

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

INFORMATION RESOURCES MANAGEMENT

DIRECTIVES MANAGEMENT

FDA ADMINISTRATIVE DIRECTIVES

Effective Date: 01/10/2005

Changed: 10/20/2005

**NOTE: This SMG is being revised**

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**1. PURPOSE**

This Guide establishes procedures for issuing administrative policy, procedures, and instructions in the form of directives relating to functions and operations of the Food and Drug Administration. These directives are written to implement Department of Health and Human Services (HHS) instructions, to set forth FDA organizations and delegations of authority, and to develop procedural guidance when HHS has not covered the subject.

**2. DEFINITIONS**

**A. Directive.** A directive is a written communication issued in an organized system to establish policy, procedures, responsibilities or organization; 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 guide or circular.

- B. Guide.** A guide is used to issue continuing instructions or information and remains in effect until rescinded or superseded. Each guide is separately identified by the administrative area covered and subject matter and is published by posting to the FDA Intranet or Internet.
- C. Circular.** A circular contains the same basic information as a guide but is used to issue temporary instructions, which are applicable for one time only or for a limited period of time.
- D. Effective Date.** The date, set by the approving official, when the directive becomes operative or active. The Effective Date is assigned after the directive has been cleared by all FDA Offices whose administrative operations are directly affected by the instructions set forth in the directive; finalized by the originating office, and issued for posting to the FDA Intranet or Internet.
- E. Revision.** Substantive amendments to the purpose, policy, responsibility or procedures, or functional statements of a current directive. The revised directive is cleared by all FDA Offices whose administrative operations are directly affected by the instructions set forth in the directive; given a new effective date; supersedes the previous directive; and is posted to the FDA Intranet or Internet.
- F. Change.** Minor/non-substantive amendments to a current directive, such as amendment of a word in a title or of dates of references. Changes to a directive do not need to be cleared, by FDA offices whose administrative operations are directly affected by the directive, before posting to the FDA Intranet or Internet. Changes to a Staff Manual Guide (SMG) can be tracked by referring to the Document History section of a SMG.

### 3. POLICY

The FDA will use the uniform system prescribed in this Guide for issuing SMGs on administrative matters.

### 4. RESPONSIBILITIES

- A. Paperwork Reduction Act and Records Management Branch, DMS (HFA-250).** The Paperwork Reduction Act and Records Management Branch is responsible for implementation of the administrative directives system within FDA, including:

1. Providing assistance and advice in promoting the issuance of instructions by other FDA organizations.
2. Reviewing FDA directives prior to final approval and issuance and preparing the directives for final publication on the FDA Intranet or Internet.
3. Controlling the assignment of appropriate numbers to FDA Guides and circulars prior to issuance.
4. Posting all finally approved directives to the FDA Intranet or Internet site and maintaining the site.
5. Updating SMG Tables of Contents and the Index pages on the FDA Intranet or Internet.
6. Maintaining a record copy of each FDA directive, Clearance Record, and related documentation.
7. Preparing directives pertaining to program areas within the Branch.

**B. Associate Commissioner for Management, FDA is responsible for:**

1. final approval and signature of a directive if it issues or revises an Agency policy, and
2. making the final decision in the event of unsettled conflicts among affected offices and the originating office regarding final form of a directive.

**C. Other Organizational Components in FDA.**

1. **FDA Directives.** FDA program components are responsible for:
  - a. Ensuring the development of instructional material into directives pertaining to their programmatic activities.
  - b. Coordinating and preparing these directives in final form including obtaining clearances for issuance from all offices whose administrative operations are directly affected by the instructions set forth in the directive.
  - c. Updating their directives when office administrative policy, procedures or instructions have changed significantly.
  - d. Designating a point of contact for each directive used.

- e. Maintaining copies of the FDA SMGs they issue, in the manner the offices choose.

**2. Internal Center and Office Directives.** Offices and Centers are also responsible for issuing internal administrative-management directives within their organizations, as needed. Such instructions are issued as Office or Center guides and circulars in accordance with the general FDA administrative directives system set forth in this Guide. Offices and Centers maintain record copies of internal Center or Office guides and circulars in the manner the offices choose.

## **5. FORMAT**

A. The format used for text, section headings, headers, footers, and tables of contents will follow the format demonstrated throughout this guidance and in Attachment C, Guidelines for Writing Directives.

B. Identification and Numbering. Each directive is identified by a three-part identification consisting of:

1. The guide acronym (SMG).
2. The four-digit subject category or sub-category number.
3. A sequential number. A number preceded by an "h" (i.e., FDA h:2240.1) indicates it pertains to Headquarters personnel only. A number preceded by an "f" (i.e., FDA f:2240.1) indicates it pertains to field personnel only.

