SMG 3280.1

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

INFORMATION RESOURCES MANAGEMENT - FDA DIRECTIVES

FDA ADMINISTRATIVE DIRECTIVES

Effective Date: 11/29/2018
Changed: 06/11/2019

1. PURPOSE

This Staff Manual Guide (SMG) establishes responsibilities and procedures for writing, coordinating and clearing, General Administration, Volume III SMGs for publication to the web; and for retiring General Administration, Volume III SMGs.

General Administration, Volume III Staff Manual Guides (SMGs) are the FDA directives that document basic administrative policy, responsibilities, procedures, and/or instructions that relate to FDA functions and operations.

This SMG also establishes guidance for the overall management, numbering, formatting, writing style, publication on the FDA Internet or Intranet, and records management of all Staff Manual Guides (Volumes I, II, III, and IV).

Responsibilities and procedures for writing, coordinating, and clearing, Staff Manual Guides for Organizations and Functions, Volume I; Delegations of Authority, Volume II; and FDA Program Directives, Volume IV are not included in this guide. Please refer to the SMGs referenced in subsection heading 8.B.1 of this guide.

2. POLICY

The FDA Staff Manual Guides (SMGs) Program is the official FDA directives system used to document and publish organizations and functions, delegations of authority, and administrative and program policies, responsibilities, and procedures. These

directives are written to interpret and implement Department of Health and Human Services (HHS) instructions and to provide official instructions when HHS has not issued directions on a subject.

3. RESPONSIBILITIES

A. FDA Office of Operations; Division of Information Governance (DIG). DIG is responsible for implementation of the FDA SMGs Program, including:

1. providing assistance and advice in promoting the issuance of SMGs by other FDA components;

2. controlling the assignment of appropriate numbers to FDA SMGs and circulars prior to issuance, and maintaining a record of assigned numbers so that numbers are not reused;

3. reviewing final approved SMGs for administrative clearance, formatting, and style, and preparing and publishing the SMGs on the FDA Internet and/or Intranet;

4. continuously updating SMG lists on the FDA Internet and/or Intranet; and,

5. storing a record of each FDA SMG, its Clearance Record, and related documentation.

B. FDA Chief Operating Officer:

1. ensures processes are in place so Staff Manual Guides are properly approved, current, and available when needed; and,

2. if requested, renders an official decision to resolve non-concurring clearance comments for a General Administration, Volume III SMG.

C. Other FDA components (organizational units and official (chartered) bodies) are responsible for:

1. ensuring that FDA administrative policies, responsibilities, and/or procedures affecting more than their component are documented in SMGs;

2. ensuring that their SMGs, or internal procedures, do not overlap or conflict with existing SMGs;

3. coordinating and preparing SMGs in final form, including obtaining clearances for issuance from all FDA components whose administrative operations are directly affected by the instructions set forth in the new or revised SMG;

4. updating their SMGs when an FDA Reorganization issues new or revised functions for their FDA component;

5. updating their SMGs when FDA components' policies, responsibilities, procedures, and/or instructions have substantively changed; and,

6. assigning responsibility to federal employee(s) for all issuance actions for SMGs per subsection heading 4.A. below; and for reviewing the currency of the SMGs per subsection heading 5.E. below.

D. FDA components listed on Form FDA 2306, "Clearance Record," whose administrative operations are affected by the new or revised SMG are responsible for the clearance of the directive and will review the directive for content and indicate on the clearance record their concurrence or non-concurrence.

E. If affected FDA components submit non-concurring comments during formal/external clearance for publication or retirement of a General Administration Volume III SMG, the originating FDA component may elect to resolve a non-concurrence issue with a clearing FDA component(s); or,

1. to grant final approval for publication or retirement of SMG, without adjustment, and to add non-concurrence comments to the record of clearance of the SMG; or,

2. to submit non-concurrence issue to the FDA Chief Operating Officer for an official decision.

4. PROCEDURES FOR WRITING AND CLEARING SMGS

A. Types of Issuance Actions for General Administration, Volume III SMGs

1. New SMG — A new SMG is issued when the responsible FDA component for a subject determines the need to establish new FDA policy, to assign responsibilities, to require action, or to set forth information needed for the effective operation of the system. A new SMG must be fully coordinated and cleared.

2. Revised SMG — An SMG is revised when substantive amendments are made to an essential section of a current SMG such as Purpose, Policy, or Responsibilities. A revised SMG must be fully coordinated and cleared.

3. Changed SMG — An SMG is changed when minor/non-substantive amendments are made to a current SMG, such as amendments to organizational names; dates of references; or when amendments are made to

a non-essential section(s) of the SMG. Changed SMGs are cleared only within the responsible office.

4. Reissued SMG — An SMG is reissued when a current SMG is assigned a new approval date and signature similar to 4.A.3 above, in order to certify that the content is current, although no amendments have been made to the SMG. The components involved in the original full clearance should be notified of the intent to reissue the SMG.

