SMG 3295.1

FDA Staff Manual Guides, Volume III - General Administration

Information Resources Management - Forms Management

Forms Management Policy

Effective Date: 03/22/2019
Changed: 05/23/2023

1. Purpose
2. Policy
3. Definitions
4. Responsibilities
5. Determining Need and Requirements for New/Revised Forms
6. Printed Forms
7. Electronic Forms
8. Periodic Review of Forms
9. Deletion of Obsolete Forms
10. References
11. Effective Date
12. History

1. Purpose

This Guide outlines the FDA Forms Management Program and establishes Agency policy and procedures for developing and/or ordering new, revised, and reprinted forms. It supplements and is to be used in conjunction with the Department of Health and Human Services (HHS) Forms Management Program.

2. Policy

The Food and Drug Administration (FDA) will use the uniform system prescribed in this Guide for creating, publishing, and managing forms.

A. The FDA Forms Management Program will:

1. Ensure the forms created within the Agency are in compliance with applicable provisions of the Paperwork Reduction Act (PRA), the Privacy Act of 1974 (Privacy Act), Section 508 of the Rehabilitation Act, and, are kept up to date;

2. Provide effective control, uniform procedures, and standards across the Agency for the creation, production, and use of both public and internal forms;

3. Ensure forms that are generated; either paper or an electronic form, are developed and designed for maximum efficiency in handling and processing data. For example, by making one simple form with well thought out fields that collect the maximum amount of information without an excessive amount of input or effort on the part of the user;

4. Eliminate unnecessary and duplicate forms across Center/Office lines and across Department lines by working with the HHS Forms Manager, and consolidate forms serving processes that all of FDA/HHS uses;

6. Support compliance and risk management activities by requiring originating offices to obtain subject matter expert (SME) advice and approvals (e.g., information security, PRA, and ensure that the Privacy Act requirements for information collections are met) for all forms;

7. Reduce the cost of forms by using the most economical methods of printing and distribution consistent with Government Printing Office (GPO) use requirements and restrictions on printing by federal agencies found in SMG h:2205.1, and promote the use of electronic forms to avoid printing, storage, and shipping costs;

8. Ensure forms do not unnecessarily request or request without legal authority the solicitation of Social Security numbers (SSNs) and where approved, that they collect only personally identifiable information (PII) that is directly relevant and necessary to accomplish the specified purposes; and

9. Ensure forms display appropriate Privacy Act Statements when collecting PII that is subject to the Privacy Act.

B. The FDA Forms Management Officer (FMO) will use workflow analysis, graphic design techniques and standardization to create or revise forms in order that:

1. Forms are easy to complete, and the instructions are clear;

2. Layout of the form is well planned, allows adequate space, and limits errors;

3. Productivity is increased in preparation, use, filing and retrieval;

4. Errors are minimized in information capture, transmission and recovery;

5. Total number of forms within the system is minimized;

6. Data element relationships are apparent through consistency and adherence to standards;

7. Effectiveness of the entire system, as well as the individual form, is enhanced;

8. Forms display required Privacy Act Statements, when applicable;

9. Information solicited on a form is limited to that which is both necessary and authorized;

10. Procurement, storage, distribution, and use costs are reduced; and

11. Resulting business tool accomplishes its intended purpose.

3. Definitions

A. Form - A fixed arrangement of captioned spaces designed for entering and extracting prescribed information. Forms may be preprinted paper forms or electronic forms.

B. FDA Forms - The prefix, FDA, identifies the Agency's forms for both Headquarters and Field activities. These forms are assigned sequential numbers which are used as specific identification and as a means of stocking, ordering, and general control.

C. Electronic Forms – Is a prescribed set of fields for collecting data that can be integrated, managed, processed, or transmitted through an information technology system.

