estimated Annual Reporting Burden¹

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	0.17 (10 minutes)	8.5

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on Agency data, we have received no more than 50 submissions since establishing the collection in 2017.

Dated: March 26, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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