POLICY AND PROCEDURES

OFFICE OF MANAGEMENT

Developing and Issuing MAPPs for CDER

Table of Contents

PURPOSE

This Manual of Policies and Procedures (MAPP) establishes a system for issuing directives (i.e., MAPPs) in the Center for Drug Evaluation and Research (CDER) for the purpose of documenting and disseminating CDER policies and procedures. This MAPP specifies policy, procedures, and responsibilities for the origination, revision, recertification, transfer, clearance, maintenance, and cancellation of MAPPs in CDER.

BACKGROUND

- The Federal Managers Financial Integrity Act of 1982 (FMFIA) requires federal agencies to establish and maintain adequate systems of internal control for accounting and administrative activities.
- U.S. General Accountability Office (GAO) *Standards for Internal Control in the Federal Government* states, "Internal control is a major part of managing an organization. It comprises the plans, methods, and procedures used to meet missions, goals, and objectives, and, in doing so, supports performance-based management."
- Office of Management and Budget (OMB) Circular A-123 requires federal agencies to establish internal control documentation to include policies and

procedures, organization charts, manuals, memoranda, flow charts, and related written materials necessary to describe organizational structure, operating procedures, and administrative practices for accomplishing programs and activities.

- FDA Staff Manual Guide 2020, FDA Quality System Framework for Internal Activities, sets minimum standards for implementation of quality system-controlled directives (including MAPPs) and training (see 5.a.Requirements §0.3(b) and §2.1(c)(2)).
- CDER's "Manual of Policies & Procedures (CDER)" system was established in 1996 and is maintained on the FDA website at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm.

POLICY

- Office-, division-, and CDER-wide operating policies and procedures should be published as MAPPs and remain in effect until revised, recertified, or canceled.
- MAPPs will be categorized as Standard, Internal, or Interim.
- The Office of Management (OM) will oversee the MAPP system.
- The office that creates a MAPP will ensure that the policies and procedures are current.
- Standard and Internal MAPPs will be reviewed[1] every 5 years from the last effective or recertified date to ensure they are current.
- Interim MAPPs will be canceled, transferred, or converted to a Standard or Internal MAPP category 3 years after the posted date.
- Standard MAPPs are publicly available. Internal and Interim MAPPs are not publicly available; however, they are available to CDER staff on the CDER intranet.
- The system and formats (e.g., procedure MAPP, policy MAPP, program description, and policy and procedure MAPP) described in this MAPP will be used to issue all MAPPs in CDER.

RESPONSIBILITIES

Office Director for Management in the Office of Management (or designee)

- Reviews and clears all MAPPs to ensure adherence to established policies and procedures for MAPP development and review.
- Confirms whether the requested MAPP category is appropriate.

[1] See definition of "Review."

Director, Office of Regulatory Policy (or designee)

- Reviews and clears MAPPs that affect regulatory policy to ensure adherence to established CDER policies.

Super Office or Office Director (or designee)

- Ensures that office policies and procedures are documented as prescribed in this MAPP or MAPP 4001.1 *Developing, Issuing, and Maintaining Standard Operating Procedures for CDER.*
- Ensures that all employees understand the MAPPs that are relevant to their job performance.
- Confirms that all MAPPs originating in the office and subordinate offices remain accurate and current.
- Approves the request for category designation for its MAPPs.
- Clears all draft MAPPs that:
  - originate in the office
  - originate in other super offices or offices, but reference the office
  - have a CDER-wide impact (clearance occurs at Senior-Staff level)
- Appoints MAPP coordinators and MAPP editors, depending on office procedures.
- May appoint MAPP authors or subject matter experts
- Ensures that Interim MAPPs on the intranet are canceled, transferred, or converted to a Standard or Internal MAPP category 3 years after the posted date.
- Ensures that an implementation plan is developed to allow an appropriate period of time between the posting date and the effective date for implementation activities, if needed.
- Ensures that employees are made aware of newly posted, revised, recertified, transferred, or canceled MAPPs.
- Signs the MAPP Services Work Request Form[2] that includes the MAPP category requested.