PRARMB (HFA-250) controls assignment of appropriate numbers to guides and circulars.

## **6. PROCEDURES FOR ISSUANCE**

### **A. FDA Directives.**

- 1. General.** FDA directives are written to interpret and implement Department of Health and Human Services instructions, to set forth FDA organization and delegations of authority, and to develop original instructions when a subject matter has not been covered by HHS. The series 1000 - 1300 is used to issue functional statements for organizations within FDA. The series 1400 is used to issue delegations of authority. The series 2000 - 3999 is used to issue basic instructions in the general administration area. (See Attachment A for subject categories.)

2. **Preparation.** Please see Attachment C, Guidelines for Writing Directives.

3. **Coordination and Clearance.**

a. **Clearance Record.** The originating organization is responsible for obtaining clearance of a new or revised directive prior to issuance. Coordination and clearance are accomplished by completing Form FDA 2306, "Clearance Record" (See Attachment B). The form is prepared by obtaining the signature of the originating office's approving official and listing all offices whose administrative operations are directly affected by the instructions set forth in the directive. When FDA directives are revised, the author of the directive should provide a concise summary of the changes and additions in section 4 of Form FDA 2306.

b. **Clearance Responsibilities.**

(1) **Originating Office.** The approving official for the originating office must sign the clearance record for each directive before forwarding the directive to affected offices. The manner in which the originating office distributes the directive and clearance record to affected offices for clearance, whether electronically or by hardcopy (sequentially or concurrently), is left to the decision of the originating office, with guidance from PRARMB.

(2) **Affected Offices.** Affected offices listed on Form FDA 2306 are responsible for the clearance of the directive and will review the directive for content and indicate on the clearance record their type of concurrence or nonconcurrence and sign the clearance record. Affected offices that have not returned the clearance within 30 days may be deemed to have concurred. Further, 45 days after the draft directive is distributed to affected offices, any unsettled conflicts among affected offices and the originating office regarding final form of a directive may be submitted to the Associate Commissioner for Management for final decision.

(3) **Paperwork Reduction Act and Records Management Branch.** After all responsible offices have cleared the directive, it is forwarded, in final form along with the completed Form FDA 2306 Clearance Record, and any supporting documents, to the Paperwork Reduction Act and Records Management Branch (HFA-250), which is responsible for administrative clearance of the directive.

After review by the Paperwork Reduction Act and Records Management Branch, the directive is forwarded to the Associate Commissioner for Management for final approval and signature on the clearance record if it issues a new Agency policy. Following the signature, the directive is returned to the Paperwork Reduction Act and Records Management Branch where it is prepared for publication by inclusion on the FDA Intranet or Internet.

## **B. Internal Center and Office Directives.**

- 1. General.** Administrative management instructions prepared for general application within a Center or Office are issued in accordance with the instructions set forth in this Guide. In most cases these directives are issued to supplement existing FDA directives and carry the same number as the supplemented material, with the center or office identification preceding the number. Internal directives, if printed, are to be printed on colored paper to distinguish them from FDA directives.
- 2. Coordination and Clearance.** Internal directives are cleared in the same manner as FDA directives. The designated organization within a Center or Office performs the same type of review and coordination for its issuances as the Paperwork Reduction Act and Records Management Branch performs for FDA issuances. The directives are reviewed for such items as format, content, and coordination prior to submission for approval to the Center or Office director. Center or Office directives may be submitted to the Paperwork Reduction Act and Records Management Branch (HFA-250) for review, if so desired.

## **7. INTRANET/INTERNET POSTING**

- A. FDA Directives.** After clearance and approval of the final digital copy, the Paperwork Reduction Act and Records Management Branch prepares and posts all directives. All current FDA directives are found on the FDA Intranet or Internet site.
- B. Internal Center and Office Directives.** The originating office prepares all their directives for posting on the FDA Intranet site.

## **8. SEARCHING FOR SMGS**

Specific SMGs may be located by using the SMG Search Box on the Intranet SMG Homepage, and SMG Tables of Contents; and on the Internet SMG Table of Contents. SMGs may also be located by browsing the Intranet SMG Table of Contents by Number/Title and/or the SMG Table of Contents by

Functional Subject; or Internet SMG Table of Contents and clicking on the desired SMG number. The SMG Tables of Contents are continuously updated to provide a listing of current issuances for ready reference. Tables of Contents list the SMG identification numbers, titles, and dates posted to the FDA Intranet/Internet.

**9. EFFECTIVE DATE**

The effective date of this guide is January 10, 2005.

