SMG 7300.1

FDA STAFF MANUAL GUIDES, VOLUME IV – AGENCY PROGRAM DIRECTIVES

COMPLIANCE

MANAGEMENT OF THE COMPLIANCE PROGRAM GUIDANCE MANUAL

Effective Date: 07/01/2016

1. PURPOSE.

The Compliance Program Guidance Manual (CPGM) provides a convenient and organized system for publishing ***compliance programs***. This Staff Manual Guide (SMG) establishes procedures for developing and maintaining the FDA compliance programs that collectively make up the CPGM.

FDA Centers and other components with functional responsibility for a ***program*** area issue compliance programs (Volume I of the FDA Staff Manual Guides for functional statements by organization). Compliance programs generally provide:

- Specific instructions for inspectional, investigational, sampling, and analytical operations
- Instructions for gathering and presenting evidence to support FDA's regulatory actions
- Instructions for gathering product or industry information to determine the existence or extent of a problem

2. POLICY.

A. Compliance programs are internal agency procedures. FDA does not provide interpretation of, or policy on, regulatory issues in compliance programs. Compliance programs are not guidance documents as defined in good guidance practices (GGPs) regulations found in 21 CFR 10.115(b) and (b)(3).

B. To promote transparency, the CPGM is available to the public on the FDA internet.

C. The development and clearance of compliance programs is a collaborative process involving the organizations pertinent to the program topic.

3. RESPONSIBILITIES.

A. Joint Responsibilities. The development and ***issuance*** of compliance programs requires cooperation between the ***originating office***, the Office of Regulatory Affairs (ORA), and any other FDA ***collaborating office*** relevant to the compliance program. These offices:

1. Collaborate on the strategic and tactical direction of a compliance program, including objectives, timetables, and goals
2. Identify appropriate approaches that FDA staff use to evaluate industry compliance with the FD&C Act and other laws administered by FDA
3. Seek and provide input into operational considerations relevant to accomplishing the compliance program's objectives and recommend changes
4. Monitor compliance programs' relevance and accuracy and make ***corrections*** or ***revisions***, or ***withdraw*** obsolete compliance programs
5. Inform affected FDA staff of new, revised, and withdrawn compliance programs
6. Update this SMG to reflect changes in the management of the CPGM

B. Originating Office. The FDA office accountable for the compliance program:

1. Develops new or revised compliance programs conforming to the requirements of this SMG
2. Coordinates reviews and clearances of new, revised, or withdrawn compliance programs
3. Coordinates with ORA or Center staff for compliance program internet posting or withdrawal, including notifying FDA staff and maintaining CPGM internet and intranet lists
4. Maintains official records for compliance programs
5. Collects feedback on compliance programs from FDA staff and acts upon the feedback
6. Reviews compliance programs and proposes corrections, revisions, or withdrawals as appropriate, in accordance with internal procedures and timeframes

C. Collaborating Office. Each collaborating office:

1. Provides input to the originating office during development, revision, or withdrawal of a compliance program
2. Coordinates internal review of new or revised compliance programs or of a recommendation to withdraw a compliance program
3. Provides consolidated comments to the originating office

D. Office of Regulatory Affairs (ORA). Designated offices and committees within ORA:

1. Act as an originating or collaborating office depending on the subject matter of the compliance program

2. Provide subject matter expertise and staff level reviews of compliance programs regarding operational policies and procedures
3. Coordinate resolution of operational disputes or inconsistencies between FDA offices
4. Coordinate ORA internal review and clearance of new or revised compliance programs or of a recommendation to withdraw a compliance program
5. Manage numbering system and, as appropriate, web-posting for compliance programs and related internet and intranet pages, according to written internal procedures