CDER MAPP Team (CMT)

The responsibilities of the CDER MAPP Team (CMT) include supporting, coordinating, and reviewing the development of MAPPs and maintaining the CDER MAPP system.

CMT supports the following:

- Documentation of CDER policies and procedures in a MAPP format.

[2] See Attachment 2.

- Tracking MAPP posting dates and the status of MAPPs, including those that are due for review, to ensure the MAPPs continue to be current.[3]
- MAPP authors, editors, and coordinators with development, editing, and clearance of MAPPs and in the review of proposed MAPPs for consistency with existing policy documents (e.g., FDA Staff Manual Guide).
- Super offices or offices without MAPP editors by providing editorial services (using the CDER Style Guide).
- MAPP development by helping to determine, if needed, the necessary clearance outside the originating office for each MAPP, based on the MAPP's impact on other CDER offices.
- Communication strategies to help office management provide information regarding newly posted, revised, recertified, transferred, or canceled MAPPs.

CMT coordinates the following:

- CDER-level clearance of proposed and revised MAPPs, including sending received comments to MAPP coordinators.
- Timely posting of all MAPPs.
- Timely removal of canceled MAPPs from the CDER MAPP web page or the CDER intranet, whichever is appropriate.

CMT works with MAPP coordinators by:

- Providing training that includes how to find and use MAPP templates.
- Ensuring that CDER staff is alerted to new, revised, recertified, and canceled MAPPs.
- Holding regular CDER-wide meetings with MAPP coordinators as a group to share information and strategies for policy and procedures management.
- Communicating regularly with individual MAPP coordinators to review the status of office MAPPs.

CMT maintains the following:

- MAPP templates.
- The MAPP numbering system.
- The CMT SharePoint site, to provide the status of all draft and posted MAPPs and advertise newly posted or revised MAPPs.
- Final copies of all archived MAPPs in eDocumentum, a system of record, in accordance with National Archives and Records Administration (NARA) guidance and the applicable FDA records control schedule.

[3] CMT provides MAPP coordinators access to the CDER MAPP Report in the CMT's SharePoint site.

- CDERMAPPTeam@fda.hhs.gov email inbox and a system for monitoring correspondence.

MAPP Coordinator[4]

- Super office or office employee who serves as the point of contact for all MAPP production, recertification, revision, transfer, and cancellation processes in the super office or office
- Assists super office or office management with documenting office policies and procedures in MAPP format
- Facilitates development and clearance of draft MAPPs, which includes assisting authors with the use of MAPP templates and discussing formatting, clearance procedures, MAPP categories, and planning implementation activities with CMT
- Submits the MAPP Services Work Request Form to initiate the MAPP and obtain a MAPP number from CMT. Attaches a draft version of the MAPP, if available
- Informs CMT, as needed, of the status of MAPP development, implementation plan, and clearance processes
- Provides authors with CDER-level comments, obtained by CMT during the clearance process
- Coordinates with authors and editors to reconcile comments on draft MAPPs from CDER subject matter experts (SMEs) and referenced super offices or offices
- Provides super-office or office-level cleared MAPPs to CMT for CDER-level clearance
- Updates CMT on MAPP status changes, including clearance, cancellation, recertification, and transfer; provides appropriate documentation to CMT
- Attends MAPP Coordinator meetings
- Coordinates office review of Standard and Internal MAPPs every 5 years to ensure the MAPPs are current
- Coordinates office review of Interim MAPPs for cancellation, transfer, or conversion 3 years after the posted date

Author

- Consults with a MAPP coordinator and CMT, as needed, regarding MAPP templates, clearance procedures, categories, and implementation activities.
- Drafts MAPPs using the appropriate MAPP template and the CDER Style Guide.
- Consults, as needed, with appropriate SMEs in and outside the originating office for development of MAPPs.

[4] Some of the described responsibilities are performed by a MAPP editor or other designee, depending on the super office or office.

