DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget (OMB) Review; Temporary Assistance for Needy Families (TANF) Data Reporting for Work Participation (OMB #0970–0338)

AGENCY: Office of Family Assistance; Administration for Children and Families; United States Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting to extend approval of the Temporary Assistance for Needy Families (TANF) Data Reporting for Work Participation, with proposed revisions. Revisions are intended to improve the clarity of the instructions, streamline reporting, and ensure all instructions are up-to-date.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review-Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: This request includes the following information collections: work verification procedures, the Caseload Reduction Documentation Process, the TANF Data Report, the Separate State Program (SSP)-Maintenance of Effort (MOE) Data Report, and TANF sampling instructions. The data and information from these reports and processes are used–and will continue to be used–for program analysis and oversight, including the calculation and administration of the work participation rate and associated penalties. Congress provides federal funds to operate TANF programs in the states, the District of Columbia, Guam, Puerto Rico, the U.S. Virgin Islands, and for approved federally recognized tribes and Alaskan Native Villages. We are proposing to continue the same information collections with only changes to instructions to improve clarity and eliminate data elements and guidance that are no longer relevant. The Work Verification Plan Guidance has been updated to reflect current regulation. The TANF and SSP–MOE Data Report instructions were revised to streamline the data collection, reduce the burden on respondents by eliminating unnecessary data elements, and clarify confusing data elements. The TANF and SSP–MOE Data Report layouts were also updated to reflect the streamlined instructions. The TANF Sample Manual was revised to eliminate outdated and unused sections.

Respondents: The 50 states of the U.S., the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Total annual burden hours
Preparation and Submission of Data Verification Procedures sections 261.60–261.63	54	1	640	34,560
Caseload Reduction Documentation Process, ACF–202 sections 261.41 and 261.44	54	1	120	6,480
Reasonable Cause/Corrective Compliance Documentation Process sections 262.4, 262.6, and 262.7; section 261.51	54	2	240	25,920
TANF Data Report Part 265	54	4	2,100	453,600
SSP–MOE Data Report–Part 265	29	4	714	82,824
TANF Sampling and Statistical Methods Manual Part 265.5	30	4	48	5,760

Estimated Total Annual Burden Hours: 609,144.

Authority: 42 U.S.C. 601, 607, 609, 611, 613, and 1302.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–20165 Filed 9–18–23; 8:45 am]

BILLING CODE 4184–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3636]

Food and Drug Administration Information Technology Strategy; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of an information technology (IT) strategic plan entitled the ''FDA Information Technology Strategy'' and a request for comment on this IT Strategy. As part of our User Fee Program commitments and Omnibus Bill requirements, FDA will develop and publish an FDA Data and Technology Strategic Plan by September 29, 2023. This plan will define and shape the future course of FDA's data and technology capabilities, building on the existing FDA Modernization Framework. The plan will also integrate Agency and center strategies.

DATES: Submit either electronic or written comments on the Strategy by October 30, 2023, to ensure that the Agency considers your comments on this Strategy for future iterations of the IT Strategy.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–3636 for ''FDA IT Strategy.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

Submit written requests for single copies of this IT strategy to the Office of Digital Transformation, Food and Drug Administration, FDA Library, 5630 Fishers Lane, Rm. 1087, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the strategy may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft strategy.

FOR FURTHER INFORMATION CONTACT: Casi Alexander, Office of Digital Transformation, Food and Drug Administration, FDA Library, 5630 Fishers Lane, Rm. 1087, Rockville, MD 20857, 240–402–5171, email: *Casi.Alexander@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a request for comment on its draft strategy, entitled ''FDA Information Technology Strategy''.

The Office of Digital Transformation (ODT) was established in September 2021 and reports directly to the Office of the Commissioner. ODT provides the vision and leadership in information technology, data, and cybersecurity needed to advance FDA's mission and strategic priorities. ODT has published a series of strategy documents known as the FDA Modernization Framework. The framework includes the Technology Modernization Action Plan, Data Modernization Action Plan, Enterprise Modernization Action Plan, Cybersecurity Modernization Action Plan, and the Leadership Modernization Action Plan. The FDA Modernization Framework aims to develop an integrated technology, data, cybersecurity, business, and leadership approach to advancing FDA's public health mission in collaboration with industry.

As part of FDA's fulfillment of requirements in section 3627 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), and commitments described in section IV.A.2. of the ''PDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027'' (PDUFA VI commitment letter), FDA will work with industry while developing a comprehensive framework for guiding the Agency's work and allocating annual technology budgets and resources. The FDA IT Strategy, covering Fiscal Years 2024–2026, defines and shapes the future course of FDA's data and technology capabilities as FDA transitions to the next phase of its journey. The Agency took a collaborative approach to strategy development by gathering input from numerous internal and external stakeholders that resulted in the draft FDA IT Strategy. Stakeholder input is crucial for developing a comprehensive plan that best meets the needs and goals of industry and the Agency. Comments on the strategy will be considered for future iterations of the FDA IT Strategy. Once adopted, this strategy will serve as the basis for developing an internal operational plan with objectives, tactics, and performance measures.

