SMG 3295.1

FDA Staff Manual Guides, Volume III – General Administration

Information Resources Management - Forms Management

Forms Management Policy

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Guidelines for Forms Management Program

1. Purpose

This Guide outlines the Food and Drug Administration (FDA) Forms Management Program (FMP) and establishes Agency policy and procedures for creating, revising, mailing, and archiving forms that adhere to Federal compliance standards. It supplements and is to be used in conjunction with the Department of Health and Human Services (HHS) Forms Management Program.

2. Policy

- FDA forms shall fulfill a legitimate requirement. Information collected on a form must be essential to accomplish a mission need and necessary for the efficient and economical operation of the FDA.

- Digital systems shall be employed to the greatest degree feasible for developing, circulating, and utilizing forms (encompassing digital formats) and for capturing, maintaining, and sharing data submitted on such forms. Digital documentation shall serve as the standard approach. Ongoing assessment and enhancement shall be conducted on technological platforms that support form administration. This is in compliance with OMB Memorandum M-23-22 Delivering a Digital-First Public Experience.

- Design of electronic form must be consistent with accessibility requirements for people with disabilities in accordance with Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. § 794d), as amended by the Workforce Investment Act of 1998 (Public Law 105-220).

- Forms collecting personally identifiable information that the FDA, or a party acting on behalf of FDA, will maintain in a Privacy Act system contain a Privacy Act Statement that discloses the authority, purpose, uses, and voluntary or mandatory nature of the information collection in accordance with the Privacy Act of 1974 (5 U.S.C. § 552a).

- Public facing forms and those providing services to the public shall be offered in electronic format to the maximum extent feasible in compliance with 21st Century Integrated Digital Experience Act, Public Law 115-336.

3. Responsibilities

A. FDA Chief Information Officer

- Oversees and ensures agency policy and procedures are in place for FDA's Forms Management Program.

B. FDA Forms Management Officer

- Serves as the FDA forms point of contact for services for the Agency and provides overall direction, guidance, and technical assistance for the Forms Management Program.

- Reviews and approves or disapproves the creation, revision, and cancellation of FDA forms and ensure they are consistent with issuance and in accordance with Standard and Optional Forms Management Program (FMR 41 CFR, Chapter 102 Subchapter G, 102-194).

- Ensures all FDA forms meet federal accessibility standards under Section

508 of the Rehabilitation Act and the plain language principles as outlined in the Plain Writing Act of 2010.

- Maintains necessary information and a historical record for each FDA form which includes retaining all editions of a form from creation to cancellation.

- Evaluates the overall effectiveness of the Forms Management Program and recommends changes to improve process efficiency.

- Creates or participates in surveys and studies to review forms workflow, data collection methods, and related procedures to implement process that improve the efficiency and effectiveness of forms development and the program.

- Manage shipping form inventory by coordinating warehouse requests, facilitating shipment of requested forms, monitoring stock levels, arranging reprints with the form POC as needed.

- Publish and maintain FDA forms web pages on the Internet and intranet platforms.

C. FDA Program Offices

- Propose new forms and revisions to existing forms, including justification of need and proposed content within their regulatory authority.

- Coordinate with FDA Forms Program to ensure all new and revised forms comply with the FDA Privacy Act Program requirements and the Paperwork Reduction Act provisions as applicable.

- Obtains approval from Office of Management and Budget for public-use forms.

- Collaborate with the FDA Forms Management Program throughout the form lifecycle including development, revision, distribution, use, and archiving to ensure that the either the printed or electronic forms are properly approved and made available through the FDA Forms Library.

- Verify the forms contain accurate technical content and adhere to applicable laws, regulations, and FDA directives.

- Advises the Forms Management Officer when a form needs to be reprinted or when a form becomes obsolete

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D. FDA Privacy Office

- Reviews all forms that collect personally identifiable information to ensure compliance with the Privacy Act of 1974 (5 U.S.C. § 552a) and the E-Government Act of 2002 (44 U.S.C. § 101).

4. Applicable Regulations and Authorities

- Public law, issuances, and authorities affect the design and content of a form. Service and staff program offices must consider these requirements when working with the Forms Management Program to develop a new or revising an existing form.

- Standard and Optional Forms Management Program (FMR 41 CFR, Chapter 102 Subchapter G, 102-194). Establishes controls for consolidating Federal, departmental, and agency forms similar in type and function into SFs for authorized mandatory use, and OFs for authorized, but not required use.

- Federal Requisition System, Standard and Optional Forms (FPMR (41 CFR) 101-26.302)). Outlines GSA Global Supply requisition procedures for SFs and OFs through GSA Advantage that cannot be stored electronically or within the GSA Forms Library.

- Government Paperwork Elimination Act (Public Law 105-277, 112 Stat 2681). Promotes the use of electronic forms to meet program office data collection needs.

