SMG 3280.2

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

INFORMATION RESOURCES MANAGEMENT

DIRECTIVES MANAGEMENT

FDA PROGRAM DIRECTIVES SYSTEM

Transmittal Number 84-5 -- Date: 01/16/1984

NOTE: This SMG is being revised

1. PURPOSE

This Guide sets forth procedures to be followed in issuing program directives, in hardcopy or microfilm, which relate to functions and operations of the Food and Drug Administration.

2. DEFINITIONS

A. Program Directive. A program directive is a written communication issued in an organized manual system to establish policy, procedures, and/or responsibilities; to provide information; to require action; or to set forth instructions to be used in the effective operation of a program.

B. Manual. A manual is an orderly collection of written instructions, directions, facts, or data pertaining to the affairs and activities of an organization or operating system.

3. TYPES OF PROGRAM DIRECTIVES

A. Internal Program Directives. Directives issued by an FDA Bureau/Center/Office outlining specific policy or procedures applicable only to that particular organization (i.e., Bureau of Foods Laboratory Quality Assurance Manual) are considered to be internal program directives and are not covered under this Guide. However, many of the principles outlined in this Guide may be applied to directives developed within a Bureau/Center/Office.

B. Agency Program Directives. Directives issued by an FDA Bureau/Center/Office outlining overall Agency policy, procedures, and/or instructions which are applicable to Headquarters, the Field, or both (i.e., Compliance Program Guidance Manual, Regulatory Procedures Manual, etc.) are considered to be Agency program directives and are covered by this Guide. Attachment A sets forth a list of program directives and a brief description of each directive.

4. RESPONSIBILITIES

A. General. In most cases the organization which originates a program directive is also the issuing organization but there are some exceptions. The Management Methods Branch, Division of Management Services, has responsibility for coordinating the issuance of specific program directives including Analyst Operations Manual, Compliance Policy Guides, Compliance Program Guidance Manual, Pesticide Analytical Manual, and Regulatory Procedures Manual. In these instances the Management Methods Branch has the **same responsibilities for coordinating issuance as an originating office.**

B. Management Methods Branch, DMS. The Management Methods Branch (MMB) is responsible for:

1. Publishing guidelines pertaining to the issuance of program directives and assisting organizations in their efforts to comply with these guidelines.

2. Monitoring all phases of directives activities throughout the Agency.

3. Preparing and distributing specific program directives, which have been identified in 4.a. of this Guide, for issuance including:

a. Establishing and maintaining functional distribution lists.

b. Preparing tables of contents.

c. Preparing cover information for new and revised directives specifying the purpose of the directive and explaining the changes in the revisions.

d. Responding to requests for program directives from Federal, State, and local government employees.

4. Maintaining permanent record copies of directives within its area of responsibility.

5. Ensuring that program directives are issued under proper numbering systems.

6. When necessary, processing manual material for microfilming and monitoring production of microfilm products.

7. Submitting purged material or ensuring that purged material is submitted to the National Technical Information Service (NTIS) and the Freedom of Information Staff for distribution under the Freedom of Information Act.

8. Negotiating with NTIS for submitting manuals into their system.

C. Bureaus/Centers/Offices. Organizational components in FDA who are preparing and issuing program directives are responsible for:

1. Ensuring that directives pertaining to their assigned functions and programs are planned, developed, issued, and revised as needed.

2. Ensuring that all directives developed in their offices meet the standards and requirements set forth in this Guide.

3. Ensuring that the program directive subject matter is clear and concise.

4. Coordinating directives in final form including clearance for issuance.

5. Preparing and distributing program directives, within their area of responsibility, for issuance including:

a. Establishing and maintaining functional distribution lists.

b. Preparing tables of contents.

c. Preparing cover information for new and revised directives which specifies the original purpose of the material and changes as they occur.

d. Submitting material to NTIS and FOI staffs (thru MMB) for distribution under the FOI Act.

6. Reviewing annually all existing directives to revise or terminate those directives which have become obsolete.

7. Maintaining permanent record copies of directives within their area of responsibility.

5. COORDINATION AND CLEARANCE PROCEDURES

A. General. Usually the originating organization is responsible for obtaining clearance of program directives, when necessary, prior to issuance. However, the Office of Regulatory Affairs/Executive Director of Regional operations, is responsible for preparing and obtaining clearances for new or revised policy statements that are published in the Compliance Policy Guides. (If a program directive affects only the issuing organization, formal clearance will not be necessary.) The clearance process is used to review directive material in order to resolve differences and incorporate suggestions or improvements.

B. Clearance Record. Coordination and clearance are accomplished by using Form FD 2306, "Clearance Record". The form should be prepared as set forth in Attachment B. The form should list all offices whose operations will be directly affected by the directive. Special care should be taken to insure that program material is cleared by those having proper authority.

6. MANUAL FORMAT

A. Introduction. Each manual should contain an "Introduction", which describes the manual's design and the mechanics of its use, including the organization of the manual, page numbering system, index, and updating procedures. The "Introduction" should also set forth the purpose of the manual and any specifics which will enhance the use of the manual.