As part of this effort, FDA will hold an FDA Digital Transformation Symposium on December 4 to 7, 2023, to discuss this groundbreaking IT Strategy and encourage further collaboration, innovation, and transformation. On December 4 and 5, the Symposium will be shaped around the six new strategic goals, highlighting supporting objectives and initiatives. The FDA Digital Transformation Symposium will extend to December 6 and 7 to engage IT vendors in a Reverse Industry Day and other vendor-focused events. Registration information will be found on *www.FDA.gov* for this event.

II. Requested Feedback

Interested persons are invited to provide detailed comments to ODT (see **ADDRESSES**) on the specific IT Strategy Goals and Objectives within FDA's Agency-wide IT Strategy. To facilitate comment, FDA has developed a series of questions in this section. The questions are not meant to be exhaustive, and FDA is also interested in any other pertinent information stakeholders would like to share on this topic. FDA encourages stakeholders to provide the specific rationale and basis for their comments, including any available supporting data and information.

1. Which goals and objectives are most important to you? Why?
2. Describe up to five ways the FDA IT Strategy will impact your industry?
3. What gaps do you see in the FDA IT Strategy's goals or objectives?
4. What challenges or risks do you foresee in executing the FDA IT Strategy?

III. FDA IT Strategy Goals and Objectives

Goal 1: Create a Shared OneFDA Ecosystem: Establish greater access to trusted data and shared resources across Centers, Offices, and external stakeholders. Encourage and facilitate cross-functional investment in technology to support enterprise business objectives for speed, scale, and value through robust Agency level governance processes, enhanced collaboration channels, and technology products and services. Shift FDA's culture to make sharing across Centers and Offices and with external stakeholders (where appropriate) the norm—where prioritizing Agency-level public health outcomes improves results for everyone.

Objectives

- *Enhance Communication and Collaboration:* Foster information and resource sharing with internal and external stakeholders to achieve both Agency and specific stakeholder outcomes, using a variety of communication channels to reach broader audiences. Enable collaboration and develop strong partnerships across Centers and Offices through integrated technologies and platforms.
- *Promote Transparency:* Actively involve impacted stakeholders in IT solution planning, development, and execution to drive expected outcomes.
- *Optimize Investments:* Align the diverse needs across FDA to the overarching strategy through stronger financial fidelity, enhanced budget coordination, and improved financial planning. Ensure effective IT resource utilization, transparency in IT budget allocation, and measurement of results achieved.
- *Strengthen Governance:* Ensure the effective and efficient use of IT in enabling FDA to achieve mission outcomes through established standards, responsible procurement, and more robust decision-making and accountability mechanisms.

Goal 2: Strengthen IT Infrastructure: Continue to modernize and secure the foundational IT infrastructure for all IT services and solutions. Proactively provide the ability to adapt to changes in workload demand, detect issues before they impact stakeholders, and quickly resolve technology issues to avoid disruptions to day-to-day operations.

Objectives

- *Provide Flexible Infrastructure Offerings:* Provide a marketplace with usage-based models for users to identify and implement the infrastructure solutions based on their business requirements with an appropriate chargeback model.
- *Accelerate Cloud Adoption:* Empower users with cloud offerings to meet their mission needs, *e.g.,* scalability and agility. Provide best practice guidance on cloud models, *e.g.,* hybrid and transition strategies based on the unique needs across Centers and Offices.
- *Ensure Service Availability:* Provide stable access to IT services through proactive, continuous monitoring of IT infrastructure service performance (*e.g.,* Service Level Agreements, Operating Level Agreements) and feedback from FDA users to identify potential problems and implement targeted improvements.
- *Implement Zero Trust Approach:* Establish a comprehensive zero trust and risk-based approach to obtain optimal maturity level by upgrading, modernizing, and enhancing FDA's security and cyber defenses.

Goal 3: Modernize Enterprise Services and Capabilities: Optimize the IT services portfolio to support everyday needs with cross-cutting, mission-critical offerings and benefit from economies of scale. Ensure enterprise IT services are stable, resilient, and adaptive, with opportunities for stakeholders to tailor solutions, where appropriate, and feedback loops to drive continuous improvement.