**10. Document History -- SMG 3280.1, FDA Administrative Directives**

**NOTE: This SMG is being revised.**

<b>STATUS (I, R, C)</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
Initial	01/06/2005	n/a	PRA and Records Management Branch (HFA- 250)	Mark Pincus, PRARMB Chief
Change	10/20/2005	4.C.1.	PRA and Records Management Branch (HFA- 250)	Mark Pincus, PRARMB Chief

FDA Administrative Directives System - SMG 3280.1 Attachment A

SUBJECT CATEGORIES AND RESPONSIBLE OFFICES

SUBJECT CATEGORIES	FDA OFFICES HAVING PRIMARY RESPONSIBILITY
1000-13000 <u>ORGANIZATIONS AND FUNCTIONS</u>	Office of Management Programs
1005            Organizational Changes	
1010            Administrative (Organizational) Codes	
1100            Office of the Commissioner	
1120            Office of Regulatory Affairs-Headquarters	
1210            Center for Biologic Evaluation and Research (CBER)	
1220            Center for Food Safety and Applied Nutrition (CFSAN)	
1240            Center for Veterinary Medicine (CVM)	
1250            Center for Devices and Radiological Health (CDRH)	
1260            Center for Drug Evaluation and Research (CDER)	
1280            National Center for Toxicological Research (NCTR)	
1300            Office of Regulatory Affairs-Field	
1400 <u>DELEGATIONS OF AUTHORITY</u>	Office of Management Programs
1400            General Agency	
1410            General Administration	
1425            Material Management	
1430            Personnel	
1435            Printing	
1440            Procurement	
1445            Facilities Management	
1450            Telecommunications	
1455            Travel	
1460            Committee Management	
1465            Financial Management	
2000 – 3999     GENERAL ADMINISTRATION	
2000 <u>FDA Official Councils and Committees</u>	Office of the Commissioner
2110 <u>Committee and Conference Management</u>	Office of External Relations
2111     Advisory Committees	
2120 <u>External Relations</u>	
2123     Meetings	Office of Legislative Services
2127     Hearings	
2129     GAO and HHS/IG Audit Guidelines	Office of Policy and Planning Office of Management Programs
2130 <u>Safety and Occupational Health Programs</u>	Office of Real Property Services

FDA Administrative Directives System - SMG 3280.1 Attachment A

SUBJECT CATEGORIES AND RESPONSIBLE OFFICES

SUBJECT CATEGORIES		FDA OFFICES HAVING PRIMARY RESPONSIBILITY
2150	<u>Grants Administration</u>	Office of Acquisitions and Grants Services
2170	<u>Motor Vehicle Management</u>	Office of Financial Management
2180	<u>Consumer Affairs</u>	Office of Consumer Affairs
2200	<u>Administrative Services</u>	Office of Management Programs
2205	Printing – General	
2220	Acquisition of Printing and Duplicating Equipment	
2240	Office Services	
2250	Mail Management	Office of Real Property Services
2260	Personal Property	
2280	Security	Office of Management Programs
2300	<u>Financial Management</u>	Office of Financial Management
2310	Budget	
2340	Travel	Office of Financial Services
2350	Financial Integrity	Office of Management Programs
	Facilities Management	Office of Real Property Services
2530	Construction	
2560	Space Management	
2600	<u>Procurement and Supply Management</u>	Office of Acquisitions and Grants Services
2610	Procurement	
2620	Personal Property	
2800	<u>Agreements with Other Government Agencies</u>	Office of Acquisitions and Grants Services
2810	Interagency Agreements	
2820	Memorandums of Understanding	
2830	Arrangements with Foreign Governments: MOUs, Confidentiality Commitments	Office of International Programs
3100	<u>Personnel</u>	Office of Management Programs
3111	General Personnel Provisions	
3112	Employment	
3113	Incentive Awards	
3114	Position, Classification, Pay and Allowance	
3115	Attendance and Leave	
3116	Personnel Relations and Services	
3117	Insurance and Annuities	
3118	Conflict of Interest	Office of Management Programs
3119	Staff Development and Training	Office of Shared Services
3130	Reasonable Accommodation and Accessibility	Office of Equal Employment Opportunity and Diversity Management
3140	Ethics and Labor Management Relations	Office of Management Programs

FDA Administrative Directives System - SMG 3280.1 Attachment A

SUBJECT CATEGORIES AND RESPONSIBLE OFFICES

SUBJECT CATEGORIES

FDA OFFICES HAVING  
PRIMARY RESPONSIBILITY

3200 Information Resources Management

Office of the Chief  
Information Officer

- 3210 Information Technology Management
- 3215 Internet/Intranet Management
- 3220 Telecommunications Management
- 3230 Information Systems Architecture
- 3235 Information Technology Connectivity
- 3240 Information Technology Acquisitions
- 3250 Information Technology Security
- 3260 Data Management
- 3270 Paperwork Reduction Act/OMB Clearance
- 3280 Agency Directives
- 3291 Records Management
- 3295 Forms Management
- 3298 Information Dissemination

## GUIDELINES FOR WRITING DIRECTIVES

### Document Size

All guides should be formatted for 8.5 by 11-inch paper.