4. PROCEDURES.

A. Maintaining Information for the CPGM.

1. **General:** The CPGM is located within the FDA Staff Manual Guide Volume IV, Program Directives, 7300 series. Individual compliance programs have numbers within the 7300 framework.
2. **Organization:** The CPGM is organized by chapters spanning FDA program areas. A chapter consists of individual compliance programs. Compliance programs may be cross-referenced (see Attachment A). ORA assigns chapter and compliance program numbers consistent with the ***Program and Project Structure*** (PPS) according to ORA procedures.
3. **Access:** For public access, ORA maintains an introductory CPGM page on the FDA internet to provide links to tables of content maintained by the originating offices. For FDA staff, ORA maintains a CPG/CPGM Resources page on the FDA intranet to provide links to contacts, instructions, templates, and transmittals, plus links to CPGM lists and relevant ORA procedures. (See §7.B for internet and intranet link information.)
4. **Formatting:** The originating office formats compliance program format in a standard format designed to be readily identifiable (see Attachments A and B).

B. Initiating Development, Revision, or Withdrawal of a Compliance Program.

1. **Initiate action:** The originating office may develop, revise, or withdraw a compliance program in response to:
   - New legislation, regulations, scientific advances, and court decisions
   - Feedback from users, stakeholders, and risk and data analyses
   - Alignment with Compliance Policy Guides, Investigations Operations Manual, Regulatory Procedures Manual, and other agency operational publications
2. **Collaborate**
   a. The originating office:
      (1) Notifies ORA of planned action according to contact information available on the CPG/CPGM Resources page on the FDA intranet
      (2) Works in conjunction with ORA and other collaborating offices in developing a new or revised compliance program, or a withdrawal
      (3) Requests document numbering from ORA for a new compliance programs
   b. Staff in collaborating offices keep their respective management informed of progress.

c. The originating office submits the compliance program collaborative draft for review.

C. Reviewing a Compliance Program. Organized and planned staff reviews are necessary for effective and efficient management of compliance programs.

1. The originating office provides review instructions to ORA and collaborating office reviewers, as needed. In the instructions, the originating office:
   a. Suggests a review timeframe (due-date)
   b. Identifies
      (1) Collaborative participants (for example consults or workgroup members)
      (2) Significant changes and rationale for the changes
      (3) Sections of the compliance program to be reviewed and for what purpose.
2. ORA, and other collaborating offices, provide the originating office with relevant, authoritative, non-conflicting, and consolidated comments.
3. The originating office works with the collaborating offices to resolve issues identified during the review using the following decision-making roles:
   a. The originating office is the lead for:
      (1) Regulation and policy interpretation
      (2) Compliance program strategy, priorities, and risk criteria
      (3) Scientific and technical issues related to the program area
      (4) Documentation and reports of comment reconciliation
      (5) Determination of whether to withdraw a compliance program
   b. ORA is the lead for:
      (1) Existing agency procedures on investigational, sampling, and analytical techniques
      (2) Regulatory or technical issues related to sampling, inspection, investigation, firm interactions and data collection and reporting
      (3) Other logistical issues relevant to Field operations
      (4) Quality control issues relating to compliance program format and numbering for agency consistency
4. The originating office prepares the reconciled compliance program for clearance.

D. Clearing a Compliance Program.

1. **Preparing the Clearance Record:** For agency clearance, the originating office prepares form *FDA 2306, Clearance Record* with the following:
   - Purpose: A brief summary of changes and any other information useful to the clearing officials, such as collaborators or workgroup participants

- Originating Office Clearance: Final approving official's name and title as determined by the originating office's procedures.
- Clearance Routing: ORA and collaborating offices whose clearance is requested

NOTE: An office may use a local form for internal approvals.

2. **Concurrence**

   a. For new compliance programs and compliance program changes, the originating office obtains management concurrences from collaborating offices prior to issuing or withdrawing the compliance program. Check §7.B, References, for formal delegation of authorities, otherwise obtain signatures from:

      - For ORA, the Office of Operations Program Director
      - For other collaborating offices, the Office Director or designee.

   b. See the CPG/CPGM Resources intranet page for contact information for submitting compliance programs for clearance. When submitting:

      - Provide a due date for clearances allowing for complexity and scope of changes
      - Request electronic signatures whenever possible

E. Issuing or Withdrawing a Compliance Program.

1. **Posting**

   a. The originating office informs ORA of the planned publication for ORA's quality system tracking.

   b. The originating office arranges the posting of the approved compliance program on the FDA internet and the removal of withdrawn or superseded versions.

