

GENERAL MANAGEMENT AND ADMINISTRATION

Developing and Issuing Manuals of Policies and Procedures (MAPPs)

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PURPOSE

- This MAPP establishes a system for issuing MAPPs within the Center for Drug Evaluation and Research (CDER) and disseminating Center policy and procedures to all Center employees. It specifies policy, responsibilities, and procedures for the origination, update, clearance, maintenance, and issuance of policies and procedures within the Center.

BACKGROUND

- The Federal Managers' Financial Integrity Act of 1982 (FMFIA) requires management to establish and maintain adequate systems of internal control for accounting and administrative activities.

- The Office of Management and Budget (OMB) states that internal control documentation shall include system documentation of policies and procedures, organization charts, manuals, memoranda, flow charts, and related written materials necessary to describe organizational structure, operating procedures, and administrative practices. The documentation shall communicate responsibilities and authorities for accomplishing programs and activities. Maintaining the Center's MAPPs helps to strengthen internal controls by documenting the policies and procedures required by FMFIA, the General Accounting Office, and OMB.
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REFERENCES

- Federal Managers' Financial Integrity Act of 1982 (PL-97-255).
 - *Standards for Internal Controls in the Federal Government*, U.S. Government Accounting Office.
 - Circular A-123, Revised, Internal Control Systems, Office of Management and Budget.
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DEFINITIONS

- **MAPP.** A written statement issued by CDER management to prescribe policies, responsibilities, or procedures to be applied within the Center in the conduct of its work or daily operations. MAPPs may be issued by any CDER administrative level (Center, Office, Division, Staff, Branch or Section). MAPPs are available electronically to all CDER employees on the Internet. (See Attachment D for directions on how to find electronic copies of MAPPs). In addition, hard copies are printed on yellow paper and maintained in a CDER manual binder available in each CDER organization down to the Division level.
 - **Interim MAPP.** A written statement with a stipulated termination date, usually one year from date of issuance, which may be issued as a memorandum with a formal cover sheet to identify the contents as an Interim MAPP. The termination date will appear on the cover sheet. Interim MAPPs will not be made publicly available because the policies and procedures are temporary. (See Attachment C for example cover sheet).
 - **Sponsor.** The person, usually a management-level individual, who directs the development or revision of a particular MAPP.
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- **Originator, Drafter.** The individual who actually develops or revises a particular MAPP and who may, or may not, be the sponsor. For the purposes of this MAPP, the terms originator and drafter are synonymous.
 - **MAPP point of contact.** The individual at each management-level (down to the division level) that is responsible for maintaining the MAPP. The individual is appointed by the Office/Division Director.
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POLICY

Office, Division, and Center-wide operating policies and procedures will be published as MAPPs in the CDER Manual of Policies and Procedures and will remain in effect until their termination date is reached, or they are rescinded or superseded. The system and format prescribed in this MAPP will be used to issue all MAPPs in the Center. MAPPs will be written, cleared, published, and updated on a timely basis and according to the responsibilities and procedures stated in this MAPP.

RESPONSIBILITIES

The Associate Director of Policy or his/her designee

- Reviews and concurs on all proposed and revised MAPPs.
- Archives all expired MAPPs.
- Consults with originators of proposed MAPPs on format and content.
- Coordinates the clearance of proposed MAPPs in the Center. Assigns identification numbers and prepares final copy of MAPPs for publication.
- Maintains record copies of all MAPPs.

Office and Division Directors, and other Sponsors (e.g., Staff Directors)

- Originate MAPPs to reflect policy and procedures within their organizational areas for inclusion in the CDER MAPP, and notify the Associate Director for Policy of the initiation of a MAPP.
 - Appoint a person as MAPP point of contact.
 - Coordinate with the Associate Director for Policy to obtain concurrence of
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affected units when MAPPs cross organizational lines.

Supervisors

- Ensure that all subordinates understand their responsibilities to become familiar with the MAPPs related to their positions.

Drafters of MAPPs

- Ensure that content of the MAPP is accurate and current.
- Review all pertinent references to ensure consistency with existing policy.
- Ensure that the content is clear, complete, concise, and in the prescribed format.
- Ensure that the draft MAPP is reviewed by the appropriate parties (see below) and that sufficient time is allotted for the review (usually 10 business days).
- For Team-specific, Division-specific, or Staff-specific MAPPs, route the MAPP through the Team Leader, Division Director, or Staff Director who will check the MAPP for accuracy, endorse it, and return it to the drafter.
- For Office-wide MAPPs, route the MAPP through the Office Director who will check the MAPP for accuracy, endorse it, and return it to the drafter.
- For Center-wide MAPPs or those that cross-Office lines, route the MAPP through the Associate Director for Policy for distribution to the appropriate Office/Division Directors and coordinating committee chairs for clearance.
- Revise the proposed MAPP to incorporate appropriate comments made by reviewers and preparing a final package containing the revised draft and all memoranda or comments relating to important controversies and their resolution.
- Submit a clean, hard and electronic copy of the draft MAPP to the Associate Director for Policy or his/her designees.