- Paperwork Reduction Act (5 CFR 1320). Outlines maximizing public benefit and practical utility of information collection.

- Privacy Act of 1974, as amended (5 U.S.C. §552a). Assurance of application of the Privacy Act Statement to forms, protecting personally identifiable information (PII) and other types of data deemed sensitive by this act.

- Electronic Signatures in Global and National Commerce Act of 2000 (Public Law 106-229). Outlines signature reviews and security protocols to protect validity of data collection.

- Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. § 794d), as amended by the Workforce Investment Act of 1998 (Public Law 105-220). Ensures persons with disabilities will be able to read and complete the forms.

- 21st Century Integrated Digital Experience Act (Public Law 115-336). Ensures all

forms are available in an electronic format as well as in paper format when electronic forms are not feasible.

- H.R.946 - 111th Congress (2009-2010): Plain Writing Act of 2010 | Congress.gov | Library of Congress. Requires federal agencies to use clear, concise, and well-organized language in public communication, forms, documents, and websites.

- OMB Memorandum M-23-22 Delivering a Digital-First Public Experience. Mandates that agencies ensure their websites, digital services, and forms are accessible, consistent, easy to understand, discoverable, secure, user-centered, customized, and mobile-friendly.

- E-Government Act of 2002 (44 U.S.C. § 101). U.S. statute enacted to enhance the management and promotion of electronic government services through technology.

5. Determining the Need for Forms

Each FDA office shall assess its business requirements to determine whether an electronic form is necessary to support its operational functions. Prior to submitting a request for a new form development, the program office must conduct a thorough review of the FDA Forms Library to verify that no existing form can fulfill the identified requirement. This preliminary research ensures efficient resource utilization and promotes standardization across the agency by leveraging established forms whenever feasible.

The FDA Forms program is limited to the development of standard forms that do not require complex or dynamic logic. Forms requiring advanced functionality, including complex business rules or interactive behavior, must not be developed within this program. Offices requiring such capabilities must use alternative approved solutions that support these requirements.

To maintain compliance with OMB Memorandum M-23-22 Delivering a Digital-First Public Experience, all FDA forms will be developed in an electronic format as the primary method of delivery. This digital-first approach ensures accessibility, efficiency, and alignment with federal standards for public-facing services. However, it is recognized that certain limited types of forms must still be made available in printed format to accommodate specific needs. In these cases, the responsible program office should work with the FDA Forms Management Officer (FMO) to determine the appropriate format and distribution method while maintaining the digital version as the standard.

6. Privacy Act

All forms that collect information about individuals (aka personally identifiable information (PII)) must be reviewed to ensure compliance with the Privacy Act of 1974 (5 U.S.C. § 552a) and the E-Government Act of 2002 (44 U.S.C. § 101). This review is mandatory before any form is approved for use and when existing forms are revised. Specific privacy compliance actions may be required. For example, forms collecting information about individuals may be required to display additional content such as a "Privacy Act Statement." Such collections may also require separate actions such as the completion of a Privacy Impact Assessment (PIA) or the development and publication in the Federal Register of a System of Records Notice (SORN). The originating office for the form is responsible to submit new forms and substantive revisions to existing forms to the FDA Privacy Office for review prior to implementation.

Programs responsible for developing or managing forms and collections must understand whether their collection is subject to Privacy Act requirements and their specific obligations under the Act. Failure to comply with Privacy Act requirements may result in civil liability for the agency and potential criminal penalties for willful violations.

7. Form Compliance with Section 508

All FDA forms must comply with Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. § 794d), as amended by the Workforce Investment Act of 1998 (Public Law 105-220), which requires federal agencies to make their information communication technology (ICT) accessible to people with disabilities. This legal requirement ensures that individuals with visual, auditory, physical, or cognitive disabilities can access, use, and interact with FDA forms effectively. The U.S. Access Board, an independent federal agency, develops and maintains accessibility standards and guidelines under Section 508, including the Revised 508 Standards that incorporate the Web Content Accessibility Guidelines (WCAG) as the technical standard for web content and electronic documents. Failure to comply with Section 508 may result in forms being rejected, legal liability, and barriers that prevent members of the public and FDA employees with disabilities from participating fully in agency programs and services.

8. Form Numbers

The FMO provides form numbers through a standardized process designed to ensure consistent identification, tracking, and management of FDA forms across the agency. When a form sponsor requires a new form number, they submit a request directly to the FMO through email. While this is usually handled during

the initiation process of a new form there are times that an originating office will create their own form, or a form is tied to an application.

The FMO will review the request to verify it meets FDA form requirements, confirms that a familiar form does not already exist in the agency's inventory, and ensures alignment with agency policies and regulatory requirements.