      (1) The originating office may issue an approved compliance program before its ***implementation date*** by publication on the intranet, internet, or an internal collaborative workspace. If publishing the document on the internet, the posting uses a temporary URL address so that the current version remains in place until the revised version's implementation date.

      (2) If the originating office redacts an internet-posted compliance program, a non-redacted version is posted on the intranet for FDA staff.

2. **Lists:** ORA maintains an introductory CPGM internet page. Each originating office maintains an internet page for listing their compliance programs and, optionally, an intranet page. As needed, the originating office updates the compliance program lists.

   Remove information from the internet list for a withdrawn compliance program.

3. **Notification:** The originating office documents their announcement of a new, revised, or withdrawn compliance program to FDA staff via an email transmittal notice (see Attachment C for recommended template and instructions).

   The originating office requests ORA to update the intranet CPG/CPGM Resources page to post (or link to) the transmittal.

   Corrections do not require a transmittal notice although one may be used.

4. **Feedback:** Originating offices are encouraged to maintain a process by which FDA staff may comment on compliance programs and a procedure for evaluating and acting on the comments to ensure compliance programs are current and clear.

5. RECORDS.

A. The originating office follows its Center or Office records management policies and procedures for draft, final, superseded, and withdrawn compliance programs.

B. At the originating office's request, ORA maintains an unofficial, convenience copy of the editable version of the compliance program.

Note: For the CPGM, apply FDA programmatic record control schedule file code 1130.

6. AMENDMENT OF THIS STAFF MANUAL GUIDE.

An originating office, as defined in this SMG, may edit this SMG and issue the revision without full agency clearance in limited circumstances. SMG management is described in FDA SMGs 3280.1 and 3280.2.

A. The circumstances allowing originating office edits to this SMG without full agency clearance are constrained to:

- Making corrections or office information updates
- Adding references to §7, Supporting Information
- Documenting, via a dated attachment, specific program governance agreements (for example, a multi-office council that will approve compliance programs)

B. In making edits, the office:

- Documents the change in the clearance form FDA 2306 and obtains clearances from other affected centers and offices, if any
- Adds appropriate information in SMG §9, Document History
- Does not change the SMG's effective date
- Informs non-affected centers and offices of the edit

7. SUPPORTING INFORMATION.

A. Background.

A structured format for compliance programs was implemented in October 1974 when the CPGM and the Inspector Program Manual were combined. To enhance the use of reporting data, the numbering system of the CPGM was revised in 1977 so that compliance program numbers and project numbers according to the Project and Program Structure (PPS) would agree. The format of the CPGM was revised in 1982 to make compliance programs clearer and more concise. In 2003, the internet became the default method of publication. In 2016, the present Staff Manual Guide was developed and the FDA CPGM forms were retired.

B. References.

1. "Compliance Program Guidance Manual" access at http://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/default.htm.

2. Delegation for ORA clearance to Field Committees: see ORA FMD 30 "ORA Program Committees" at http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm056665.htm.
3. FDA Form 2306 "Clearance Record" at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM426972.pdf
4. FDA SMG 3280.2 "FDA Program Directives System" at http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm213235.htm.
5. FDA web publishing rules for accessibility available at "Accessibility Resources for 508 Compliance" at http://www.fda.gov/aboutfda/aboutthiswebsite/accessibility/ucm210036.htm and Frequently Asked Questions on FDA intranet, see Information Technology > Internet/Intranet: Web Content Management.