MAPP Point of Contact

- Reviews and updates existing MAPPs, or develops new MAPPs as needed to reflect current policies and operating procedures, and appropriate methods to ensure current information within their organizational units;
- Maintains the hard copy of the MAPP in their organizational unit.

PROCEDURES

Clearance of Office and Division MAPPs

1. Upon receipt of the draft and approval of content and format, the Associate Director for Policy or his/her designee will attach a clearance record and return the draft for signature by the management of the originating component.
2. The Director of the originating Office or Division will indicate approval of the draft MAPP by signing and dating the clearance record and returning it with the draft MAPP to the Associate Director for Policy or his/her designee for clearance and distribution.

Clearance of Center MAPPs

1. Upon receipt of the draft and approval of content and format, the Associate Director for Policy or his/her designee will attach a clearance record and obtain the signature of the management of the originating component, or lead on the specific issue (e.g., Chair of responsible coordinating committee, working group).
2. For Center-wide MAPPs, the Associate Director for Policy or his/her designee will distribute copies to all **affected** Office Directors for final clearance. Generally, 10 working days will be provided for concurrence, and the draft MAPP should be returned to the Associate Director for Policy or his/her designee with the signed clearance form and any comments attached.
3. Any CDER component that has not responded within the 10-day (or other date specified) time limit will be considered as having concurred. If circumstances require a longer-than-normal time frame, an extension of the time limit may be requested from the Associate Director for Policy.

Correction and Final Package Preparation

1. The Associate Director for Policy or his/her designee will compile all comments received and forward them to the originator via memorandum signed by the Associate Director for Policy or his/her designee.
2. The originator will revise the proposed MAPP to incorporate appropriate comments made by reviewers, prepare a final package containing the revised draft and all memoranda or comments relating to important controversies and their resolution, and submit it to the Associate Director for Policy or his/her designee. The originator will attempt to reconcile disparate comments/concerns through discussions/meetings.

3. As needed, the Associate Director for Policy or his/her designee will circulate the revised draft and its comments for clearance to the Office Directors as described above.

Conflict Resolution

1. Any reviewing Office Director who identifies a conflict or controversy in a draft MAPP during the comment period will resolve the issue with the originating Office Director. Conflicts still unresolved one month after the clearance process ends will be directed to the Associate Director for Policy for final resolution.
2. If necessary, the Associate Director for Policy may choose to initiate the following conflict resolution procedures:
 - The controversy will be presented to the CDER Deputy Director or Office Director who has responsibility for the issue for resolution, or, for cross-cutting issues, to other appropriate members of the CDER management team. If this is successful, the results will be returned through the Associate Director for Policy to the originating Office Director.
 - Any controversy/conflict that cannot be resolved through the Deputy or Office Directors will be decided by the Director, Center for Drug Evaluation and Research, within one month from date of receipt of the package.

Copy Preparation, Publication, and Distribution

1. Upon receipt of an approved Policy and Procedure, the Associate Director for Policy or his/her designee will prepare final copy and arrange for its publication and distribution.

Updating/Revising Existing CDER MAPPs

1. Sponsors will periodically evaluate MAPPs originated within their organizations to ensure that MAPPs are up to date. They will ensure that MAPPs are updated promptly when Center policy, procedures, methods, or subject areas have changed significantly, or when current procedures or methods are ineffective in accomplishing the Center's diverse functions in a satisfactory and timely manner.
2. Originators will review their MAPPs periodically and update if necessary.
3. The Associate Director for Policy or his/her designee will work with programs to monitor the accuracy and currency of MAPPs.

4. The Associate Director for Policy or his/her designee will process revised MAPPs in the same manner as new MAPPs.

Format

1. The format used for text, outlines, headers, footers, and tables of contents will follow the format demonstrated throughout this guidance (See Attachment A). A template is available electronically (in Word) on the CDER Intranet at <http://cdernet.cder.fda.gov/guidancedoc/gssquaredindex.htm>.

