PROCEDURES

OFFICE OF STRATEGIC PROGRAMS

CDER Electronic Application Forms Oversight

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PURPOSE

This MAPP describes procedures for oversight of CDER's electronic application forms. This MAPP is in alignment with the FDA Staff Manual Guide (SMG) 3295.1, FDA Forms Management.

BACKGROUND

The Office of Management and Budget (OMB), in accordance with the Paperwork Reduction Act (PRA), approved CDER to collect specific mission-critical information as outlined in the Code of Federal Regulations (CFR). Application forms, such as the Investigational New Drug (IND) 1571 and the New Drug Application (NDA) 356h were developed to facilitate the application review process. Over time, many paper-based forms have been converted to 508 compliant Adobe fillable Portable Document Format (PDF) forms with electronic signature capability. The CDER Electronic Document Room (EDR) extracts data from the forms. The data is stored in one of several internal FDA information technology (IT) systems. The collection of information is reapproved by OMB every third year.

In 2008, CDER established the FDA forms workgroup to define and oversee the steps necessary for the development of new electronic forms, and to review and update existing application forms. CDER's forms are reviewed regularly as required by the OMB review schedule.

RESPONSIBILITIES

Director, OBI

- Appoints FDA Forms Workgroup Manager.

CDER Office of Business Informatics

- Provides core membership, project management and coordination for the FDA forms workgroup.
- Ensures the content of the applicable forms posted on the intranet is accurate.
- Provides maintenance to email accounts, and collaboration and content management support tools
- Provides informatics expertise for CDER IT applications.
- Provides support for the document room processes, for both paper and electronic drug applications.

FDA Forms Workgroup Manager

- Manages facilitation of the FDA Forms Workgroup.
- Manages the OMB renewal schedule for all forms covered by this MAPP.
- Manages CDER's collaboration and information sharing efforts, and documentation working spaces, such as eRoom, eDocumentum, and SharePoint.
- Manages the CDEROBIFormsWorkGroup@fda.hhs.gov email account reviewing and responding to email inquiries**.**
- Updates this MAPP as necessary.

FDA Forms Workgroup

- Analyzes form change requests to ascertain what additional subject matter experts (SMEs), are required for review and approval of changes requested for each form.
- Facilitates and coordinates the FDA Forms Workgroup meetings, biweekly or as needed.
- Reviews and manages OMB's renewal schedule. Initiates form reviews with appropriate CDER and other Center Staff one year prior to each form's expiration.
- Issues formal change requests. Maintains change request log for coordination.
- Reviews and tests all changes requested with the Program Support Center (PSC).
- Tests the final updated forms within the appropriate electronic document rooms.

FDA Forms Manager

- Works with the CDER FDA Forms Workgroup.
- Ensures change requests and forms reviews are in alignment with the PSC, the PRA Office, and the Office of Freedom Information (FOI).
- Ensures all FDA Forms are 508 compliant.
- Assigns form number to all new forms.
- Ensures new and recently revised forms are appropriately posted.
- Coordinates with PRA Specialists and Assistant Reports Clearance Officers (ARCO).
- Coordinates final posting of all cleared forms to the FDA Intranet, and to FDA.gov.

Paperwork Reduction Act (PRA) Specialist:

- Maintain records and inventories of the Agency's clearance activities.
- Reviews and provides technical support and guidance to Agency program organizations on PRA issues. Assures all proposed rules and regulations meet standards for approval by OMB.
- Reviews 60-day Federal Register (FR) notices.
- Prepares 30-day FR notices.
- Prepares FR notices of approval.
- Serves as focal point to coordinate with FDA centers and offices.
- Serves as the FDA's liaison with Division of Health and Human Services (DHHS) and OMB.

Assistant Reports Clearance Officer:

- Liaisons between PRA specialists and CDER program personnel.
- Reviews and alerts PRA specialists of final rules, surveys and guidances.
- Manages the Center's information collection inventory.
- Ensures the complete preparation of 60-day FR Notices.
- Ensures final forms are accurate and complete prior to submission.
- Manages the development of the annual Information Collection Budget (ICB) activities.

Program Support Center (PSC):

- Develops or modifies FDA forms in accordance with the formal FDA forms change request.
- Provides resources and members to the FDA forms workgroup.
- Liaisons between FDA forms workgroup and contractors performing the requested changes.
- Ensures FDA forms are in compliance with section 508 of the Americans with Disability Act (ADA).
- Ensures FDA forms satisfy all compliance and functionality requirements.

PROCEDURES

1. Requests for development of new forms or changes to existing forms may originate from:
   - 3-year OMB Renewal Cycle
   - Congressional Mandates
   - FDA Center personnel
   - Industry requests for changes
   - Corrections, due to functionality issues.
   - Other sources, within CDER.

All requests for development of new application forms or changes to existing application forms must be submitted to the CDEROBIFormsWorkGroup@fda.hhs.gov for review, approval, and processing.

The following types of forms requests require OMB review and approval:

- All new forms requesting public information.
- All updates that include the collection of information not previously approved by OMB.
- Any form requesting public information that has not been reviewed by OMB in the past three years.

2. The FDA forms workgroup meets as necessary to:
   - Initiates review of each form, beginning one year prior to the current OMB expiration date.
   - Reviews each change request received from internal or external sources to:
     1. Identify and invite business and IT SMEs required to participate in the review.
     2. Identify all effected IT systems. Evaluate if impacted systems will require additional code programming.
     3. Review the requested changes; develop mockup of new or edited form. Create a forms change request log.
     4. Clear requested changes or new information collection through the PRA staff.
     5. Review and test new or updated forms to ensure accuracy, 508 compliance and functionality for electronic submission.
     6. Clear forms for Intranet posting, and for public use.

Once final approval is obtained, the Forms Workgroup Manager will submit the final approved form to the FDA Forms Manager for posting to the Inside FDA Intranet and to the FDA.gov internet site.

REFERENCES

1. FDA, 2011. Staff Manual Guide 3295.1, FDA Forms Management.
2. OMB, 2010. Paperwork Reduction Act.
3. DOJ, 2005. Freedom of Information Act, revised.
4. DOJ, 2009. Americans with Disabilities Act (ADA), Section 508, revised.
5. U.S. Code of Federal Regulations (CFR), Title 21, Chapter 300.
6. U.S. Code of Federal Regulations (CFR), Title 42, Chapter 282.

DEFINITIONS

Information Technology (IT): Referring to the development, maintenance, and support of computer and network systems.

FDA Forms Workgroup: The FDA Forms Workgroup is made up of a team coordinated and managed by the Office of Strategic Programs (OSP), Office of Business Informatics (OBI), Division of Data Management Services and Solutions (DDMSS) with members from CDER's Electronic and Paper Document Rooms, the FDA forms manager and the Program Support Center designee. The forms workgroup is supplemented by subject matter experts (SMEs) within CDER, and from other FDA Centers, as required, when forms are used across Centers. Necessary updates are made during the three-year review cycle, or as necessary, to keep abreast of regulatory changes.

The FDA Forms Workgroup Manager can be reached at CDEROBIFormsWorkGroup@fda.hhs.gov.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
10/02/13	Initial	n/a

ATTACHMENT 1: Forms Process Flow Chart