NOTE: FDA staff will find additional resources such as templates and contacts on the FDA intranet "CPG/CPGM Resources" page (see intranet - Policies & Procedures - Guidance & Regulations).

C. Definitions.

1. **Collaborating office** – FDA office that works with the originating office to develop, review, and clear the content of a compliance program. Collaborating offices may be in the same or different centers or super-offices as the originating office
2. **Compliance program** – Published programmatic plans and instructions directed to FDA personnel for conducting activities to evaluate industry compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other laws administered by FDA.
3. **Correction** – Typographical, grammar, numbering, formatting, or similar errors, and changes such as those resulting from reorganizations (for example, renaming of offices or divisions), and relocations (for example, new addresses or phone numbers).
4. **Dates** – The dates in Table 1 are used in the CPGM:

Table 1

Date Type	Definition	Location
Issuance	The date the new, revised, or corrected compliance program is available to the public. In most cases, the issuance date is the same as the transmittal notice date	Transmittal notice
Implementation	The date the compliance program is effective: • use an actual date; do not use "upon receipt" or similar phrase • date is reset with major revision	Cover page
Completion	(Optional) The date the compliance program implementation is planned to end. Use only for compliance programs with finite completion date. • use an actual date: do not use "continuing," "ongoing," or similar phrase	Cover page

5. **Issue** – Incorporating a compliance program into the CPGM. The compliance program is made available to the public via electronic means.
6. **Originating office** – FDA office with functional responsibilities for regulatory programs that leads the development of a new or revised compliance program or compliance program withdrawal in that program area.

7. **Program** – Commodity area, such as human and animal Food, human and animal pharmaceuticals, biologics, devices and radiological health, and tobacco or other areas such as bioresearch monitoring (BIMO).
8. **Program and Project Structure (PPS)** – The PPS is used to track operational activities and is related to Program Assignment Codes (PACs). CPGM chapter and compliance program numbering system follows the PPS. (See FDA intranet for "PAC Master List").
9. **Revision** – Action to change a compliance program:
10. **Major** – changes that affects the compliance program's fitness for use.
11. **Minor** – changes or clarifications that do not affect the compliance program's fitness for use.
12. **Withdrawal** – Action to remove a compliance program from the CPGM.

8. EFFECTIVE DATE.

07/01/2016

- Originating offices format new compliance programs—those approved after the effective date of this SMG—according to the requirements of this SMG.
- Originating offices reformat issued compliance programs according to the requirements of this SMG when the compliance program is revised.

9. DOCUMENT HISTORY.

SMG 7300.0, Management of the FDA Compliance Program Guidance Manual

STATUS (**I**nitial, **R**evision, **C**ancel)	**DATE APPROVED**	**LOCATION OF CHANGE HISTORY**	**CONTACT**	**APPROVING OFFICIALS**
Initial SMG	6/20/2016	Transmittal	ORA Ofc. of Policy and Risk Management	Kate Bent, Assistant Commissioner for Compliance Policy

ATTACHMENT A
COMPLIANCE PROGRAM COVER PAGE

NOTE: A template for CPGM Cover Page is available on the FDA intranet CPG/CPGM Resources page

1. DATA FIELDS ON COVER PAGE

Field Name	Notes
A. Compliance program number	• Located in header • Assigned by ORA
B. Chapter number and title	• Place below header and before table • Assigned by ORA
C. Compliance program title	• First block in table • Additional information may be added to title block, such as correction or minor revision dates and affected Parts (see §7.C for definitions)
D. Implementation Date	• Effective date • Do not use 'upon receipt' or similar phrase • Should not precede transmittal date • Reset date when compliance program has a major revision
E. Completion Date (optional, use only if an end-date is needed)	• Date, generally 1-3 years from implementation date; use only if based on specific programmatic needs • Before the completion date is reached, originating office determines if revision, or withdrawal is warranted • Do not use "continuing," "on-going," or similar phrase
F. Product Codes	• Include all that apply
G. Program Assignment Codes	• Include all that apply • Include secondary PACs, if any • Include cross-references to other compliance programs, if any

2. FIELD REPORTING REQUIREMENTS

Include language related to Establishment Inspection Report (EIR) preparation, referencing appropriate procedures.