Objectives

- *Increase Business Alignment:* Lead with a business-first approach to modernizing enterprise services and capabilities to ensure technology enables the capabilities defined in FDA's Business Capability Model and supporting business processes.
- *Scale Operations:* Develop and drive adoption of enterprise solutions for standard capabilities, *e.g.,* Finance/Budget, Human Resources, Acquisitions, Inspections, Freedom of Information Act requests, and Complaints Management with continuous user testing, while providing flexibility for customization where relevant. Manage the lifecycle of applications within the enterprise portfolio.
- *Increase Digital Maturity:* Maximize the use of technology (*e.g.,* data, automation) in core business areas and enable processes to improve their ability to adapt to changes and scale.
- *Improve Customer Experience:* Create customer-centric solutions that enhance satisfaction by improving accessibility to IT solutions, including external-facing systems (*e.g.,* Electronic Submission Gateway Next Generation), streamlining processes, and easing adoption. Increase stakeholder engagement with FDA IT services by prioritizing customer and employee feedback and establishing formal feedback loops.
- *Modernize FDA Cybersecurity Defenses:* Upgrade, enhance, and modernize FDA's critical cyber defenses and practices to address the evolving threat landscape where risks to FDA's critical assets, industry, and sensitive data exist.
- *Reduce Technology Debt:* Decommission legacy systems, applications, and End-of-Life devices and reinvest in enterprise solutions and business process improvements to minimize technical debt and enterprise risk.

Goal 4: Share Data for Mission Outcomes: Identify common data assets critical to stakeholders across FDA and make them widely available and consumable to drive operational efficiencies and excellence. Leverage valuable data assets and insights to develop new capabilities and services and enable public health innovation.

Objectives

- *Enhance Data Governance:* Implement Artificial Intelligence (AI)-powered best practices for governance and data management that improve data quality, security, and the speed and accuracy of insights and decisions.
- *Foster OneFDA Data Literacy:* Educate the workforce on best practices and the benefits of consuming, analyzing, and making data-based decisions.

• *Improve Data Visibility and Accessibility:* Prioritize which data assets to make widely available first based on value to the mission and the most significant number of stakeholders.
• *Enable Advanced Data Analytics:* Ensure experts can easily combine and analyze information from various internal and external sources to gain comprehensive insights.
• *Enhance Secure Data Exchange:* Improve interoperable and secure data exchange and collaboration across FDA and its public health partners.

Goal 5: Adopt AI and Mission-Driven Innovations: Drive exploration and address impacts of emerging technologies and trends, such as AI and virtual reality, on FDA's IT portfolio and regulatory operations. Proactively identify opportunities and risks to FDA's mission and inform responsible use of technology. Enhance partnerships with external experts to leverage these technologies and promptly respond to their impact.

Objectives

• *Balance Policy and Technology Value:* Develop ethical guidance for technology use while maximizing business value, such as Guidance on AI Strategy. Ensure responsible actions by conducting comprehensive research and analysis to fully understand technological advancements' potential impacts and implications on society.
• *Ensure Responsible Use of Innovations:* Deploy technological innovations, such as AI/Machine Learning, responsibly with an understanding of regulatory impacts and effective risk response strategies. Establish appropriate guardrails where necessary.
• *Provide Proactive Thought Leadership:* Lead as a partner in creating novel use cases for emerging technologies through a deep understanding of business processes, industry, and technology. Stay at the forefront of technological advancements by harnessing industry expertise and fostering collaboration.
• *Foster Innovation:* Create an environment where innovative approaches are encouraged, identified, shared, and evaluated for use in driving operational efficiency and developing new capabilities. Apply a structured process to manage the innovation lifecycle from ideation to investment to adoption (or project shutdown) to produce usable innovations.

Goal 6: Cultivate Talent and Leadership: Mature Agency-wide IT competencies to deepen technology expertise and keep pace with the accelerated rate of change in FDA's regulated industries and technology. Develop holistic leaders equipped to lead through change and drive FDA's digital transformation journey forward. Deliver enterprise IT services with an Agency-first mindset. Given the continued competition for talent, proactively build a robust talent pipeline for targeted roles leveraging a combination of recruitment, retention, and talent development strategies.

Objectives

• *Instill OneFDA Mindset:* Cultivate an Agency-first approach to IT so that decisions promote and protect the health of the American people first and foremost.
• *Attract and Retain Talent:* Build a diverse talent pipeline through a compelling employee value proposition and total compensation approach, talent acquisition, employee engagement, and talent development strategies. Drive improvements across the employee lifecycle from recruitment to retirement.
• *Hire and Develop Resilient Leaders:* Strengthen leadership competencies required to drive holistic transformational IT initiatives in a dynamic environment successfully.
• *Develop Skills for the Future of Work:* Develop IT skills and competencies required to deliver current and future IT services through upskilling, reskilling, and continuous learning.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the IT Strategy at *https://www.regulations.gov*.

Dated: September 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20136 Filed 9–18–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3490]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in Food and Drug Administration Fellowship and Traineeship Programs

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 ''Application for Participation in Food and Drug Administration Fellowship and Traineeship Programs.''

DATES: Either electronic or written comments on the collection of information must be submitted by November 20, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 20, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows: