

of competitors, both of which have significant share of over 20 percent. As a result, the Acquisition would eliminate competition between Aurobindo and Lannett in these markets and reduce the number of competitors in already concentrated markets.

The effects of the Acquisition may also substantially lessen competition in these markets by meaningfully increasing the likelihood that the remaining competitors would engage in coordinated interaction between or among each other post-Acquisition. The generic drug industry has a history of collusion. The Department of Justice and coalitions of State Attorneys General have conducted Federal multistate civil antitrust investigations in the generic drug industry, which resulted in charges and complaints alleging several generic drug manufactures violated the antitrust laws by fixing prices for a wide range of generic pharmaceutical products. A history of coordination in an industry creates the risk of future coordination, in particular post-Acquisition, when there will be one fewer significant competitor.

Entry Conditions

Entry in the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. *De novo* entry would not be timely due to the time required for drug development and FDA approval requirements, and no other entry is likely to occur that would be sufficient to deter or counteract the competitive harms likely to result from the Acquisition.

The Proposed Order and Order To Maintain Assets

The proposed Order effectively remedies the competitive concerns raised by the proposed Acquisition for the four relevant generic pharmaceutical markets at issue. Pursuant to the proposed Order, the parties are required to divest Respondent's rights and assets related to the four products to Quagen. The parties must accomplish these divestitures no later than ten days after the Acquisition is consummated. The provisions of the Consent Agreement ensure that Quagen becomes an independent, viable, and effective competitor in the U.S. markets for the relevant products.

Quagen has the expertise, sales infrastructure, and resources to restore the competition that otherwise would have been lost due to the proposed Acquisition. While it is a smaller generic company, Quagen has

significant manufacturing capability and experience marketing and distributing a variety of generic drugs. Quagen is well suited to take on the four products and replace the competition that would be lost as a result of Aurobindo's proposed acquisition of Lannett.

If the Commission determines that Quagen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Respondents to unwind the sale of rights and assets and then divest the affected product to a Commission-approved acquirer within six months of the date the Order becomes final. The Commission has agreed to appoint a Monitor to ensure that Aurobindo and Lannett comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to the buyer. The proposed Order further allows the Commission to appoint a trustee in the event that Aurobindo and Lannett fail to divest the products as required.

The purpose of this analysis is to facilitate public comment on the Consent Agreement and proposed Order to aid the Commission in determining whether it should make the proposed Order final. This analysis is not an official interpretation of the proposed Order and does not modify its terms in any way.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2026-12612 Filed 6-22-26; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Privacy Act of 1974; System of Records

AGENCY: Office of Family Assistance (OFA), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS) is making updates to an existing system of records maintained by the Office of Family Assistance (OFA) within HHS' Administration for Children and Families (ACF), System No. 09-80-0375, Temporary Assistance for Needy

Families (TANF) Data. The system of records contains data about TANF clients received from TANF grantee agencies in the states, territories, and Tribal organizations, as well as verification information obtained from those agencies, other HHS records, or other government agencies or entities engaged to assist ACF with program integrity reviews or projects.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this notice is effective June 23, 2026, with the exception of the new routine use described below, which is effective July 23, 2026. Please submit any comments on the notice by July 23, 2026.

ADDRESSES: Comments may be submitted to the Federal eRulemaking Portal electronically at <http://www.regulations.gov> or mailed to John Talieri, Senior Official for Privacy, Administration for Children and Families, 330 C Street SW, Washington, DC 20201. Please include "09-80-0375" in the subject line or [regulations.gov](http://www.regulations.gov) comment. Comments received will be available at [regulations.gov](http://www.regulations.gov) for public viewing, inspection or copies. ACF does not edit personally identifiable information from submissions; therefore, commenters should submit only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: General questions about the modified system of records may be submitted by mail or email to TANF Data Division, Office of Family Assistance, Administration for Children and Families, 330 C Street SW, Washington, DC 20201, or tanfdata@acf.hhs.gov; or may be submitted by telephone to John Talieri, Senior Official for Privacy, at (202) 969-3581.

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Family Assistance (OFA) oversees the cash welfare block grant called the Temporary Assistance for Needy Families (TANF) program. The TANF program provides assistance and work opportunities to needy families through grants that provide states, certain U.S. territories, and Tribes with federal funds and flexibility to develop and implement their welfare programs. Each state and U.S. territory that operates a program of assistance for low-income families using TANF funding is required by statute to collect data about the recipients of that TANF assistance. 42 U.S.C. 611. Federally recognized tribes administering TANF programs are also required by statute to collect the same core data elements. 42 U.S.C. 612(h).

II. Modifications to SORN 09–80–0375

The changes to SORN 09–80–0375 include:

- In the Authority section, adding 42 U.S.C. 1320b–7 and 8 U.S.C. 1373.
- Revising the Purpose(s) section to:
 - Clarify the first purpose description by changing “. . . grantees are meeting certain requirements. . .” to “. . . grantees are ensuring that TANF recipients are eligible in accordance with the requirements of Title IV–A. . .” and deleting “including work participation and time-limit requirements.”
 - Add a new purpose description: “to ensure and confirm grantee compliance with TANF program requirements through HHS agency oversight activities including but not limited to program integrity reviews (e.g. comprehensive assessments of how grantees administer TANF programs and follow statutory requirements), additional audits (e.g. financial audits, programmatic audits, and fraud investigations), and monitoring (e.g. regular review of data reports, on-site or virtual visits to TANF agencies, periodic review of policies and procedures). The purpose is to ensure compliance with all TANF program requirements including but not limited to the work participation rate and time-limits, the requirement to provide complete and accurate data, and the requirement to verify TANF recipients’ citizenship or immigration status in records maintained by the Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (formerly the U.S. Immigration and Naturalization Service (INS)). See 45 U.S.C. 265.7(b); 42 U.S.C. 1320b-7(d); 6 U.S.C. 552(d);”
 - Remove extraneous “The monthly TANF data are reported by the individual grantees for each Federal fiscal quarter” from the purposes section; add clarifying “‘TANF data’ refers to data from all TANF programs, including Tribal TANF programs.”
- In the Categories of Records section, introducing the existing set of record categories as “data reported to ACF by TANF grantee agencies”; introducing a new, separate set of record categories as “verification information obtained from those agencies, other HHS records, or other government agencies or entities (e.g. DHS or the Social Security Administration (SSA)) engaged to assist ACF with program integrity reviews or projects, to check whether TANF grantee agencies are complying with TANF program requirements”; and adding examples of data elements contained in the records.
- In the Record Source Categories section, adding these sources of

verification information which are not already included: “other HHS records” and “other federal or state agencies or entities engaged to assist ACF with program integrity reviews or projects.”

- Adding one new routine use (routine use 10) to the Routine Use(s) section, which will authorize disclosures to another federal or grantee agency or entity engaged by ACF (e.g. DHS or TANF program administrators) to assist ACF with program integrity reviews or projects, to verify whether TANF grantee agencies are complying with TANF program requirements, including verifying citizenship or immigration status.
 - Updating the Retrieval section to add “SSN” as a personal identifier used to retrieve verification information.
 - Updating the Record Access Procedure section to include a digital service option as required by the CASES Act and OMB Memorandum M–21–04.
- Because some of these modifications are significant, as required by the Privacy Act at 5 U.S.C. 552a(r), HHS sent a report of this modified system of records to the Committee on Homeland Security and Governmental Affairs of the Senate, the Committee on Oversight and Government Reform of the House of Representatives, and the Office of Management and Budget.

Dated: June 17, 2026.

David M. Swegle,

Director, Office for Family Assistance, Administration for Children and Families.

SYSTEM NAME AND NUMBER:

Temporary Assistance for Needy Families (TANF) Data, 09–80–0375.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

The address of the agency component responsible for the system of records is the Administration for Children and Families, 330 C Street SW—3rd Floor, Washington, DC 20201. The cloud service providers (CSP) are located at that same address and the second CSP is located at the U.S. General Services Administration’s (GSA) Technology Transformation Services headquarters, 1800 F Street NW, Washington, DC 20405.

SYSTEM MANAGER(S):

The System Manager is the Deputy Director of the TANF Data Division, Office of Family Assistance, Administration for Children and Families, 330 C Street SW—3rd Floor, Washington, DC 20201; Email: tanfdata@acf.hhs.gov.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

TANF: 42 U.S.C. 601 through 619 (Title IV–A of the Social Security Act); 42 U.S.C. 1320b–7 (sec. 1137 of the Social Security Act); and 8 U.S.C. 1373 (Communication between government agencies and the U.S. Citizenship and Immigration Services (USCIS) (formerly the U.S. Immigration and Naturalization Service (INS)). TANF data collection and reporting regulations are found in 45 CFR part 265.

Tribal TANF: 42 U.S.C. 612 (sec. 412 of the Social Security Act); and 8 U.S.C. 1373 (Communication between government agencies and the USCIS (formerly the INS)). Tribal TANF data collection and reporting regulations are found in 45 CFR part 286.

PURPOSE(S) OF THE SYSTEM:

The purposes for which TANF data are used are:

1. to determine whether grantees are ensuring that TANF recipients are eligible in accordance with the requirements of Title IV–A of the Social Security Act;
 2. to ensure and confirm grantee compliance with TANF program requirements through HHS agency oversight activities including but not limited to program integrity reviews (e.g. comprehensive assessments of how grantees administer TANF programs and follow statutory requirements), additional audits (e.g. financial audits, programmatic audits, and fraud investigations), and monitoring (e.g. regular review of data reports, on-site or virtual visits to TANF agencies, periodic review of policies and procedures). The purpose is to ensure compliance with all TANF program requirements including but not limited to the work participation rate and time-limits, the requirement to provide complete and accurate data, and the requirement to verify TANF recipients’ citizenship or immigration status in records maintained by the Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (formerly the U.S. Immigration and Naturalization Service (INS)). See 45 U.S.C. 265.7(b); 42 U.S.C. 1320b–7(d); 6 U.S.C. 552(d);
 3. to compile information used to report to Congress on the TANF program; and
 4. to perform research on the caseload dynamics and employment trajectories of TANF recipients.
- (The term “grantees” is used in this notice to refer to the Tribal TANF programs, 50 states, the District of Columbia, and the jurisdictions of Puerto Rico, the U.S. Virgin Islands, and Guam. “TANF data” refers to data from

all TANF programs, including Tribal TANF programs.)

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records are about the following categories of individuals:

1. Members of families (as defined at 45 CFR 265.2) who received assistance under the TANF program in any month. For data collection and reporting purposes only, family means:

a. all individuals receiving assistance as part of a family under the grantee's TANF or separate state program (including noncustodial parents, where required under 45 CFR 265.3(f)); and

b. the following additional persons living in the household, if not otherwise included:

- parent(s) or caretaker relative(s) of any minor child receiving assistance;
- minor siblings of any child receiving assistance; and
- any person whose income or resources would be counted in determining the family's eligibility for or amount of assistance.

2. Members of families no longer receiving assistance under the TANF program. 45 CFR 265.2(c)–(d) and 45 CFR 265.3(b)(2).

CATEGORIES OF RECORDS IN THE SYSTEM:

The records consist of data reported to ACF by TANF grantee agencies and verification information obtained from those agencies, other HHS records, or other government agencies or entities (e.g. DHS or the Social Security Administration (SSA)) engaged to assist ACF with program integrity reviews or projects, to check whether TANF grantee agencies are complying with TANF program requirements.

Data reported to ACF by TANF grantee agencies includes:

1. *Family-level data*, including, for example, county of residence, 5-digit ZIP Code, household size, type and amount of assistance received, and case number.

2. *Adult-level or minor-child-head-of-household data*, including, for example, Social Security number, date of birth, citizenship/immigration status, race, employment status, education level, hours of participation in work activities, and income.

3. *Child data*, including, for example, Social Security number, date of birth, citizenship/immigration status, race, and education level.

Data reported by other government agencies or entities includes:

1. Verification information may include SSN, date of birth, county of residence, name, address, and detailed immigration status information (e.g.,

whether an individual is a refugee, non-immigrant, has no status, has temporary protected status, requires additional verification).

RECORD SOURCE CATEGORIES:

Information in this system of records is obtained from TANF grantee agencies in the states, territories, and Tribal organizations; from other HHS records; and from other federal or state agencies or entities engaged to assist ACF with program integrity reviews or projects.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, as amended, at 5 U.S.C. 552a(b), under which ACF may release information from this system of records without the consent of the individual. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible.

1. *Disclosure of Identifiable Data for Research.* Information from this system of records may be disclosed with personal identifiers included for use solely as a statistical, research, or reporting record in response to specific requests from public or private entities. No data will be disclosed until the requester has agreed in writing not to use such data to identify any individuals and has provided advance adequate written assurance that the records will be used solely as a statistical, research, or reporting record.

a. *Note:* Data produced by matching grantee-provided data in this system of records with data from the Office of Child Support Enforcement's National Directory of New Hires system of records will only be disclosed in accordance with routine use disclosure 8 (*Disclosure to State Agencies Operating Specified Programs*) set forth in SORN 09–80–0381 OCSE National Directory of New Hires.

