POLICY

OFFICE OF MANAGEMENT

Developing, Issuing and Maintaining Standard Operating Procedures for CDER

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PURPOSE

This MAPP specifies the factors to consider when making a determination on whether to develop a Manual of Policies and Procedures (MAPP) or a Standard Operating Procedure (SOP) when delineating CDER policies and procedures. The MAPP also addresses requirements for maintaining access to, and currency of, SOPs.

BACKGROUND

The CDER Manual of Policies and Procedures (MAPP) is the official repository for CDER directives (internal policies and procedures), and meets all Office of Management and Budget (OMB) and National Archives and Records Administration (NARA) requirements for developing and archiving directives. However, many CDER offices have chosen to compile standard operating procedures (SOPs) either as stand-alone documents or as supplements to their MAPPs. SOPs have greater flexibility in format, structure, content, and clearance requirements. CDER does not generally make SOPs available to the public, although they may be releasable under the Freedom of Information Act (FOIA), unless they contain content that is FOIA-exempt, which would be redacted prior to release.

Existing legal and transparency considerations require that CDER offices carefully consider what content should be published as MAPPs. Offices may then consider what

other matters may be incorporated into the office's internal documents (SOPs). Guidelines are provided to help offices assess the suitability of utilizing these alternative forms of documentation based on several considerations. (See Attachment 1)

SOPs may be appropriate if one or more of the following criteria apply:

- The content is specifically exempt from disclosure under FOIA. (Contact CDER Office of Regulatory Policy/Division of Information Disclosure Policy for information on identifying FOIA-Exempt content.)
- The content involves only internal information of a relatively routine nature, and not of obvious interest to the public.
- The content includes only internal procedures that may require frequent updates as new systems or new technologies are created and adapted.

POLICY

MAPP 4000.1 establishes a system for issuing directives within CDER for the purpose of documenting and disseminating CDER policies and procedures, using the format described in the official MAPP templates.

MAPPs are:

- High level documentation, defining Office or Center policy, mission, and goals.
- Formal statements of CDER's operating principles, established by statute, regulations, or other controlling authority.
- Descriptions of official steps necessary to implement Center or Office policy.
- Coordinated between or among, multiple offices, or multiple Centers, because of shared work or interests.
- Of interest to the general public.
- Compliant with Section 508 of the Rehabilitation Act of 1973.

Alternative documentation of procedures, including SOPs or the equivalent, is allowable within the scope of this MAPP.

SOPs are :

- Formatted according to the preference of the originating office and distinguishable from MAPPs to reduce inadvertent public disclosure.
- Designed to include, at a minimum, background information about the subject of the SOP, responsibilities of parties to the SOP, and dates of issuance, revision, and cancellation. SOPs may also contain reference material and definitions.
- Initiated, cleared, managed and archived by the issuing office.
- Consistent with MAPPs and Staff Manual Guide (SMG) documentation on the same subject matter.
- Written using plain language principles.
- Evaluated for continued relevance and accuracy every third year after clearance.
- Maintained in a repository of the office's choice that is readily accessible to CDER staff.
- Provided to staff, with appropriate training on the system of SOPs at New Employee Orientation, and on individual SOPs, as needed, thereafter.
- Compliant with Section 508 of the Rehabilitation Act of 1973.

RESPONSIBILITIES

Super Office or Office Director (or designee(s))

- Understands the appropriate indications for the development of MAPPs vs. SOPs.
- Ensures the office has a system for considering the need for new or revised SOPs.
- Ensures all SOPs originating in the office meet the requirements listed in the Policy section of this MAPP.
- Ensures office staff members can locate and follow the office's SOPs impacting their work.
- Clears all SOPs for the office or super office.

DEFINITIONS

Manual of Policies and Procedures (MAPP) – A compilation of policies and procedures in CDER, designed to guide staff in the conduct of its work. Each numbered entry is commonly referred to as a "MAPP." CDER's MAPPs are federal directives and documentation of internal policies and procedures. Such directives are required by law

and are published on the FDA Internet Website. The Manual of Policies and Procedures is maintained by the CDER Office of Management Immediate Office.

Standard Operating Procedure (SOP) – A policy or procedure that generally applies to the internal functioning of a single office and refers to subject matter that is presumably of negligible interest to the public. SOPs often include information that changes frequently and they are cleared at the Office level. An example is a description of an office's process for answering mail. SOPs are usually not published on the FDA Internet Website but may be available to the public by request (unless exempt under the Freedom of Information Act (FOIA)). SOPs are initiated, cleared, maintained, and archived by the issuing office.

Staff Manual Guides (SMG) - Directives developed and maintained at the FDA level. The SMGs are located on the Inside. FDA Intranet Website and/or the FDA Internet site (www.fda.gov). SMGs are maintained by the FDA Office of Human Resources.

REFERENCES

1. FDA, 2011, Center for Drug Evaluation and Research, MAPP 4000.1 Rev. 3: Developing and Issuing MAPPs for CDER.
2. OMB, 2004. Circular A-123, Revised, Management's Responsibility for Internal Control.
3. Freedom of Information Act, Revised, 2000.
4. Plain Writing Act of 2010.
5. Rehabilitation Act of 1973 (29 U.S.C. § 794d), Sec. 508

EFFECTIVE DATE

This MAPP is effective upon date of publication

CHANGE CONTROL TABLE

Effective Date	Revision Number	
01/12/15	Initial Issuance	

ATTACHMENT 1: Guidelines to differentiate MAPPs from SOPs

Background: The Manual of Policies and Procedures (MAPP) is the official repository of directives for CDER. However, many CDER offices have chosen to compile standard operating procedures (SOPs) to give specific direction to staff. Internal SOPs have greater flexibility in structure and changeability.

It is important to consider what matters should be held as MAPPs, and what matters may be incorporated into SOPs.

MAPPs are:

- High level documentation, defining Office or Center policy, mission, and goals.
- Formal statements of CDER's operating principles, established by statute, regulations, or other controlling authority.
- Descriptions of official steps necessary to implement Center or Office policy.
- Often coordinated among multiple offices, or multiple Centers, because of shared work or interests.
- Available to the general public.
- In rare instances temporary and not published on the FDA Internet Website, (interim MAPPs), when it is important to provide MAPP-level guidance to staff before the MAPP is ready for publication on the website.

SOPs are:

- Detailed documentation including, for example, descriptions of the minutia of processing documents, running reports, populating databases, or sending and receiving communications.
- Specific to the internal functioning of a single office.
- Not known to be of interest to the general public.
- Not necessarily privileged information. May be available to the public, by request, unless FOIA-Exempt.

Documents that include non-public information (FOIA-Exempt):

- Cannot be published on the FDA Internet Website or otherwise publicly disclosed without redaction of exempt information.
- Non-public information includes, for example:

  - Trade secret or confidential commercial information
  - Personal privacy information
  - Classified information
  - Any information that could reasonably be expected to endanger the life or physical safety of an individual
- Contact CDER Office of Regulatory Policy, Division of Information Disclosure Policy if you have questions on whether specific content included in a document is exempt from public disclosure under FOIA.