Upon approval, the FMO assigns a unique FDA form number following the agency's established numbering convention, records it in the central forms inventory database, and ensures no duplication while maintaining sequential integrity of the numbering system. This number is associated to that specific form throughout the form's lifecycle.

9. Creating and Revising Forms

All requests for new FDA forms or revisions must be submitted to the FMO for action once the requesting office has obtained clearance from Paperwork Reduction Act (PRA) and if necessary, the Privacy Office. It is the responsibility of the requesting office to coordinate this approval with PRA and the Privacy Office prior to contacting the FMO.

Development of a new or revised form is a multi-step process that begins with approval of a non-fillable draft developed by the originating office, then followed by approval of an electronic fillable 508 compliant form.

To initiate the creation of a new form or revisions to an existing form, printed or electronic, the requesting office is to contact the FMO and provide the following information:

- Form Title – official name of the form
- Contact Information – name, building/location, and phone number for the person responsible for the form
- Brief Description – purpose and use of the form
- Electronic Version - draft of form (if available)
- Confirmation of Clearance – documentation that the form has been cleared by the PRA Officer and the Privacy office

A. Originating office submits a draft of the new or revised data to be collected to the FMO, along with any prescribing directive, written instructions, OMB Notice of Action, (approval notice); and/or concurrence of the FDA Privacy official, along

with the responses to the new or revised form request questions.

B. For new forms the FMO will review the request to verify it meets FDA form requirements, confirms that a familiar form does not already exist in the agency's inventory, and ensures alignment with agency policies and regulatory requirements.

C. FMO will apply an official form number for new forms.

D. FMO will record in the central forms database the new form or revision request.

E. Form development will commence based on who will be creating or revising the form;

1. FMO will work with the originating office and Program Support Center (PSC) as needed till the form has been finalized.

2. Originating office will develop the form and work with the FMO for finalization.

F. At the request of the originating office the FMO will post the finalized form to the appropriate website based.

10. Printed Forms

While OMB Memorandum M-23-22 Delivering a Digital-First Public Experience mandates that all FDA forms be developed in an electronic format as the method of delivery. It is recognized that certain limited types of forms must still be made available in printed format to accommodate specific needs.

Printed forms should be considered only in exceptional circumstances where electronic submission is not feasible or practical. The decision to provide a printed version must be carefully evaluated and justified based on genuine need rather than convenience or preference.

In cases where printed formats are deemed necessary, the responsible program office must work closely with the FMO to determine the appropriate format, production specifications, and distribution method. All printed forms must maintain consistency with their digital counterparts in terms of content, layout, and OMB control numbers. A digital version of the printed form must also be retained.

A. Originating office submits a draft of the proposed data to be collected to the FMO, along with any prescribing directive, written instructions, OMB Notice of Action, (approval notice); and/or concurrence of the FDA Privacy official, and the

responses to the new form request questions.

B. FMO will work with the originating office and Program Support Center (PSC) as needed till the form has been finalized.

C. After approval of the final copy, the originator will prepare a HHS-26 “Printing and Visual Services” for printing of the form(s) at the General Printing Office (GPO). Determining the number of forms to be printed may require the coordination of the FMO and personal from the HHS warehouse. Factors used to determine the printing amount is based on if the form will be used agency-wide or requested by the public.

D. Forms that are determined to be printed by the originating office are printed through the PSC Mail and Publishing Services, Program Support Center (customerservice@sscmail.psc.gov).

    1. When distributing a form(s) by mail follow Staff Manual Guide 2250.4 Selection of U.S. Postal Service Mail Classes and Services.

    2. Instructions for mailing and disposal of the printed material are included on the form and when appropriate a distribution list and/or mailing labels are attached.

11. Ordering Printed Forms

FDA forms can be ordered through the Forms Management Program by submitting a request to the FMO. Forms will be mailed at no charge, except for a rush delivery. For rush deliveries the requester is responsible to pay for the extra delivery fee by providing their U.S. Postal Service (UPS) account number. Otherwise, forms are delivered by regular delivery by the UPS which is free.

To submit a form request, download and fill out the Requesting warehouse forms FDA-4005 form. Then send the request to the FDA Forms Manager by email. Include the following information in addition to your request form, FDA-4005, with your request:

- FDA Form Number of the item you are requesting
- Quantity of the form in exact number
- Contact name, email, and phone number
- Full mailing address for shipping
- UPS shipping account number for any expedited requests

12. Reprinting of Forms

When existing FDA forms require reprinting due to inventory depletion or updates to form content, the FMO coordinates the reporting process to ensure continuity of operations.

1. FDA forms are centrally stocked at PSC's warehouse. When a form has reached a reorder point PSC will reach out to the FMO and/or the originating office. Based on usage statistics and type of form PSC will provide a recommended reorder quantity.

    a. When the form has reached a reorder point the originator will complete a Request for Publishing Services (HHS-26) and provide to the FMO who will then provide to PSC for the reorder.