Also include in this section any language specific to the commodity or inspection type discussed in the compliance program that provides new or unique Field reporting obligations or preferences.

3. TABLE OF CONTENTS – Add a table of contents for the compliance program's parts and attachments.

[End, Attachment A]

ATTACHMENT B
COMPLIANCE PROGRAM PARTS I – VII

NOTE: A template for CPGM Parts pages is available
on the FDA intranet CPG/CPGM Resources page

GENERAL

- Compliance programs do not establish policy, but may reference Compliance Policy Guides, laws, regulations, or other FDA guidance documents and provide policy implementation instructions.
- If non-public information is included in compliance programs, the originating office redacts the version posted on the internet.
- Parts I - VII are included in each compliance program. If a Part does not require text, add "intentionally left blank" rather than eliminating the Part. Some Parts have required sub-headings; however additional sub-headings may be added.

PART I - BACKGROUND

Briefly describe the following, as appropriate:

- Major events associated with development of or changes to the compliance program
- Brief history of public health issues associated with the industry or products covered by the compliance program
  - Reasons for conducting the compliance program, including evaluations of data
  - Relevant changes to agency policy, laws, regulations, or guidance documents
  - Definitions or other information to describe covered products and industries

PART II - IMPLEMENTATION

1. Objective. State what is to be accomplished under the compliance program. As appropriate, provide information as to whether the compliance program is:

- Measurable
- Surveillance or compliance
- Pilot, multi-year, or single year
- Statistical or non-statistical
- Requiring inspection, investigation, sampling, analytical, or other regulatory approach
- Related to a public health issue
- Related to complaints

2. Program Management Instructions. As appropriate, discuss the following:

- Inspection priorities
- Planning instructions
- Interactions between compliance programs
- Resource instructions
- Interactions with other Federal agencies, State and local counterparts, and foreign authorities
- Information relating to work planning, supervision, or other resource management that is not specified in another Part of the compliance program

PART III – INSPECTIONAL

1. Operations.

List and describe the inspectional operations that will be carried out under the compliance program. For each, describe what is to be accomplished by operational personnel. By reference and electronic link, incorporate applicable procedural guidance from the Investigations Operations Manual (IOM). As appropriate, include information on investigation procedures that are not covered by the IOM.

When applicable, include the following sub-headings and appropriate information for the activities performed:

A. Inspections. Include:

- Specific targeted operations or product types
- Reason for inspections (for example, for-cause, surveillance, premarket review, recall follow-up)
- Special tools, equipment, or devices needed to conduct inspection activities
- Personnel safety considerations, including applicable Personal Safety Alerts
- Coordination with other Federal agencies, State and local counterparts, and foreign authorities

B. Investigations. (add as needed)

C. Sample Collections. Specify:

- Sample type (official, investigational, domestic import, etc.)
- What is to be collected and, as appropriate, what should not be collected
- Where and how to sample
- Sample and subsample size
- Sample shipping information

D. Import Activities. Specify:

- Instructions for entry review to determine admissibility
  - Whether entries are to be subjected to field examinations or sampling
  - Whether entries are to be held pending sample analysis and district compliance branch evaluation

E. Other. (Add as needed.)

2. Reporting. Describe special reporting requirements unique to the compliance program (for example, special Establishment Inspection Report (EIR) topics, collection report flags). Include only reporting instructions to operational personnel that are relevant to the inspectional activities. Provide other reporting requirements such as data entry, EIR distribution, and submissions to Headquarters on the Cover Page.

PART IV – ANALYTICAL

1. **Analyzing Laboratories.** Identify the Field and Center laboratories responsible for the analytical work.

