4164-01-P

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: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Certification of Identity for Freedom of Information Act and Privacy Act Requests." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Cappezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North

Bethesda, MD 20852, 301-796-3794.

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 for Freedom of Information Act and Privacy Act Requests

OMB Control Number 0910--NEW

In compliance with 44 U.S.C. 3507, FDA will submit to OMB a request to review and approve a new collection of information: Certification of Identity for Freedom of Information Act and Privacy Act Requests. This new form provides the FDA with data necessary to identify an individual requesting a particular record under the Freedom of Information Act (FOIA) and the Privacy Act. The form is available at the following FDA FOIA page at: https://www.fda.gov/RegulatoryInformation/FOI/default.htm, although if an individual requests one, we will send it by mail or email. 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.

Members of the public who wish to access particular records will be asked for certain information: Name, citizenship status, social security number, address, date of birth, place of birth, signature, and date of signature.

In the Federal Register of August 4, 2016 (81 FR 51455), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

As stated in table 1, the estimates are based on the following: The number of FOIA and Privacy Act requests received by FDA each year that require a certification of identity in order for FDA to process the request. Of the 10,000 requests received per year, only a small number require a certification of identity. In some cases, the requesters provide their own certification of identity. Therefore, we have estimated the number of affected individuals at 60 per year.

Table 1.--Estimated Annual Reporting Burden[1]

FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
3975	60	1	60	0.17 (10 minutes)	10

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

Dated: April 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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