- Coordinates and reconciles input with the MAPP coordinator and MAPP editor, if applicable, on draft MAPPs from all SMEs and super offices, subordinate offices, or offices that are referenced in the MAPP.
- Provides draft MAPPs to their office editor (if the office does not have an editor, provides a draft to the MAPP coordinator who will send the draft MAPP to a MAPP editor in CMT).
- Works with the MAPP coordinator to clear MAPPs at the office or subordinate office level, according to office procedures.
- Ensures that all affected offices are represented in the working group if a working group is drafting a MAPP.
- Provides a justification for the MAPP to the MAPP coordinator to be included in the MAPP Services Work Request Form for all MAPPs.

MAPP Editor[5]

- Edits MAPPs originating in their super office or office using the CDER Style Guide. Assists with MAPP clearance according to office procedures
- Coordinates and reconciles input with the MAPP coordinator and author on draft MAPPs from SMEs and super offices and offices referenced in the MAPP

PROCEDURES

MAPP Forms

- MAPP Services Work Request Form[6] – This form is used to initiate, revise, recertify, transfer, convert, or cancel a MAPP.
- CDER Clearance Sheet[7] – This form is used throughout the clearance process. It captures office, inter-office, Office of Regulatory Policy (ORP), and OM clearance.

MAPP Numbering

- Each super office or office is assigned a range of numbers. CMT assigns individual identification numbers to each MAPP in this range, based on available numbers in proximity to posted MAPPs with similar subject matter. This numbering system consists of a three-part symbol as follows:

    1. The acronym “MAPP”

[5] If the office does not have an editor, CMT will provide one.
[6] See Attachment 2.
[7] See Attachment 3.

2. A four-digit number in the originating office's grouping[8]
3. The next sequential number, following the decimal point (.X)

- If a MAPP is a revision of a previously posted MAPP, the revision number is listed immediately following the number (e.g., MAPP 4000.1 Rev. 5).
- If the MAPP is a transfer, the MAPP number is changed to reflect the numbered grouping from the office accepting the MAPP.

Format

- All MAPPs are written in the appropriate MAPP template format. See Definitions for descriptions of each MAPP format. The templates are housed in the CMT SharePoint site. For access to this site, contact CDERMAPPTeam@fda.hhs.gov.

Conflict Resolution

- The authors, SMEs, and MAPP coordinators take reasonable steps to align MAPP policies and procedures under development.
- The following MAPPs are applicable:
  - MAPP 4151.8, *Equal Voice: Discipline and Organizational Component Collaboration in Scientific and/or Regulatory Decisions*
  - MAPP 4151.1 Rev.1, *Scientific/Regulatory Dispute Resolution for Individuals Within a Management Chain*
  - MAPP 4151.2 Rev. 1, *Resolution of Differing Professional Opinions: Review by Ad Hoc Panel and CDER Director*

Style

- All MAPPs are written and edited in accordance with the CDER Style Guide.

Draft Status

- MAPPs remain in draft status until signed by the Director for OM, or designee.
- A draft MAPP retains the "DRAFT" watermark until CMT removes it before posting and archiving.

Clearance of New MAPPs at Super Office or Office Level by the Originating Office

- At the onset of MAPP development, the MAPP coordinator contacts CMT to discuss formatting, clearance, providing a draft, if available, and obtaining a MAPP number.

[8] Numbers may change when MAPPs are transferred from one office to another. See "Transfer" for more information.

- Once the MAPP has been drafted, the MAPP coordinator or designee submits the completed MAPP Services Work Request Form, signed by the office director, to CMT.
- MAPPs are cleared by the directors of the originating office, subordinate office, super office, and offices referenced in the MAPP, using the CDER Clearance Sheet.
- MAPP coordinators submit the cleared MAPP and the CDER Clearance Sheet to CMT for clearance at the CDER level.

Clearance at CDER Level

- CMT submits MAPPs affecting CDER-wide operations to Senior Staff for clearance with a deadline of 10 business days from receipt. Senior Staff may request a deadline extension. Non-response by the deadline signifies concurrence with the MAPP and the proposed implementation plan.
- In addition, CMT submits those MAPPs affecting regulatory policy to ORP for clearance. CMT sends the MAPP and clearance forms to CDER-ORPRequests@fda.hhs.gov.
  CMT submits all MAPPs to the Director of OM for final clearance.