Identification and Numbering of MAPPs

1. The Associate Director for Policy or his/her designee will assign identification numbers to all MAPPs issued in the Center. This numbering system consists of a three-part symbol (e.g., MAPP XXXX.X) which identifies:
 - The manual acronym (MAPP).
 - A four-digit subject category number or sub-category number assigned by the Associate Director for Policy or his/her designee (XXXX).
 - The next sequential number (.X).

Transmittal

1. The Associate Director for Policy or his/her designee will distribute all MAPPs under transmittals which reference superseded material, provide filing instructions, and an explanation of changes. (See Attachment B.)

Filing

1. MAPPs will be filed behind the appropriate tabs in numerical order by the MAPP point of contact. Specific filing instructions will appear on the transmittals.
2. Existing MAPPs are to be retained until canceled or superseded.

Table of Contents Update

1. Tables of Contents are provided for the MAPP and for each chapter. Tables are periodically updated to provide a listing of current MAPPs for ready reference. A consolidated Table of Contents shows the MAPP

identification number, title, and date of issuance.

Effective Date

1. The effective date for all MAPPs will be the date of issuance on the transmittal.

Interim MAPPs

1. Originators should follow the procedures for new MAPPs with the following additions:
 - Originators should inform the Associate Director for Policy of the expiration date of the Interim MAPP.
 - The Associate Director for Policy will attach a cover sheet (see Attachment C) to the Interim MAPP.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

SAMPLE FORMAT FOR MAPPs

[CATEGORY]

[Title]

CONTENTS

PURPOSE (of guide)
BACKGROUND (if needed)
REFERENCES (related CDER, FDA, FPM, PHS,
DHHS and others)
DEFINITIONS (when new terms are used)
POLICY
RESPONSIBILITIES
PROCEDURES
FORMAT
AUTHORITY (additional paragraphs as necessary)
EFFECTIVE DATE

Attachment A - (as necessary)

PURPOSE

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BACKGROUND

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REFERENCES

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DEFINITIONS

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POLICY

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RESPONSIBILITIES

-
-

PROCEDURES

-
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FORMAT

-
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AUTHORITY

-
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EFFECTIVE DATE

This MAPP is effective upon date of publication.

Created by:
Reviewed by:
Cleared by:

This template is available electronically (in Word) on the CDER Intranet at <http://cdernet.cder.fda.gov/guidancedoc/gquaredindex.htm>.

Attachment B

CENTER FOR DRUG EVALUATION AND RESEARCH
POLICY AND PROCEDURE TRANSMITTAL

MAPP

Date

Policy and Procedure: MAPP XXXX.X

Name:

Filing Instructions and Explanation of Changes:

Remove:

Insert:

Explanation:

To update the table of contents for the CDER Manual for Policies and Procedures, print the mapp list from the Internet at <http://www.fda.gov/cder/mapp.htm>.

Associate Director for Policy

This template is available electronically (in Word) on the CDER Intranet at <http://cdernet.cder.fda.gov/guidancedoc/gssquaredindex.htm>.

Attachment C

MANUAL OF POLICIES AND PROCEDURES

CENTER FOR DRUG EVALUATION AND RESEARCH

MAPP XXXX.X

INTERIM MAPP

DATE:

TO:

SUBJECT:

ISSUED BY:

EXPIRATION DATE:

This document is being issued as an interim directive while certain records retention issues are resolved. Once they are resolved, the policies will be revised appropriately and the document converted to a MAPP.