### Page Margins

Set the top and bottom margins at 1.00 inch and the right and left margins at 1.25 inch.

### Outline Structure

The outline structure for the section headings is as follows:

1. Section Heading 1
  - A. Heading 2
    1. Heading 3
      - a. Heading 4
        - (1) Heading 5
          - (a) Heading 6
            - i. Heading 7

### Section Headings and Paragraphs

Number all section headings sequentially. Use Arabic numerals and separate title numbers and the section title text with a period and two spaces.

Use capital letters for all words in section headings. Use initial capital letters for all words in paragraph headings.

The following are section headings that can be included:

**NOTE:** Some are **MANDATORY** and others are **OPTIONAL**.

## SMG 3280.1, FDA Administrative Directives – Attachment C

- **PURPOSE**

State the reason for the publication. Describe why it is needed and what it is intended to do. **MANDATORY**.

- **REFERENCES**

List references in the same sequence as they are cited in the text of the document. Regulations related to this guide are not necessarily cited. **OPTIONAL**

- **HISTORY**

Paperwork Reduction and Records Management Staff (PRRMS) will complete this section on the history of the SMG and post it with the directive to the FDA Internet or Intranet. Please provide the following information on Form FDA 2306, Clearance Record: the date of final approval; point of contact for the SMG; and name and title of the final approving official for the SMG. **MANDATORY**

- **DEFINITIONS**

Use only if a publication introduces new terms or establishes a specific meaning to a term. List within this paragraph unless large numbers of definitions are used. If large numbers are used, list within an appendix. **OPTIONAL**

- **BACKGROUND**

Summarizes pertinent information that helps the reader better understand the guide. **OPTIONAL**

- **FORMS**

Use only if a publication introduces forms. List in this paragraph if five or fewer items are cited; if six or more items are cited, list in an appendix. **OPTIONAL**

- **POLICY**

Include policy statement(s) when OC policy is established.

**OPTIONAL** for Organizations and Functions, Volume I and Delegations of Authority, Volume II.

**MANDATORY** for General Administration Guides, Volume III.

## **SMG 3280.1, FDA Administrative Directives – Attachment C**

- **RESPONSIBILITIES**

Identify by title the specific official(s) responsible for implementing the policy(s) and procedure(s) in the publication. When appropriate, identify by title the action office responsible and state any limitation of authority. **MANDATORY**

- **PROCEDURES**

This portion is the "how to" of the publication; that is, it tells how the office intends to carry out its policy. **OPTIONAL**

- **EFFECTIVE DATE**

State the date, set by the approving official, when the directive becomes operative or active. **MANDATORY**

State which SMG(s) is being superseded, and if the SMG is being renumbered. **OPTIONAL**

- **Other Section Headings**

Use other major section headings required to accommodate material that does not logically fall into the above categories. **OPTIONAL**

- **Appendices**

Use appendices to include lengthy supplementary, illustrative, and other material that cannot be incorporated into the body of the publication. Give brief descriptive titles to all appendices. The appendices will be posted as attachments to the directive.

### **Spacing**

Set the line spacing at 1.0.

Use a blank line to separate section headings from the text that precedes and follows. Also use a blank line to separate paragraphs.

Avoid widows and orphans (single lines of text at the top or bottom of a page).

### **Acronyms/Abbreviations**

When a set of words has an acronym or a word has an abbreviation that will be used more than once in the text, spell out the word or phrase the first time it is used, then follow with its acronym/abbreviation in parentheses (e.g., Office of the Commissioner (OC)). Thereafter, the acronym/abbreviation can stand-alone.

## **SMG 3280.1, FDA Administrative Directives – Attachment C**

### **Bolded Words**

A bold font may be used to emphasize those words, phrases and sentences that are really important.

### **Capitalization**

Use initial capital letters for all words in paragraph titles, column heading titles and table titles except the following words:

- Articles such as "the", "a", "an." (Capitalize them only when they are the first word in the title.)
- Prepositions such as "for", "in", "of", "on", "to." Capitalize prepositions longer than five letters, such as "between" and "during"; the word "to"; when it is part of an infinitive verb, such as Procedures To Implement Changes; and any preposition when it is the first word in a sentence.