Initiation of a MAPP and Conduct of a Regular Review

- MAPP coordinators use the MAPP Services Work Request Form on the CMT SharePoint site to initiate a new MAPP.
- CDER offices and divisions continually evaluate their existing policies and procedures to ensure current information has been captured and documented using the CDER MAPP system.
- Each super office or office reviews its currently posted Standard and Internal MAPPs every 5 years from the last effective or recertified date. These reviews ensure that MAPPs are current and reflect office and CDER missions.
- Each super office and office reviews Interim MAPPs after 3 years from the last posted date to determine if the MAPP should be canceled, converted, or transferred.

Recertification

- Super offices or offices recertify Standard or Internal MAPPs every 5 years to ensure MAPPs reflect current CDER policy and procedures. The super office or office director signs the MAPP Services Work Request Form available on the CMT SharePoint site.
- CMT maintains documentation of recertification.
- CMT inserts the recertified date in the footer of the MAPP and in the Change Control Table and arranges for web posting.

Revision

- Super offices and offices revise MAPPs needing substantive updating or conversion.
- Offices use the MAPP Services Work Request Form to request a revision to a MAPP.
- A revised MAPP is cleared as if it were a new MAPP.
- A revised MAPP supersedes the previous version of the MAPP by the same title (or covering the same subject matter).
- A MAPP may be removed and given a placeholder message while it is being evaluated and updated.
- CMT assigns the revised MAPP the same MAPP number as the previous version and includes the revision number listed immediately following the MAPP number (e.g., MAPP 4000.1 Rev. 5).
- Interim MAPPs that are converted to Standard MAPPs and posted on the public MAPPs web page retain the original MAPP number. No revision number is necessary because previous iterations were never public.
- Super offices and offices provide significant changes in the revised MAPP in a numbered list in the Change Control Table on the last page of the MAPP.
- CMT notes effective dates of all previous versions of the MAPP in the lower left footer of the MAPP in strike-through format.

Non-substantive Changes

- CDER offices may suggest non-substantive changes to an existing MAPP at any time; such changes do not require formal clearance. Effective and recertification dates stay the same.
- MAPP editors, coordinators, or CMT specifies the non-substantive changes, and CMT forwards changes to the CDER Web team for posting.
- Examples of non-substantive changes include changes in contact information, office names, internet addresses, corrections to formatting, and typographical errors.

Transfer

- A MAPP may be transferred from one office to another. The office requesting the transfer uses the MAPP Services Work Request Form (available on the CMT SharePoint site) to request a MAPP transfer. The office director from the office that accepts the transfer will also sign the MAPP Services Work Request Form. The signature line for the accepting office will appear on the form when the "Transfer" radio button is selected.
- Super offices clear transfers of MAPPs owned by their component offices.
- A transferred MAPP receives a new MAPP number that corresponds to the receiving office.

Cancellation

- Super offices or offices request cancellations of MAPPs using the MAPP Services Work Request Form.
- CMT alerts the CDER Web team to remove canceled MAPPs.

REFERENCES

1. OMB, 2004, Circular A-123, Revised, Management's Responsibility for Internal Control.
2. NARA, 2003, Records Management Handbook.
3. GAO, 1999, Standards for Internal Control in the Federal Government.
4. OMB, Federal Managers Financial Integrity Act of 1982.
5. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.1 Rev. 1: Scientific/Regulatory Dispute Resolution for Individuals Within a Management Chain.
6. FDA, 2006, SMG 2020 FDA Quality System Framework for Internal Activities.
7. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.2 Rev. 1: Resolution of Differing Professional Opinions: Review by Ad Hoc Panel and CDER Director.
8. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.8 Equal Voice: Discipline and Organizational Component-Collaboration in Scientific and/or Regulatory Decisions.
9. FDA, CDER Style Guide.
10. U.S. Code Title 5 Government and Employees, Administrative Procedure, section 552(b)(2) Public information; agency rules, opinions, orders, records, and proceedings.

DEFINITIONS

Note to reader: The following three definitions are out of alphabetical order for clarity:

Office – An office that reports to the CDER Director and is neither a super office nor a subordinate office.

Super Office – An office that reports to the CDER Director and to which subordinate offices report.

Component Office – An office that reports to a super office.

Author – Staff in the originating office with responsibility for drafting or revising a MAPP.

Cancellation – Process by which an originating office requests to cancel a MAPP because the policies and procedures are no longer applicable. A MAPP may be canceled by the originating office at any time.

CDER MAPP Team (CMT) – OM team that assists CDER staff with the development, review, and posting of new MAPPs; manages the system of existing MAPPs; and archives canceled MAPPs.

Conversion – Process by which an office requests to change an Interim MAPP to a Standard or Internal MAPP.

Manual of Policies and Procedures (MAPP)

- Standard MAPP – A Standard MAPP has no termination date and is available to the public. A Standard MAPP establishes office policies and procedures to guide staff in the conduct of their work. Each numbered entry is commonly referred to as a "MAPP." Standard MAPPs will be reviewed every 5 years to ensure their relevance to current FDA practices.

- Internal MAPP – An Internal MAPP has no termination date and is not available to the public because (1) it contains internal information that, if publicized, could interfere with important CDER objectives such as enforcement proceedings or confidential investigations; (2) is of little or no interest to the public; or (3) includes internally accessible information (e.g., CDER links to travel forms, passport forms, and other administrative information), the publication of which could weaken the FDA firewall protections. An Internal MAPP is posted on the CDER intranet for CDER staff reference. Internal MAPPs will be reviewed every 5 years to ensure their relevance to current FDA practices.

- Interim MAPP – An Interim MAPP is canceled, converted, or transferred after 3 years from the posted date. Interim MAPPs are not available to the public because the content is temporary (e.g., used for training before it becomes a Standard MAPP, used to test a pilot program). Interim MAPPs are posted on the CDER intranet for staff reference.

MAPP Coordinators – Representative(s) of each office or super office, appointed by their office directors, who coordinate MAPP evaluation, drafting, development, clearance, revision, transfer, recertification, and cancellation. Coordinators for super-offices generally coordinate MAPPs for their subordinate offices. For the name of an office MAPP coordinator, contact the MAPP Team at CDERMAPPTeam@fda.hhs.gov.

MAPP Editors – Professional writer/editors located in several offices, super offices, and in CMT. Super-office writer/editors generally edit MAPPs for their subordinate offices.

Originating Office – Super office or office that recognizes the need for a MAPP, drafts the MAPP, and coordinates its review in all offices that are referenced in the MAPP. The originating office ensures that the content of the MAPP is current.

Policy MAPP – Describes a high-level principle or plan affecting regulatory policy to guide decisions and actions in support of CDER goals.

Procedure MAPP – Documents the specific steps necessary to accomplish some aspect of the work of CDER or its component offices or divisions.

Policy and Procedure MAPP – Contains both policy statements and procedures for implementing the policies identified in the MAPP.

Program Description MAPP – Identifies and documents the roles, responsibilities, and operational procedures of CDER teams, programs, boards, or committees.

Recertification – Process by which an originating office certifies that an existing MAPP remains current after review.

Regulatory Policy – Setting policy that guides the Agency's decisions in a lawful and consistent manner.

Review – Process of regularly reevaluating MAPPs for accuracy and currency by the originating office. Such review will occur at the appropriate intervals defined in this MAPP. Following review, MAPPs may be recertified, revised, transferred, converted, or canceled.

Revision – Process by which an originating office makes substantive changes to a MAPP. Revisions require the same clearance process as the initial MAPP. A MAPP may be revised by the originating office at any time.

Senior Staff Clearance – Concurrence by staff members who report to the Center Director.

Subject Matter Expert – CDER staff with unique knowledge of the content of a MAPP.

Transfer – Moving the responsibility for a MAPP from one office to another.

Working Group – Representatives of two or more offices coordinating the development of a MAPP.