4. Responsibilities

A. FDA Forms Management Officer (FMO), Office of the Chief Information Officer

1. Reviews and approves/disapproves all FDA forms requests;

2. Provides overall direction, guidance, and technical assistance to the Forms Management Program throughout the FDA and carries out responsibilities as assigned in the HHS Forms Management Manual;

3. Consults with management officials and assists in the development of forms in support of specific programs, and coordinates with related management programs;

4. Initiates periodic review of forms for current need, possible improvements, or consolidation while ensuring that information necessary for all the interested Centers/Offices is included in any consolidated form. FMO also ensures that electronic forms are 508 compliant;

5. Issues the FDA forms web pages on both the Internet (public forms) https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm and Intranet (all FDA forms) http://inside.fda.gov/Administrative/Forms/FDA/index.htm;

6. Ensure forms that are processed through the FDA Forms Program are compliant with Section 508 and meet the Plain Language in Government Writing initiative;

7. Maintains records of all Agency forms as well as documentation of forms histories;

8. Serves as the primary liaison for FDA to PSC for the development of fillable PDF forms.

B. Printing Management Officer, Office of Acquisitions and Grants Services (OAGS); SMG h: 2205.1, "Printing Procurement (Headquarters)".

1. Provides technical direction for the conduct of a coordinated program controlling the development of materials to be printed or duplicated;

2. Assures the procurement and production of printed matter for FDA Headquarters activities through the Program Support Center (PSC), Publication Technologies Branch, GPO, other Government agencies, and outside contractors;

3. Ensures that the most economical and efficient printing process and class of mail for each request is utilized. (For assistance in determining the most appropriate class of mail service, please refer to SMG 2250.4, "Selection of U.S. Postal Service Mail Classes and Services");

4. Reviews and approves requests for printing procured from commercial sources on Form HHS-393, "Purchase/Service/Stock Requisition" and for obtaining waivers from GPO for requests over $1,000 (Refer to SMG 2205.3, "Contractor Supplemental Mailings");

5. Collects and compiles all required reports relating to the Agency's Printing Management Program.

C. All Offices; when requesting the development of new or the revision of existing forms, offices are responsible for:

1. Initiating timely requests for forms for the FMO to coordinate work schedules with PSC and, if a public-use form, to gain approval from OMB. (Prior to date of finalization, external forms typically require one month for design and approval of proof and several months for OMB clearance);

2. Coordinating proposed forms with other centers by requesting the FMO's assistance in determining whether there are other offices that may be interested in the form, and in helping to resolve issues that may come up in the coordination effort;

3. Developing and issuing adequate instructions for use of forms;

4. Coordinating proposed forms and procedures with other interested organizations prior to final development and printing;

5. Coordinating with the FDA Privacy Office (for internal use and public use forms), their Center Disclosure Officers and/or the central Division of Freedom of Information, and (if a public use form) the Paperwork Reduction Act Team, to timely meet all legal and other compliance requirements in these areas; and

6. Advising the FMO when a form needs to be reprinted or when a form becomes obsolete.

5. Determining Need and Requirements for New/Revised Forms

Each FDA office will determine the need for both hard copy and electronic forms required in that organization's area of functional responsibility. A form can be an effective management tool but care must be exercised to ensure that the costs and staff time expended are commensurate with the benefits received. The originator should look beyond the development, printing, and supplies costs and consider the more important costs of:

A. Collecting information solicited by the form;

B. Completing the form;

C. Analyzing and processing the data collected; and

D. Utilizing the data.

The originator will coordinate with other interested organizations regarding a proposed form and procedure for its use prior to submitting a request to the FMO for development of their form. The originator may ask the FMO to assist in determining whether there are other offices that may be interested in the proposed form, for example through the FMO's center/office contacts, to partner in the developing the form. The FMO will assist in the review and development of the form draft and give final approval. The originator will decide when to make revisions to the form, when to make the form obsolete, and when the use of old editions of forms is allowed.

6. Printed Forms

All requests for new and revised FDA forms must be submitted to the FMO for action by sending an electronic version of the form to: formsmanager@oc.fda.gov. Submit a completed draft of the form and include the contact person of the form to the FMO. Requests for a form action must be submitted as early as possible for external forms. Issuing forms on an emergency basis often results in forms that have not been properly developed and coordinated. A forms action requires one month for design and approval of proof. The FDA Privacy Office may need several months to review and assess the privacy impact and identify applicable laws and requirements bearing on form content and agency use of information gathered via forms. Offices must engage the Privacy Office in the very early stages of the form conception and development process, to avoid any delay in the use of the form and collected information, including the OMB PRA submission.