5. Retired SMG — An SMG is retired when the responsible FDA component for an SMG determines that it has served the purpose for which it was intended, is no longer needed, and is not appropriate for incorporation into a new or existing SMG.

B. Steps for Processing a General Administration, Volume III SMG for Issuance

NOTE: *The following Tips, Tools and Templates are available on the FDA Intranet: Policies & Procedures page, Staff Manual Guide section, under "Find a Staff Manual Guide".*

- *Subject Categories and Responsible Offices*
- *SMGs Numbering/Subject System*
- *Guidelines for Formatting and Writing Directives*
- *Special Considerations Checklist*
- *Sample Clearance Record (Publication)*
- *Sample Clearance Record (Retirement)*
- *SMG Templates*

1. **Development of the new or revised SMG**: Draft the SMG, and coordinate and clear internally.

    a. Review "SMG Numbering/Subject System," and SMG Lists to ensure your SMG will not overlap or conflict with other current SMGs, and to suggest a four digit subject series number to assign to a new SMG.

    b. Review "Guidelines for Formatting and Writing Directives," and "Special Considerations Checklist," for reference while drafting your SMG.

    c. Select a template (use of template is required).

    d. Draft the new or revised SMG using "Guidelines for Formatting and Writing Directives," and "Special Considerations Checklist" and the template.

    e. Optional: Send draft SMG and/or Clearance Record to the OO/OEMS/DIG for formatting and writing style review.

f. Coordinate and clear the draft of the SMG using the internal procedures of the originating FDA component.

2. **Pre-coordination:** Prepare SMG for formal FDA coordination and clearance.

   a. Determine the FDA components whose administrative operations are directly affected by the instructions set forth in the new or revised SMG, and list on the Form FDA 2306, "Clearance Record". If the originating official body represents the FDA components affected by the draft SMG, list the member's names and office acronyms on the Form FDA 2306 "Clearance Record".

   b. Obtain the signature of the originating FDA component's approving official on the clearance record.

3. **Formal Coordination and Clearance:** Coordinate and clear externally.

   a. Submit the draft SMG and Clearance Record(s) sequentially or concurrently to, and obtain clearances and signatures from, the FDA components listed on the Form FDA 2306, "Clearance Record". Concurrence may be assumed after 30 days if there is no response. Submit copies of the draft SMG to the FDA Executive Officers.

   b. Submit SMG and Clearance Record(s) to originating FDA component approving official (or highest approving official) for final approval and signature.

4. **Administrative Review and Posting to the Web:** Submit SMG and clearance documentation to the OO/OEMS/DIG.

   a. Unless otherwise selected on the Form FDA 2306 "Clearance Record" by the originating FDA component, SMGs will be posted on the www.fda.gov by the OO/OEMS/DIG.

   b. The OO/OEMS/DIG will ensure that SMGs and associated documents are Section 508 accessible.

   c. Submit the following to the OO/OEMS/DIG for administrative clearance and publication of your SMG on the FDA SMGs Internet and/or Intranet Web site:

      (1) Finalized SMG and associated documents in MS Word.

      (2) Completed Clearance Record(s) in PDF.

(3) Metadata for inclusion in FDA Web Content Management System for the SMG:

(a) Detailed Description — A description or summary of the content, limited to 300 characters. The Detailed Description is used by third-party search engines, such as Google and Bing, and is displayed on search results pages. Because search engines can vary in how they display the Detailed Description, include the most important information in the first 140-160 characters for broadest support and to avoid awkward truncation.

(b) Short Description - A concise summary, lead paragraph, or call-to-action, limited to 160 characters. The Short Description can be displayed on FDA.gov web pages to help users scan content. It is displayed on social media networks, such as Facebook and Twitter, when users share content from FDA.gov.

5. PUBLICATION OF SMGS TO THE WEB

A. SMGs may be found by reviewing the SMG Master Lists on Inside.FDA.gov, the SMG Lists on www.fda.gov, or by using the search box for the FDA Internet or the Google SMG Search Box for the FDA Intranet.

B. The SMGs Internet and Intranet Web sites are the sole Web sites where SMGs, and the requirements for writing and publishing SMGs, are posted.

C. FDA components web sites link to their SMGs included on the official SMG Web site, in order to ensure there is one official web page URL for each SMG on the FDA Web sites.

D. The OO/OEMS/DIG will adjust the effective date of a new or revised SMG in General Administration, Volume III or Agency Program Directives, Volume IV to the date an SMG appears on the web

1. New SMGs may be posted to the web with effective date set for a future date.

2. Revised SMGs may not be posted to the web with effective date set for future date (a circular may be posted to the web in the interim).

E. The OO/OEMS/DIG will send notice for scheduled reviews to verify currency of Volume III SMGs on the FDA Web sites.

1. Prior to five years after the publication of a new, revised or reissued SMG, the OO/OEMS/DIG will send 6 month and 3 month reminders to the FDA component with functional responsibility so they may elect:

a. to revise the SMG; or
b. to reissue the SMG (with or without minor changes) as current; or
c. to retire the SMG.