SUMMARY OF CHANGES

1. Establishes an Internal MAPP option
2. Updates forms and clerical issues
3. Includes editorial changes

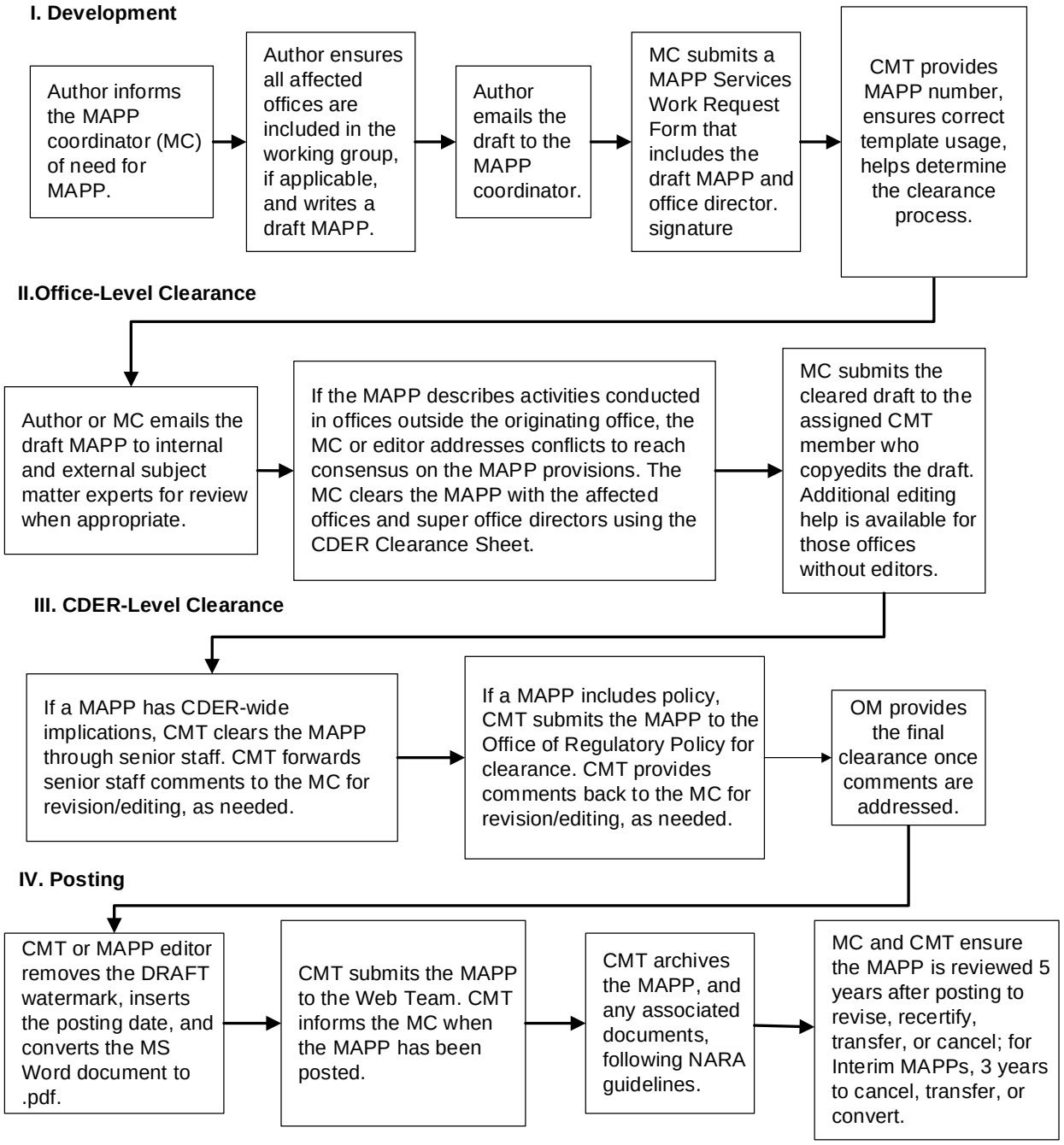
EFFECTIVE DATE

This MAPP is effective upon date of publication.