All forms actions are reviewed by the FMO for duplication of existing forms and information systems, effectiveness, and economy from the standpoint of good forms management.

Responsibility for developing new or revised forms is shared by the originating office and the FMO. The FMO decides the final version of a form.

Originating offices should:

A. Create a draft of the proposed form or data to be collected.

B. Provide a contact person for the form.

C. Include a copy (or draft) of the prescribing directive, e.g., staff manual guide, memorandum, etc, with every request for an FDA form. This allows the forms analyst to design and construct the form per the objective of the directive, reduce the change of errors, and subsequent changes and/or corrections.

D. When appropriate, written instructions should be developed for FDA forms. These instructions should accompany the proposed form.

E. FDA is responsible for complying with the provisions of the Privacy Act for FDA forms (public-use and other) that are used to collect information which is retained in a “Privacy Act system of records”. To determine whether the form is subject to review under the Privacy Act, consult the FDA’s Senior Official for Privacy at FDAPrivacyOffice@fda.hhs.gov. The FDA Privacy Office may need several months to review and assess the privacy impact. It is difficult to predict a timeline as it will vary case-by-case and originating offices are strongly encouraged to involve agency Privacy experts very early in the form development process. This is essential to avoid any delay for the OMB PRA submission (if required) and the implementation of a privacy-compliant form.

F. Forms that collect information from the public, i.e., individuals, businesses, States, etc., are called public-use report forms and require OMB approval as prescribed by the PRA. These forms must be submitted to the center PRA representatives and the FDA PRA Staff for clearance and submission to OMB for approval before the form can be reproduced. Allow several months for this review and clearance process to be completed. The OMB number, expiration date, and the public protection provision should be displayed on the front page of the form.

G. Submit a draft of the proposed form or 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 Senior Official for Privacy, FDA Privacy Office.

H. The FMO will forward a final electronic copy of the form to the originator for approval.

I. After approval of the final copy, the originator will prepare a HHS-26, "Printing and Visual Services" for printing the form(s) at GPO. Determining the number of forms to be printed may require the coordination of the FMO and the warehouse at Dept. of Health & Human Services, 4 Center Drive, North East, MD,21901 or customerservice@sscmail.psc.gov, if the form is one that is used agency-wide or requested by the public.

J. Forms that are determined to be printed by the originating office, are printed through the Printing, Distribution, and Stocking Office; pscpublishing@psc.hhs.gov.

- When distributing a form(s) by mail, follow Staff Manual Guide: 2250.3 Contractor Supplemental Mailings, 2250.4 Selection of U.S. Postal Service Mail Classes and Services, and/or 2250.5 Format for Printing FDA Return Address (formerly 2420.11). Contact FDA's Mail Manager for further assistance

- 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.

- The PSC Personal Property Facility will establish a reorder point for stocked forms and notify the FMO when replenishment is required. When the originator stocks FDA forms, that Center/Office will be responsible for initiating appropriate and timely reprint or revision action.

K. Reprinting Forms.

1. FDA Forms Stocked Centrally. The PSC Personal Property Facility warehouse will inform the FMO when a form has reached a reorder point. Based on usage statistics and type of form, the PSC Personal Property Facility will recommend a reorder quantity. The FMO will periodically check on the status of the form and will request the originator to prepare a form HHS-26. The originator must email the FMO at: FormsManager@OC.FDA.GOV, if a delay in the submission of the printing request is anticipated.

2. FDA Forms Stocked by Originator. When the form has reached a reorder point, the originator will forward a Form HHS-26, "Printing and Visual Servicers" electronically to: FormsManager@OC.FDA.GOV.

L. Forms Ordering Procedures.

1. Order forms from the Internet using form FDA 4005 that can be found at, "Public Use Forms and How to Obtain them" web page, and the Intranet FDA Electronic Forms Catalog.