2. Quarterly the FMO will check the number of printed forms stored at PSC.

13. Periodic Form Review and Assessment

The FMO conducts a comprehensive, biannual review of all FDA forms to assess their status and ongoing business need. This review verifies that designated points of contact are accurate and up-to-date, identifies and retires obsolete or duplicative forms, and ensures that all forms hosted on FDA platforms remain current, compliant, and operationally effective.

14. Transfer of Form Responsibility

If ownership of an FDA form transfers from one program office to another then the losing and gaining offices must perform the following:

1. Losing office notifies the FMO within five days of the transfer and provides the new POC and gaining office information.

2. Gaining office ensures there is a continuing need for the transferred form.

3. FMO will update the form record in the central forms database and if needed on any sites.

15. Expiring Forms

To expire an existing FDA form the responsible program office or form POC submits an email to the FMO at FormsManager@OC.FDA.GOV providing the timeline of

when the form will expire.

Upon receiving the request, the FMO will update the forms record in the central forms database, remove the form from the FDA platform(s), and ensure the expired form follows the appropriate records retention schedule (FDA-9141a).

16. Design Guidelines for FDA Forms

The effectiveness of a form in capturing data and distributing information is dependent on the design of the form. Forms must be easy to fill in, have a functional layout and a logical sequence to the information they collect.

To help design forms, the guidelines provided in Public Law 111-274 have been adopted for Federal forms design and analysis. Exceptions may be granted when a special requirement of the functional use of the form precludes the use of these standards.

A. Form Size

- If printed, forms must be designed to 8.5 X 11 inches.
- Postcard forms must measure a minimum of 3.5 X 5 inches and a maximum of 4 ¼ X 6 inches.

B. Form Boarders and Margins

- With the exception of certificates, tags, and labels the entire body of the form must not have lined border.

C. Form Font Styles

Form Part	**Font Size***	**Letter Casing**
Form Title	10 point	UPPERCASE
OMB Statement	8 point	Sentence case
Form Number and Edition Date	10 point bold	UPPERCASE
* Arial or Helvetica for sans serif, and Times New Roman for serif, both are acceptable for 508 The font size is 9pt for body, 8pt for field heads Font size can increase or decrease by a point or two, which must be determined duri ng the design process		

D. Form Layout

- Forms must be designed in box style with fillable fields.
- Layout and number items are to be in sequential order of fill-in.
- Group common items together on the form. Use sections.
  If data elements pertain to the same area, individual, etc. use a section.

E. Form Instructions

Placement of instructions should be consistent throughout the entire form.

- Preferred placement of instructions is on the first page.
- If the instructions are lengthy, they can be divided into columns and placed where applicable or when justified, they can be issued on a separate page.
- Instructions should be limited in length and should only provide guidance on the completion of the form.

F. Abbreviations and Acronyms

Spell out abbreviations and acronyms the first time they are used, followed by the abbreviation or acronym in parentheses. After the first use, use only the abbreviation or acronym. Exceptions may be made for commonly used or widely known abbreviations.

G. Using Illustrations or Graphics on a Form

Illustrations or graphics may be used only if it serves a functional purpose.

H. Form Font Styles

Arial or Helvetica for sans serif fonts and Times New Roman for serif fonts are used for FDA forms. Both options are acceptable for Section 508 compliance. Font size may be adjusted by one to two points as determined during the design process.

Font sizes: Body text: 9 pt
Field headings: 8 pt

17. Effective Date

The effective date of this guide is May 20, 2026.

18. Document History - SMG 3295.1, Forms Management Policy

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	06/08/2007	N/a	Elizabeth Sands, OCIO/PRRMS	Ginger Leo, Deputy Chief Information Officer, OCIO
Change	10/08/2008	Section Heading 5.A.5; Section Heading 8.A	Elizabeth Sands, OIM/ DBPS/IIB/WMAT	Elizabeth Sands, FDA Forms Management Officer, OIM
Change	03/10/2011	Sect. Hd 3.C.; Sect. Hd. 5.A.6.	Elizabeth Sands, OIM/DBPS/IIB/WMAT	Elizabeth Sands, FDA Forms Management Officer, OIM
Revision	03/22/2019	N/a	Forms Mgmt Off OIMT/DBPS/IIB/WST	Forms Mgmt Off OIMT/DBPS/IIB/WST
Change	5/11/2023	Change Freedom of Information to Privacy Office	Forms Mgmt Off OIMT/DBPS/IIB/WST	Forms Mgmt Off OIMT/DBPS/IIB/WST
Revision	05/19/2026	N/A	Forms Mgmt Off OIMT/DBPS/IIB/WST	Joshua Lehman, Director ODT/OIMT/OBCA/DBPS