B. Identification and Numbering.

1. Series and Non-Series Identification. A numerical series has been designed which designates various Agency program management

areas. The series, which numbers from 4000 through 8999, is broken down into the following specific parts:

a. Laboratory Programs (Analytical) 4000 - 4999

b. Laboratory Programs (Methodology) 5000 - 5999

c. Inspection 6000 - 6999

d. Compliance 7000 - 7999

e. FDA-State Relations 8000 - 8999

2. Numbering. Program directives covered under this Guide should be issued In standard manual format with the manuals subdivided into parts. (Not all program directives are issued under this system. In those cases, the introduction to the manual should set forth the specific numbering system and how it is used.) The use of numbers and letters following the decimal point, will make further breakdown possible. Generally, the program directives should follow the format illustrated below:

7			Part
	3		Manual
		03	Chapter
		.001	Section
		.001A	Subsection

C. Tables of Contents.

1. Manual Table of Contents. Each manual should have a consolidated table of contents for the entire manual which is issued periodically. The table should show the title; date of issuance; the directive identification; and, if appropriate, transmittal numbers.

2. Chapter Table of Contents. Each chapter of a manual should have a table of contents which shows the material contained in the chapter. The individual tables should show the title; date of issuance; the directive identification; and, if appropriate, transmittal numbers. The chapter table of contents should be updated each time material in that chapter is changed.

D. Page Format. The format of pages to a manual should include the following information:

1. Title of the manual

2. Document number

3. Publication or revision dates

4. Page Number

   (The pages on some microfiched manuals no longer show the title of the manual since on microfiche it is not possible for a page to be misplaced or confused with a page from another manual.)

E. Forms To Be Used. Many of the program directives use specific forms for publishing material. These forms should be used at all times. The FDA Section of the PHS Forms Catalog lists appropriate forms to be used and the particular stocking point for each form.

7. MANUAL TRANSMITTALS

All program directives should be issued under a transmittal or covering document whether in hardcopy or on microfiche. The following information should appear on the transmittal:

1. Transmittal number and date. (Microfiche transmittals are not numbered since the date serves as identification.)

2. Title of transmitted material and identification number.

3. Superseded material, if appropriate.

4. Filing instructions.

5. Explanation of changes.

8. MANUAL INFORMATION RETRIEVAL

Information in manuals should be easy to retrieve. There are various techniques that can be used for facilitating the retrieval of information. Attachment C sets forth some useful tips on information retrieval.

9. PRINTING

After clearance and approval of the final typed copy, the directives should be prepared for printing. Printing should be accomplished through the PHS Administrative Services Center by use of Form HHS-26, "Request for Duplicating, Photographic, and Miscellaneous Processing".

10. DISTRIBUTION

Distribution of program directives should he accomplished in accordance with established mailing lists. Requests for additions or deletions to distribution lists should be referred to the office responsible for the distribution of a particular manual. (See Attachment A.) The responsible office should ensure that (1) Form HEW-26 contains instructions for distribution and (2) the distribution lists are current.

11. MICROFICHE PRODUCTION

All program manuals which are issued on microfiche should be forwarded to the Management Methods Branch for processing. The distribution of the manuals should be accomplished in accordance with established distribution lists maintained either by the Management Methods Branch or the originating organization. Additions or deletions to these lists should be referred to the office responsible for distribution of the particular manual. (See Attachment A.)

12. STORAGE OF STOCK

A supply of directives, in excess of that needed for initial distribution, should be retained for stock to fill requests for additional copies. The originating office may take advantage of the storage facilities and distribution services provided by the Material Management Operations Division (MMOD), PHS. The Management Methods Branch will provide consultant services to FDA organizational components who desire to store and distribute their stock through MMOD.

13. RECORDS

A record copy of each program directive issued should be maintained as a permanent record by the issuing office. The record copy should consist of the completed Clearance Record (Form FD 2603), related documentation, and a printed copy of the directive.

NOTE: This SMG is being revised.

Techniques to Enhance Information Retrieval of a Program Manual

Transmittal Number 84-5 -- Date: 01/16/1984

A. General.

Information retrieval should be a prime consideration in the development of program manuals. Manual users must be able to obtain information in a quick, accurate, and convenient manner. If a manual proves otherwise, the user may become frustrated and may not consult the manual. In considering retrieval of information, one should keep in mind the principle, "Think of the User." If this fundamental approach is followed, then implementation of the techniques outlined below will not be an add-on function but an integral part of the development plan.

B. Techniques.

1. Binders.

The binder is the users first exposure to the program manual. If the binder looks attractive, perspective users will open the manual, but if it looks forbidding they might avoid it. The first impression can influence one's attitude toward the contents; it immediately portrays how much (or how little) effort has gone into the development of the manual. When selecting binders, one should consider factors such as size, capacity, style, construction, color, cover design, imprinting, durability, and cost.

2. Title of the Manual.

The title of the manual should be placed on the binder's spine. In multi-volume manuals, the title of the manual and a sub-title for the particular volume should be placed on the spine. As an example, when a manual comprises four volumes with each volume titled, "Policy and Procedures" and differentiated only by numbers I, II, II, and IV on the spine, the user plays a guessing game in determining which volume contains the information that is desired. Since each volume probably contains a particular class of information, it would be a simple matter to give each its own distinctive sub-title.

3. Tabbed Dividers.

Tabbed dividers permit a further breakdown of program information. They should contain distinctive titles instead of numbers so that the user can accurately pinpoint the part of the manual that they can reasonably expect to find the information they are seeking.

4. Index.

The index is probably the most important tool used in retrieval of information from a manual. Three types of indexes generally used are as follows:

a. General Index. This is a list of alphabetically arranged keywords that were extracted from the documents which make up the manual. It is similar to the indexes one finds in a textbook.

b. Contents or Numeric Subject Index. This index lists the subjects by number.

c. Alpha Subject Index. This index lists the subjects alphabetically. A cross reference check is also developed within this index to provide an additional resource.