2. *Disclosure for Law Enforcement Purpose.* Information may be disclosed to the appropriate federal, state, local, Tribal, or foreign agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, if the information is relevant to a violation or potential violation of civil or criminal law or regulation within the jurisdiction of the receiving entity.

3. *Disclosure for Private Relief Legislation.* Information may be disclosed to the Office of Management and Budget at any stage in the legislative coordination and clearance

process in connection with private relief legislation as set forth in OMB Circular No. A–19.

4. *Disclosure to Congressional Office.* Information may be disclosed to a congressional office from the record of an individual in response to a written inquiry from the congressional office made at the request of, and on behalf of, the individual.

5. *Disclosure to Department of Justice (DOJ) or in Litigation.* Information may be disclosed to DOJ, or in a proceeding before a court, adjudicative body, or other administrative body before which HHS is authorized to appear, or in proceedings arguably relevant to the litigation, when: HHS, or any component thereof; or any employee of HHS in his or her official capacity; or any employee of HHS in his or her individual capacity where DOJ or HHS has agreed to represent the employee; or the United States, if HHS determines that litigation is likely to affect HHS or any of its components, is a party to the proceedings or has an interest in such proceedings, and the use of such records by DOJ or HHS is determined by HHS to be arguably relevant to the litigation.

6. *Disclosure to the National Archives and Records Administration (NARA).* Information may be disclosed to NARA in records management inspections.

7. *Disclosure to Contractors, Grantees, and Others.* Information may be disclosed to contractors, grantees, consultants, or volunteers performing or working on a contract, service, grant, cooperative agreement, job, or other activity for HHS related to the purposes of this system of records and who have a need to have access to the information in the performance of their duties or activities for HHS.

8. *Disclosure in the Event of a Security Breach Experienced by HHS.* Records may be disclosed to appropriate agencies, entities, and persons when (1) HHS suspects or has confirmed that there has been a breach of the system of records, (2) HHS has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, HHS (including its information systems, programs, and operations), the federal government, or national security, and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HHS's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

9. *Disclosure to Assist Another Agency Experiencing a Security Breach.* Records may be disclosed to another federal agency or federal entity, when HHS determines that information from

this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the federal government, or national security, resulting from a suspected or confirmed breach.

10. *Disclosure to Another Agency/ Entity Engaged to Assist ACF With Program Integrity Reviews or Projects, for TANF Program Compliance Purposes.* Records may be disclosed from this system of records to another federal or grantee agency or entity engaged by ACF (e.g., DHS or TANF program administrators) to assist ACF with program integrity reviews or projects, to verify whether TANF grantee agencies are complying with TANF program requirements, including verifying citizenship or immigration status.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic records are stored in a restricted database on a cloud computing network or in secure files on a restricted computer network.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records reported by TANF grantee agencies are retrieved by an SSN or case number. Verification information is retrieved by SSN.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The records (family-level data; adult-level or minor-child-head-of-household data; and child data) are retained for administrative, audit, legal, or operational purposes, and in accordance with records schedule DAA-292-2016-0006, Item 7.1 *Data, Reports and Tables* and Item 7.2 *Other Reports*, approved by the National Archives and Records Administration (NARA).

- Item 7.1 *Data, Reports and Tables* provides for records related to cash assistance caseloads, work participation data, and caseload characteristics to be cut off at the end of the fiscal year and transferred to NARA 20 years after cutoff, for permanent retention, due to its significant research value.

- Item 7.2 *Other Reports* provides for routine administrative supporting documents for the National Directory of New Hires (NDNH) match reports, and Temporary Assistance for Needy Families and maintenance of effort reports submitted by states, territories, and tribes, to be cut off at the end of the

fiscal year the reports are completed and destroyed three years after cutoff.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Safeguards conform to the HHS Information Security and Privacy Program, <https://www.hhs.gov/ocio/securityprivacy/index.html>. The information technology system used to store the records leverages cloud service providers that maintain an authority to operate in accordance with applicable laws, rules, and policies, including Federal Risk and Authorization Management Program (FedRamp) requirements.