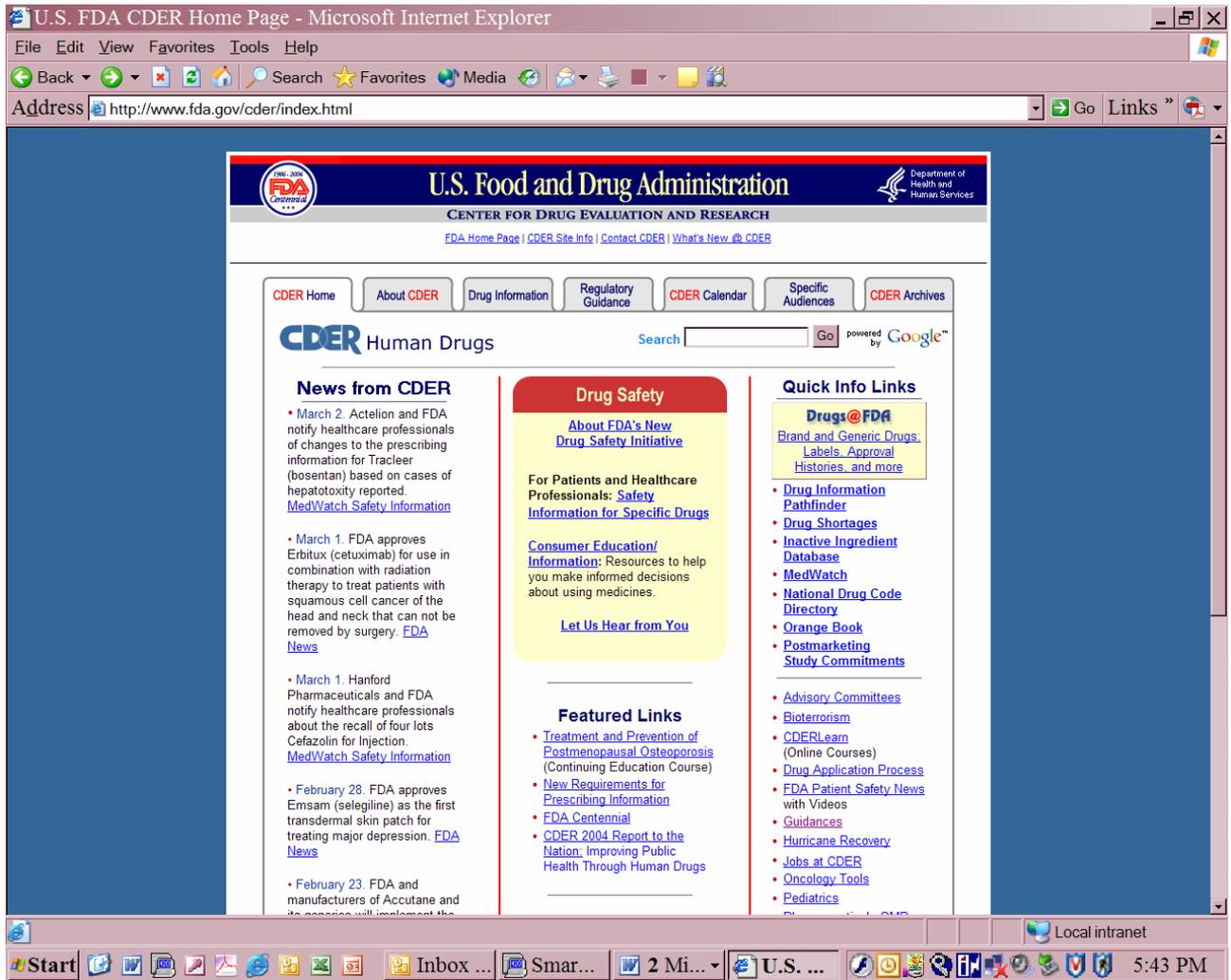
NOT PUBLICLY AVAILABLE

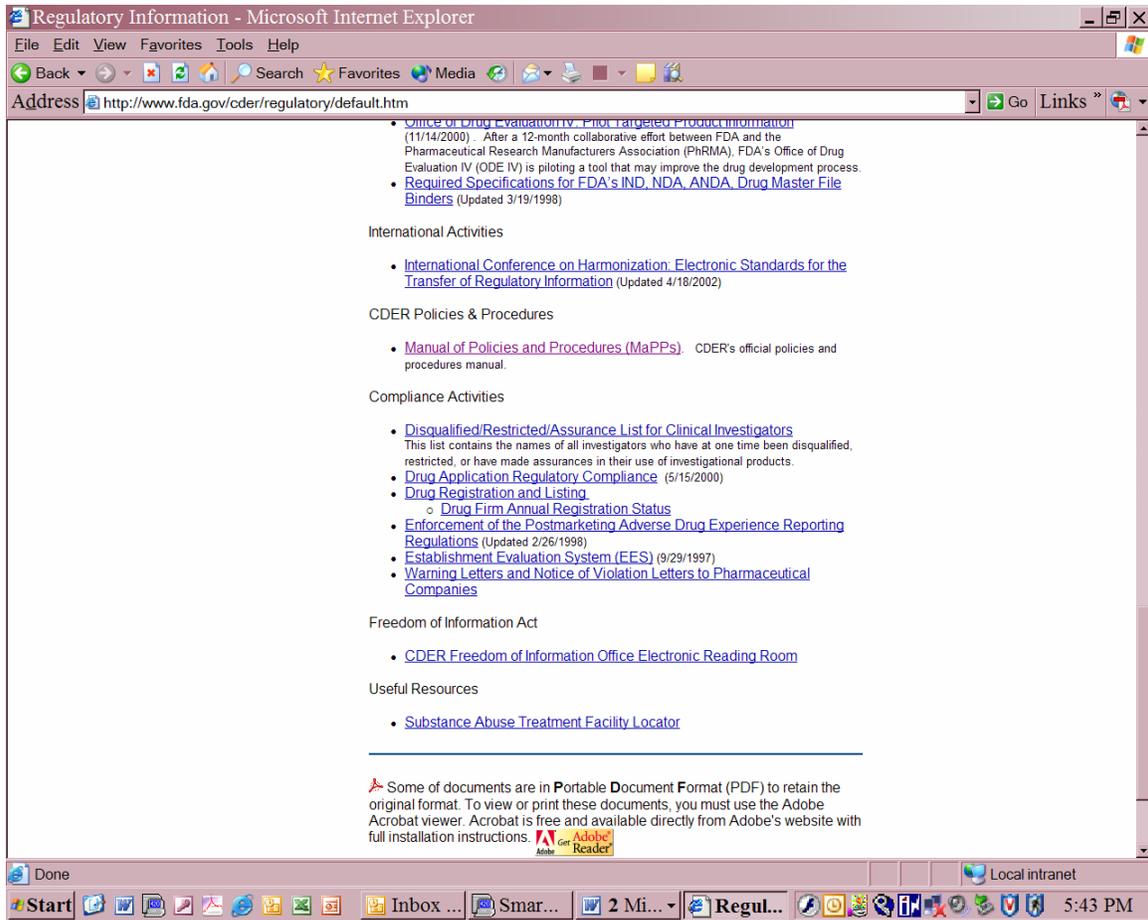
This template is available electronically (in Word) on the CDER Intranet at <http://cdernet.cder.fda.gov/guidancedoc/gquaredindex.htm>.