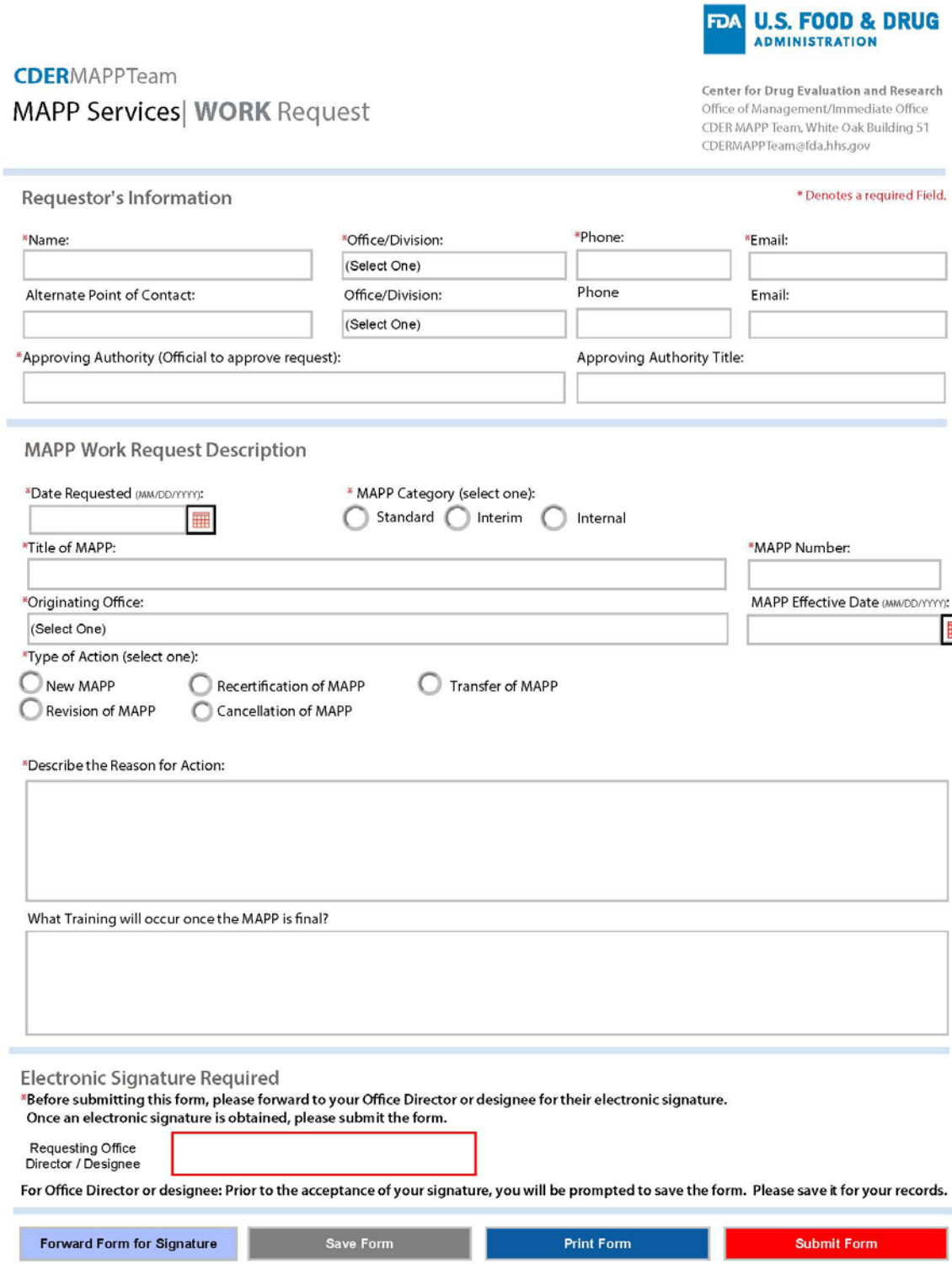
CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
4/22/96	Initial	n/a
9/24/96	Rev. 1	Adds policy on Interim MAPPs. Identifies new MAPP categories.
3/17/06	Rev. 2	1. Changes a number of definitions and responsibilities. 2. Shortens CDER-wide clearance period from 15 to 10 days. 3. Attaches template and cover sheet. 4. Adds screen shots of MAPPs on (1996) Internet.
9/26/11	Rev. 3	1. Reflects OM responsibility for the MAPP system. 2. Establishes guidelines for MAPP revision, recertification, and cancellation. 3. Requires all MAPPs be recertified every fifth year. 4. Modifies the conflict resolution and clearance process. 5. Updates definitions, responsibilities, and templates. 6. Adds six references.
9/19/14	Rev. 4	1. Updates the list of references. 2. Replaces references to eRoom with SharePoint site. 3. Establishes new responsibilities and procedural steps for developing an implementation plan (activities and time period) for MAPPs affecting more than one super office.
8/24/17	Rev. 5	1. Establishes an Internal MAPP category. 2. Updates forms and clerical issues. 3. Includes editorial changes.