Information is safeguarded in accordance with applicable laws, rules and policies, including the HHS information security policies, the E-Government Act of 2002, which includes the Federal Information Security Management Act of 2002 (FISMA), 44 U.S.C. 3541 through 3549, as amended by the Federal Information Security Modernization Act of 2014, 44 U.S.C. 3551 through 3558, all pertinent National Institutes of Standards and Technology (NIST) publications, and OMB Circular A-130, Managing Information as a Strategic Resource. Records are protected from unauthorized access through appropriate administrative, physical, and technical safeguards. Agency personnel, contractors, and grantees who have access to the records are required to maintain confidentiality by assuring that case records are kept in a safe, secure environment within agency, contractor, or grantee facilities. They are also required to sign a confidentiality agreement and to receive annual training on records management, cybersecurity, privacy, and confidentiality policies and procedures, including methods of protecting client confidentiality.

Case records are filed electronically according to Office of Family Assistance protocols, and access to records is controlled through log-in/out processes for computer logs. The records are accessible only to authorized users using two-factor authentication through a secured system that is protected by encryption, firewalls, and intrusion detection systems and requires additional encryption for any records stored on removable media. Records that become eligible for destruction are disposed of in alignment with the secure destruction methods prescribed by the NIST Special Publication (SP) 800-88. The associated information technology (IT) system(s) receive Authority to Operate (ATO) under the guidance of NIST SP 800-53.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about them in this system of records may submit a request through a secure web portal or via mail. To submit through the web portal, individuals should go to [FOIA.gov](https://www.foia.gov). Email is not considered to be sufficiently secure to safely transmit sensitive information, so individuals should not use email to submit a sensitive request or sensitive attachments; any sensitive information should be sent to the System Manager by mail or submitted via the web portal. A written request must contain the requester's full name, Social Security number, address, telephone number and/or email address, date of birth, and signature, and should identify the state, Tribe, or territory where the requestor participated in the TANF program. For more information, see: <https://www.hhs.gov/foia/privacy/how-make-privacy-act-request.html>.

For mail requests to the System Manager, so that HHS may verify the requester's identity, the requester's signature must be notarized or the request must include the requester's written certification that the requester is the individual who the requester claims to be and that the requester understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a fine of up to \$5,000.

Individuals may also request an accounting of disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURES:

Individuals seeking to amend records about them in this system of records must submit a written amendment request to the relevant System Manager identified in the "System Manager(s)" section of this SORN, containing the same information required for an access request. The request must include verification of the requester's identity in the same manner required for an access request; must reasonably identify the record and specify the information contested, the corrective action sought, and the reasons for requesting the correction; and should include supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

NOTIFICATION PROCEDURES:

Individuals who wish to know if this system of records contains records about them must submit a written notification request to the relevant System Manager identified in the "System Manager(s)" section of this SORN. The request must contain the same information required

for an access request and must include verification of the requester’s identity in the same manner required for an access request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:
None.

HISTORY:
89 FR 25880 (Apr. 12, 2024).
[FR Doc. 2026–12514 Filed 6–22–26; 8:45 am]
BILLING CODE 4184–42–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2025–N–1732]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Certification of Identity, Form FDA 3975

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 July 23, 2026.

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 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: Patrick Clouser, Office of Operations, Food and Drug Administration, 12420 Parklawn Drive, Rockville, MD 20852, (240) 402–5276, 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 titled, “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 on our website (<https://www.fda.gov/media/107210/download>). If an individual requests one, we will send it by mail or email. 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 the right to access Federal records not normally prepared for public distribution. The

Privacy Act grants the 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 July 11, 2025 (90 FR 30944), FDA published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received. They did not generally pertain to the Paperwork Reduction Act or the burden of information collection. To the extent that any of them did in part pertain to the information collection, the comments expressed confusion regarding the information disclosure requirement of the Freedom of Information Act and the information protection requirement of the Privacy Act. This information collection is a mechanism by which an individual can by make a FOIA request for records covered by the Privacy Act pertaining to themselves, per the Conditions of Disclosure set forth in 5 U.S.C. 552a(b).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3975	24	1	24	.17 (10 minutes)	4

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

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
[FR Doc. 2026–12579 Filed 6–22–26; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2026–N–6540]

Agency Information Collection Activities; Proposed Collection; Comment Request; Potential Tobacco Product Violations Reporting Form

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Potential