Attachment D

TO ACCESS MAPPS ON THE INTERNET

1. Type in the following url address: <http://www.fda.gov/cder/index.html> and follow
2. the next steps (or go directly to <http://www.fda.gov/cder/mapp.htm>.)
3. Click on the “Regulatory Guidance” link.
4. Click on the “Manual for Policies and Procedures”
5. Click on the MAPP you would like to view. MAPPs are available in pdf format.





CDER Manual of Policies and Procedures (MaPP) - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://www.fda.gov/cder/mapp.htm> Go Links

U.S. Food and Drug Administration
Department of Health and Human Services

CENTER FOR DRUG EVALUATION AND RESEARCH

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CDER Manual of Policies and Procedures (MaPP)

This page contains the current CDER Manual of Policies and Procedures in Adobe Acrobat Format (PDF). [See bottom](#) for more information.

Contents:

Document Development and Management	New Drug Chemistry Testing and Research	Discipline Specific Biopharmaceutics
Center Director	Review Management	Chemistry
Controlled Substances	Office of Drug Evaluation I	Medical/Statistical
Training and Communications Management	Office of Drug Evaluation I	Pharmacology and Toxicology
Compliance	Office of Drug Evaluation III	Project Management
Pharmaceutical Sciences	Office of Drug Evaluation IV	Information Technology
Clinical Pharmacology	Office of Drug Evaluation V	Research
Generic Drugs	Epidemiology and Biostatistics	
	Office of Drug Safety	

Document Development and Management

- [4000.1](#) Guide to Issuance of Directives in the CDER
- [4000.2](#) Developing and Issuing Guidance (Issued 9/13/2005, Posted 10/3/2005)
- [4000.3](#) Submitting Proposals to the Office of Regulatory Policy (ORP) for Early Analysis of Rulemaking Initiatives (Issued 10/18/2001, Posted 10/23/2001)
- [4000.4](#) Clinical Pharmacology and Biopharmaceutics NDA Review Template (Issued 4/27/2004, Posted 6/24/2004)
- [4000.8 BLA](#) Biostatistics Biologics Licensing Application (Issued 4/20/2005, Posted 4/22/2005)
- [4000.8 NDA](#) Biostatistics New Drug Application Review (Issued 4/20/2005, Posted 4/22/2005)
- [4000.10](#) Indication-Specific Guidance Template (Issued 5/12/2005, Posted 5/12/2005)

Chapter 4100 - Center Director

Done Local intranet

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Attachment E

TO ACCESS MAPP TEMPLATES ON THE INTRANET

1. Type in the following url address: <http://cdernet/> and follow the next steps (or go directly to <http://cdernet/guidancedoc/gquaredindex.htm>).
2. Click on the “Disciplines and Subjects” link.
3. Click on the “Guidance on Guidance” link.
4. Click on the “MAPP Templates” link.