Some forms are stocked by the originating office, which may be contacted by the name and phone number listed in the electronic catalog on the FDA forms web pages.

2. PSC Forms Download Site provides a list of HHS forms and forms used by other DHHS agencies that may be downloaded. http://intranet.hhs.gov/forms/

3. Electronic forms designed by the FMO are posted on the web site when they are approved by the originating office and by OMB. Responsibility for making forms available on the web is shared by the originating office and the FMO. Originating offices have their own updating procedure for internal forms posted to the web.

4. Copies of all obsolete FDA forms are retained by the FMO for five years after the form is determined to be obsolete by the originating office. Copies of these editions are available on request.

7. Electronic Forms

All requests for new and revised FDA forms must be submitted to the FMO for action by sending an electronic version. Submit a completed draft of the form and a contact person to the FMO at: FormsManager@OC.FDA.GOV. Requests for a form action must be submitted as early as possible for external forms. Issuing forms on an emergency basis often results in forms that have not been properly developed and coordinated. A forms action requires one month for design and approval of proof. The FDA Privacy Office may need several months to review and assess the privacy impact and identify applicable laws and requirements bearing on form content and agency use of information gathered via forms. Offices must engage the Privacy

Office in the very early stages of the form conception and development process, to avoid any delay in the use of the form and collected information, including the OMB PRA submission.

All forms actions are reviewed by the FMO for duplication of existing forms and information systems, effectiveness, and economy from the standpoint of good forms management.

Responsibility for developing new or revised forms is shared by the originating office and the FMO. The FMO decides the final version of a form.

The FMO working with the originating office will determine if the form should be electronic and if so, what format it should take. The originating office makes the final decision whether a form will be paper, electronic, or both.

The Forms website is maintained by the FMO. The Forms Website is the official place for all electronic forms. All revisions are updated on the web by the FMO. Any versions on center/office web sites that do not link to the FMO's web site should be updated by the originating office to reflect the same changes that are in the official version.

The following steps must be followed to initiate the development of new or revision of existing electronic forms; or the creation of electronic forms from existing printed forms.

A. Contact the FMO for directions on making the electronic form accessible in compliance with Section 508 of the Rehabilitation Act. In 1998, Congress amended the Rehabilitation Act to require Federal agencies to make their electronic and information technology accessible to people with disabilities. Inaccessible technology interferes with an individual's ability to obtain and use information quickly and easily. Section 508 was enacted to eliminate barriers in information technology, to make available new opportunities for people with disabilities, and to encourage development of technologies that will help achieve these goals. The law applies to all Federal agencies when they develop, procure, maintain, or use electronic and information technology. Under Section 508 (29 U.S.C. 794d), agencies must give disabled employees and members of the public access to information that is comparable to the access available to others (see also Agency Policies on Section 508).

B. Create a draft of the proposed form or data to be collected, in hardcopy or electronically.

C. Provide a contact person for the form.

D. Include a copy (or draft) of the prescribing directive, e.g., staff manual guide, memorandum, etc., with every request for a FDA form. This allows the forms

analyst to design and construct the form per the objectives of the directive, and reduce the chance of errors, and consequent later changes and/or corrections.

E. If appropriate, written instructions should be developed for FDA forms used in more than one office within the Agency. These instructions should accompany the proposed form.

F. FDA is responsible for complying with the provisions of the Privacy Act for FDA forms (public-use and other) that are used to collect information which is retained in a "Privacy Act system of records." To determine whether the form is subject to review under the Privacy Act, consult the FDA's Senior Official for Privacy at FDAPrivacyOffice@fda.hhs.gov. The FDA Privacy Office may need several months to review and assess the privacy impact. It is difficult to predict a timeline as it will vary case-by-case and originating offices are strongly encouraged to involve agency Privacy experts very early in the form development process. This is essential to avoid any delay for the OMB PRA submission (if required) and the implementation of a privacy-compliant form.