### **Figures and Tables**

Figures and tables should be functional, not decorative or simply nice to have. An effective figure or table is one that replaces or clarifies a complicated verbal explanation and gives the user insight and added clarification.

Figures and tables must be keyed and cited in the text. Number figures and tables separately and in the order in which they are cited.

Figures and tables may be in the text near the topics they relate to or at the end of the chapter. However, wide separation between the two may discourage their use and/or obscure their meaning.

### **Images**

Images used in directives must be Section 508 Accessible. When sending the finalized directive to the PRRMS for publishing on the Intranet or Internet, include a JPG or GIF version of the image, along with alternate text which is a text description of the image that will be linked to the image in the web version of the directive.

### **Font**

Use Times New Roman 12 throughout the body of the directive.

## **SMG 3280.1, FDA Administrative Directives – Attachment C**

### **Gender Distinctions**

Avoid using male-oriented job titles, such as "fireman" and "policeman." Use "firefighter" and "police officer" instead. Use other gender-neutral references, such as "the investigating officer," "the applicant" or "the traveler."

Avoid using masculine and feminine pronouns by substituting interchangeable words that convey the meaning of the text. Substitute the plural forms (they, them or their) for the singular forms (he, she, him, her, his) to avoid gender distinctions.

Use inclusive singular pronouns when possible. Instead of using "he," "his" or "him," use "he or she," "his or her" or "him or her."

### **Justification**

Use left justification for all documents.

### **Lists – General**

Make sure there are at least two items in a list.

### **Lists – Vertical**

In vertical lists, separate the numbers or letters from the text with two spaces (see fig. 1). Use numbered lists to list steps in a procedure or for lists in which items must be shown in an ascending sequence.

Each item in the enumeration begins its own line, which is indented. Run over lines are aligned with the first word that follows the number or letter, and figures are aligned on the periods or closed parenthesis that follow them. Each item on the list is capitalized if the items are syntactically independent of the words that introduce them. The items do not end with periods unless at least one of the items is a complete sentence, in which case a period follows each item. Items that are syntactically dependent on the words that introduce them begin with a lowercase letter and carry the same punctuation marks that they would if they were a run-in series in a sentence.

**Fig. 1**

1. XXXXXXXXXXXXXXXXXXXXXXXXXXXX
  - a. XXXXXXXXXXXXXXXXXXXXXXXXXXXX  
XX
    - (1) XXXXXXXXXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXX
    - (2) XXXXXXXXXXXXXXXXXXXXXXXXXXXX
    - (3) XXXXXXXXXXXXXXXXXXXXXXXXXXXX

If possible, make sure that all items in the list are in parallel grammatical form. For example, if one item is a complete sentence then all items should be complete sentences.

**Lists – Bulleted**

A bulleted list may be used if the sequence of the items is not important (see fig. 2).

**Fig. 2**

- XXXXXXXXXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXXXXXXXXX
- The first level of the list is indented one tab stop and uses a small bullet. Indent the text one tab stop.
    - The second level uses a small circle. Use one indent before and after the circle.
      - The third level uses a dash. Use two indents before and one tab stop after the dash.

If you have additional information attached to a bulleted item, indent the text so that it is flush with the text in the bulleted item (see fig. 3).

**Fig. 3**

- Bulleted information  
Information that relates to the bulleted information.

If all items in a bulleted list are single lines of text, compress them so that there are no empty lines between them (see fig. 4).

**Fig. 4**

- XXXXXXXXXXXXXXXXXXXXXXXXXXXX
- XXXXXXXXXXXXXXXXXXXXXXXXXXXX

## SMG 3280.1, FDA Administrative Directives – Attachment C

If one or more items in the bulleted list wrap to two or more lines of text, insert a blank line between items (see fig. 5).

**Fig. 5**

- XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXXXXXXXXX
  
- XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXXXXXXXXX

### Note Form

Use the heading "NOTE" to call attention to important information. However, do not use too many notes or they will lose their importance (see fig. 6).

**Fig. 6**

**NOTE:** Treat a note as a paragraph. The word note should appear flush left to the margin, in boldface type, and be followed by a colon. Leave two spaces between the colon and the note text.

### Numbers

Spell out numbers of one or two words or those that begin a sentence (e.g., two, twenty-one, Ten people attended the meeting).

Use figures for numbers that require more than two words to spell out (e.g., 325).

**NOTE:** Time, money, and measurement are always written as figures.