The OO/OEMS/DIG will update the record of the SMG with the notice to, and the response or non-response from, the FDA component that has functional responsibility for the SMG.

2. The OO/OEMS/DIG will automatically retire SMGs over ten years old that have not been revised, reissued or retired.

   a. After the initial 5-year notification (E.1 above), the DIG will send yearly notices of automatic retirement to the FDA component with functional responsibility and to the FDA Executive Officers.

   b. Before 3 months of the automatic retirement date, the DIG will initiate the circulation of Clearance Records for the automatic retirement.

6. PROCEDURES FOR RETIRING AN SMG

A. If, during the review of an SMG or at any other time, the responsible FDA component determines an SMG has served its purpose, is no longer needed, and is not appropriate for incorporation into a new or existing issuance, the responsible FDA component shall initiate its retirement.

B. All retirements may be accomplished by preparing a Form FDA 2306 “Clearance Record” and obtaining the signature of the Director of the responsible FDA component. Send the signed Clearance Record to the OO/OEMS/DIG for administrative clearance and removal of the retired SMG from the SMGs Program Web site.

C. Responsible FDA components also have the option of retiring a SMG by fully coordinating and clearing the retirement of the SMG by the following process.

   1. Follow established procedures within the responsible FDA component to coordinate the retirement internally.

   2. Prepare Form FDA 2306, “Clearance Record,” by listing on the Clearance Record all the FDA components that originally cleared the SMG, and the FDA components that are affected by the retirement of the SMG.

   3. Send the SMG and Clearance Record to, and obtain clearances and signatures from, all the FDA components that originally cleared the SMG and the FDA components affected by the retirement of the SMG. After 30 days, concurrence may be assumed if there is no response. Include copies to the FDA Executive Officers.

4. If an FDA component listed on the Clearance Record submits non-concurring comments, the responsible FDA component may elect to follow one of the steps in subsection heading 3.E. of this guide.

5. Send signed clearance record(s) to the OO/OEMS/DIG for administrative clearance and removal of the retired SMG from the SMGs Program Web site.

7. DEFINITIONS

A. **Approving Official:** The director or chair of the originating FDA component grants final approval for a new or revised SMG. When an SMG publishes or revises FDA policy, the director of the FDA office that has functional responsibility for developing the subject policy grants final approval (see SMGs Organizations and Functions, Volume I). A higher approving official may be designated by consensus for cross-cutting FDA SMGs.

B. **Circular:** A circular contains the same basic information as an SMG but is used to issue temporary instructions, which are applicable for one time only or for a limited period of time.

C. **Directive:** A directive is a written communication issued in an organized system to establish organizations, functions, delegations, policies, responsibilities, or procedures; to require action; or to set forth information needed for the effective operation of the system. As used in this Guide, the term “directive” refers to a Staff Manual Guide or circular.

D. **Effective Date:** The date when the SMG becomes operative or active.

E. **Originator:** The FDA component that creates or revises an SMG.

F. **Responsible component:** The FDA component that is the lead for publishing, certifying as current, or retiring an SMG. The functional statements in Organization and Functions, Volume I of the SMGs document the subjects for which FDA components are responsible.

G. **Staff Manual Guide:** An SMG is used to publish authoritative guidance, and continuing instructions or information, and remains in effect until rescinded or superseded. Each SMG is separately identified by the administrative or program area covered and the subject matter and is published by posting to the FDA Intranet and/or Internet.

8. BACKGROUND

A. Authorities

1. Department Staff Manual System. (Reference: HHS Administrative Manuals, https://www.hhs.gov/about/hhs-manuals/index.html)

B. References

1. Directives for Writing, Coordinating, and Clearing SMGs.

   a. Organizations and Functions, Volume I: SMG 1005.1, "Policy and Procedures Regarding Organizational Changes," and SMG 1005.2, "Guidelines for Editing/Creating Organizational Charts."

   b. Delegations of Authority, Volume II: SMG 1401.1, "Policy and Procedures Governing Regulatory and Administrative Delegations of Authority (DOAs)."

   c. General Administration, Volume III: SMG 3280.1, "FDA Administrative Directives."

   d. FDA Program Directives, Volume IV: SMG 3280.2, "FDA Program Directives System."

2. FDA Intranet resources:

   a. Plain language site

   b. SMG Tips, Tools and Templates

9. EFFECTIVE DATE.

The effective date of this guide is November 29, 2018.

10. Document History — SMG 3280.1, FDA Administrative Directives

STATUS (I,R,C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	01/06/2005	N/a	PRA and Records Management Branch (HFA-250)	Mark Pincus, PRARMB Chief
Change	10/20/05	4.C.1.	PRA and Records Management Branch (HFA-250)	Mark Pincus, PRARMB Chief
Revision	11/28/2018	N/a	OO/OIMT/OIM/ OBCA/RERM	Tiffany Branch, OC Executive Officer, Acting
Change	06/11/2019	Change RERM to DIG. Sect. 8.A.1.	OO/OEMS/DIG	Jonna Capezzuto, Director, Division of Information Governance

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