G. Public-Use Report Forms. Forms that collect information from the public, i.e., individuals, businesses, States, etc., are called public-use report forms and require OMB approval as prescribed by the PRA. These forms must be submitted to the Center PRA representatives and FDA PRA Analysts for clearance and submission to OMB for approval before the form can be made available electronically. Allow several months for this review and clearance process to be completed. The OMB number, expiration date, and the public protection provision should be displayed in the instructions, near the title of the electronic collection instrument or on the first screen viewed by the respondent for online applications.

H. Database forms. Equipment on which the form is processed should be listed, along with the software used and the structure of the database for review by the forms designer and/or systems analyst for compatibility.

I. Creating electronic forms from existing printed forms. Keeping the same information to be collected is vital.

J. Submit the draft of the proposed form or data to be collected, or electronic form to the FMO, along with any prescribing Directive, written instructions, OMB Notice of Action (approval notice); and/or concurrence of the FDA's Senior Official for Privacy.

K. The FMO will coordinate the design of the form and return an electronic version of the form for approval to the originating office

L. The originating office may send approval of the form to the FMO. The FMO will post the form to the FDA Forms Internet and Intranet site if it is a public form or to the FDA Forms Intranet site if it is an internal form.

8. Periodic Review of Forms

The FMO will periodically conduct a review of the status and continued need for forms used in FDA, both printed and electronic, to clear out space being taken up to store unneeded forms and to update the FDA Internet "Public Use Forms and How to Obtain them" web page and the FDA Intranet Electronic Forms Catalog.

9. Deletion of Obsolete Forms

To delete obsolete forms, the originating office should submit an email to: FormsManager@OC.FDA.GOV. The FMO will coordinate the deletion of the obsolete form with PSC and update files as necessary to ensure forms are maintained based on the records schedule.

10. References

A. Government Paperwork Elimination Act "Procedures and Guidance." http://inside.fda.gov:9003/PolicyProcedures/PaperworkReductionAct/GeneralInformation/default.htm

B. GSA Information Resources Management Technical Guide - Electronic Forms Systems Analysis and Design. Order or download for a fee from National Technical Information Service at (800) 553-6847. Order Number PB95250239.

C. HHS Forms Management

D. OMB Memorandum M-17-12 (Preparing for and Responding to a Breach of Personally Identifiable Information (January 3, 2017) https://obamawhitehouse.archives.gov/sites/default/files/omb/memoranda/2017/m-17-12_0.pdf.

E. Plain Language in Government Writing Initiative, http://inside.fda.gov:9003/ProgramsInitiatives/Communications/PlainLanguage/default.htm

F. The Privacy Act of 1974 (5 U.S.C. 552a), and related OMB Circular A-108, Federal Agency Responsibilities for Review, Reporting and Publication under the Privacy Act) FDA regulations (21 CFR 21)https://fda.sharepoint.com/sites/oc-intranet-oc-oo-oems-dig-privacy , and FDA Staff Manual Guides http://inside.fda.gov:9003/AboutFDA/FreedomofInformation/Privacy/ucm464520.htm.

G. The E-Government Act of 2002 and related OMB Circular A-130, Managing Information as a Strategic Resource (Appendix II)(2016).

https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/OMB/circulars/a130/a130revised.pdf

H. Section 508 http://www.section508.gov/

J. Staff Manual Guide h:2205.1, "Printing Procurement (Headquarters)"

K. Staff Manual Guide 2250.3, "Contractor Supplemental Mailings"

L. Staff Manual Guide 2250.4, "Selection of U.S. Postal Service Mail Classes and Services"

M. Staff Manual Guide 2250.5, "Format for Printing FDA Return Address" (formerly 2420.11)

N. Staff Manual Guide 3130.3, "Electronic and Information Technology Accessibility for Individuals with Disabilities Under Section 508 of the Rehabilitation Act Amendments of 1998"

O. Staff Manual Guide 3270.1 “Obtaining OMB Clearance for Collections of Information as Required by the Paperwork Reductions Act (PRA) of 1995”

P. Staff Manual Guide 3297.4. Implementation of the Privacy Act and the FDA Privacy Program: Overview, and 3297.7 and 3297.8 regarding Privacy Act Requests and Privacy Act System of Records Notices

11. Effective Date

The effective date of this guide is March 22, 2019.

12. 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