ATTACHMENT 1 – MAPP Clearance Flow Chart



ATTACHMENT 2 – MAPP Services Work Request Form



U.S. FOOD & DRUG ADMINISTRATION

CDERMAPPTeam

MAPP Services| WORK Request

Center for Drug Evaluation and Research
Office of Management/Immediate Office
CDER MAPP Team, White Oak Building 51
CDERMAPPTeam@fda.hhs.gov

Requestor's Information

* Denotes a required Field.

*Name:
*Office/Division: (Select One)
*Phone:
*Email:
Alternate Point of Contact:
Office/Division: (Select One)
Phone
Email:
*Approving Authority (Official to approve request):
Approving Authority Title:

MAPP Work Request Description

*Date Requested (MM/DD/YYYY):
* MAPP Category (select one): Standard Interim Internal
*Title of MAPP:
*MAPP Number:
*Originating Office: (Select One)
MAPP Effective Date (MM/DD/YYYY):
*Type of Action (select one):
New MAPP Recertification of MAPP Transfer of MAPP
Revision of MAPP Cancellation of MAPP

*Describe the Reason for Action:

What Training will occur once the MAPP is final?

Electronic Signature Required

*Before submitting this form, please forward to your Office Director or designee for their electronic signature. Once an electronic signature is obtained, please submit the form.

Requesting Office Director / Designee

For Office Director or designee: Prior to the acceptance of your signature, you will be prompted to save the form. Please save it for your records.

Forward Form for Signature | Save Form | Print Form | Submit Form

ATTACHMENT 3 – CDER Clearance Sheet

CDER CLEARANCE SHEET

[A] CDER Tracking Number:	[B] FRDTS No:	[C] Date:

[D] DOCUMENT TYPE

☐ Rule – ANPR	☐ Rule – Direct Final	☐ Guidance – Revised Draft	☐ Citizen Petition Response
☐ Rule – Proposed	☐ Rule – Interim Final	☐ Guidance – Revised Final	☐ Notice
☐ Rule – Final	☐ Guidance – Draft	☐ Guidance – Final	☐ Other (identify)

[E] Document Title:

[F] Originating Office:	☐ CTECS	☐ OC	☐ OEP	☐ OGD	☐ OM	☐ OMP	☐ OND	☐ OPQ	☐ ORP	☐ OSE	☐ OSP	☐ OTS	☐ Other

[G] FINAL CLEARANCE

To: (Name)	Cleared No Comments	Cleared – Once Comments Addressed	Cleared Optional Comments	Date
Tracker/Editor:				
Director, Office of Regulatory Policy or designee:				
Center Director or designee:				
Other Center/Office (if applicable):				
Other Center/Office (if applicable):				
Other Center/ Office (if applicable):				
Tracker/Editor:				
OCC (if applicable):				
Tracker/Editor:				

[H] REMARKS:

[I] From(Tracker/Editor Name):	**Email:**	**Phone:**

[J] This document has been prepared and reviewed by (name, organization)

1. Lead Author: _____ 2. Sponsor: _____

3. Work Group Chair: _____ 4. CDER Editor: _____

5. Other: _____

(CDER Clearance Sheet) Updated 01/02/2015