2. **Analyses to be Conducted.** Identify types of analyses to be performed (for example, PCBs, *Salmonella*, sterility).
3. **Methodology.** Cite the analytical methods that must be used and indicate when alternative methods may be used. As appropriate, provide an electronic link to referenced methods. As appropriate, provide relevant information regarding:
    - Sample preparation and handling
    - Extraction and cleanup procedures
    - Analyses, including adjustments to or deviations from the analytical method
    - Quality assurance
    - Reserves to be maintained
4. **Reporting**. Provide laboratory reporting requirements specific to the compliance program.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

Provide the enforcement strategy and instructions for regulatory and administrative follow-up. As appropriate, include:

- Regulatory approaches to consider (for example, voluntary compliance, advisory action, or judicial action)
- Regulatory opinions
- Coordination of regulatory follow-up with other Federal agencies, State and local counterparts, and foreign governments
- Special case information on the particular program area
- Special instructions and information on implementation of the enforcement strategy
- For imports, enforcement strategy including instructions for detention and refusal of entries
- Guidance on evidence development and documentation needed to support regulatory action
- Specimen charges for both domestic and import enforcement actions

NOTE: Use cross-references to other procedural manuals or policy documents (for example, IOM, RPM, CPG) rather than restating or copying text from those documents.

PART VI - REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

- Add electronically linked references for relevant documents (for example, Compliance Policy Guides, memoranda, Import Alerts, regulations, FD&C Act and other laws).
- List attachments to the compliance program, and program contacts.
- Ensure that electronic links to references are public and correct, and that the list of contact persons is current.

PART VII - CENTER RESPONSIBILITIES

Provide information on the originating office's responsibilities to monitor activities under the compliance program.

ATTACHMENTS (AS NEEDED)

Use attachments to provide additional information relevant to the successful implementation of the compliance program, such as forms that need to be completed or checklists. Identify attachments alphabetically. Use the CPGM header at the top of each attachment page.

[End, Attachment B]

ATTACHMENT C
EMAIL TRANSMITTAL NOTICE EXAMPLE

NOTE: A CPGM transmittal template is available on FDA intranet CPG/CPGM Resources page

Instructions: For new, revised, and withdrawn compliance programs, the originating office documents their announcement of the change in an electronic transmittal notice to ORA for posting. For example, an email to affected FDA staff may include:

From: *[automatic]*

Sent: *[automatic]*

To: *[for example]* ORA DDs; ORA DIBs; ORA DCBs; *[Insert appropriate ORA Field Committee]*; *[Insert originating office distribution]*

Cc: *[for example]* ORA RFDDs; ORAHQ Office Directors; ORAHQ OEIO; ORAHQ OPRM Employees; ORA Quality System Managers; FDA Quality Resource and Guidance

Subject: Compliance Program *[Insert Number and Title]* – TRANSMITTAL

Date: *[automatic; Note: add this date to Cover Page footer]*

Transmittal Number: [Insert: YYYY–CPGM–Center–XXX; Note: add number to program footer]

Document Title: Compliance Program [Insert Number and Title]

Implementation Date:

Actions Requested:

1. Recipients of this Transmittal should ensure that:
   - appropriate staff are knowledgeable of the transmitted document or revisions, and
   - previous versions are destroyed or clearly marked as obsolete.
2. [Insert other actions requested such as Q&As, training]

Location of Document: [Insert electronic link to either the appropriate web-based list of CPs or to the web posting of the un-redacted version of the compliance program. If the originating office makes multiple renditions of a compliance program available, for example on the internet and in an application for mobile devices, the transmittal notice lists the location of all renditions that need to be controlled for currency. Do not attach a Word or PDF copy of the compliance program as this practice creates copies that cannot be updated as needed and may lead to out-of-date programs being used]

Change History:

[Insert an explanation of the changes to the compliance program. If the compliance program is new, explain the purpose and summarize the products and industries that are covered.]

Sent under the authority of: [Office Director - name, title]

[End, Attachment C]