

SMG 7100.1

FDA STAFF MANUAL GUIDES, VOLUME IV – AGENCY PROGRAM DIRECTIVES

COMPLIANCE

MANAGEMENT OF THE FDA COMPLIANCE POLICY GUIDES MANUAL

Effective date: 07/01/2016

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1. PURPOSE.

The FDA *Compliance Policy Guides* (CPGs) manual provides a convenient and organized system for issuing statements or explanations of compliance policy to FDA staff. CPGs provide interpretations of FDA statutory or regulatory requirements as agreed upon by the Office of Regulatory Affairs (ORA) and *program* centers or offices.

FDA Centers and other components responsible for a specific regulatory program area issue CPGs (see [Volume I of the FDA Staff Manual Guides](#) for functional statements by organization). FDA may issue CPGs for many reasons, including new legislation, regulations, guidances, court decisions, and similar legal, scientific, and public health factors.

This Staff Manual Guide (SMG) establishes procedures for developing and maintaining FDA compliance policies that collectively make up the CPG manual. This SMG does not cover the agency procedures that are part of typical guidance development activities.

2. POLICY.

- A. CPGs are guidance documents prepared for FDA staff as defined in the good guidance practices (GGPs) regulations found in 21 CFR 10.115.
- B. Consistent with GGPs and to promote transparency, CPGs are available to the public on the FDA internet and notices are published in the *Federal Register (FR)* as required in the advisory opinion regulations found in 21 CFR 10.85.
- C. The development and clearance of CPGs and *FR* notices is a collaborative process involving the organizations pertinent to the program topic.

3. RESPONSIBILITIES.

This SMG covers responsibilities in the CPG process for the offices listed below. The term “CPG” in these responsibilities also encompasses the associated *FR* notice. Other FDA offices involved in the clearance and issuance of guidance documents and associated *FR* documents follow existing agency procedures (for example, FDA Office of Policy clearance, or use of the Federal Register Document Tracking System, FRDTS).

A. Joint Responsibilities. The development and *issuance* of CPGs requires cooperation between the *originating* and *collaborating* offices. These offices:

1. Collaborate on the strategic and tactical direction of compliance policy, including objectives and implementation
2. Seek and provide input for operational considerations relevant to the compliance policy’s regulatory and enforcement guidance, and recommend changes
3. Monitor CPGs’ relevance and accuracy and make *corrections* or *revisions*, or *withdraw* obsolete CPGs
4. Inform affected FDA staff of new, revised, and withdrawn CPGs
5. Update this SMG to reflect changes in the management of the CPG manual

B. Originating Office. The FDA office accountable for a program’s compliance policy:

1. Develops new or revised CPGs conforming to the requirements of GGPs, FDA procedures, the originating office’s procedures, and this SMG
2. Coordinates reviews and clearances of new, revised, and withdrawn CPGs within the scope of this SMG
3. Coordinates with ORA for CPG internet posting or withdrawal, notifying FDA staff of CPG changes, and maintaining CPG internet page information
4. Ensures official records of the development, clearance, withdrawal, and issuance of a CPG are maintained
5. Collects feedback on CPGs from FDA staff and other stakeholders, and acts upon the feedback
6. Reviews CPGs and proposes revisions or withdrawals, as appropriate, in accordance with internal procedures and timeframes (reference 21 CFR 10.115 (k))

C. Collaborating Office. Each collaborating office:

1. Provides input to the originating office during development, revision, and withdrawal of CPGs
2. Coordinates internal review of new or revised CPGs or of a recommendation to withdraw a CPG
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 CPG
2. Provide subject matter expertise and staff-level reviews of CPGs for consistency with other agency CPGs
3. Coordinate resolution of policy disputes or inconsistencies between major program areas
4. Coordinate ORA review and clearance of new or revised CPG, or of a recommendation to withdraw a CPG
5. Manage numbering and web-posting for CPGs and related internet pages, according to written internal procedures

4. PROCEDURES.

A. Maintaining Information for the CPG Manual.

1. **General:** The CPG manual is located within the FDA Staff Manual Guide [Volume IV, Program Directives](#), 7100 series.
2. **Organization:** The CPG manual is organized by chapters for general topics and for specific FDA program areas. A chapter consists of individual CPGs organized by sub-chapters. ORA assigns unique CPG chapter, sub-chapter, and section numbers, according to internal procedures.
3. **Access:** For public access, ORA maintains the [CPG page](#) on the FDA internet, the CPG manual's chapter lists for each program area and the manual's change history information. 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 relevant ORA procedures. (See §7.B for internet and intranet link information.)
4. **Formatting:** The originating office formats CPGs according to GGP requirements for draft and final guidance documents. Some older CPGs are not in guidance format: if the originating office revises a pre-guidance-format CPG, they add the appropriate guidance identification information (see Attachment A).

B. Initiating Development, Revision, or Withdrawal of a CPG.

1. Initiate Action

- a. The originating office may develop, revise, or withdraw a CPG in response to:
 - (1) New policy or changes in compliance policy (for example, Office of the Commissioner memoranda, center memoranda and other informational issuances, agency correspondence with trade groups and regulated industries, and advisory opinions)
 - (2) Precedent-setting court decisions
 - (3) Multicenter agreements regarding jurisdiction over FDA-regulated products
 - (4) Preambles and final regulations or other *FR* documents
 - (5) Significant regulatory actions or public health events
 - (6) Information from FDA staff and other users and stakeholders
 - (7) Technical or scientific information, such as risk and data analyses, etc.

- b. The originating office considers if they should list CPG action in a guidance agenda if the Center or office posts such a list (for example, “CDRH Fiscal Year 2016 Proposed Guidance Development. . .”)
- c. The originating office determines, in consultation with OCC:
 - (1) If the CPG action is designated as a GGP level 1 or 2 action (see 21 CFR 10.115(c))
 - (2) If a new or revised CPG will be issued as a *Draft CPG* or a *Final CPG*

NOTE: The originating office may be exempt from the *FR* notice requirement in the limited circumstance of a simple *correction* of a CPG.

2. Collaborate

- a. The originating office, using contact information available in the FDA intranet “CPG/CPGM Resources” page:
 - (1) Notifies ORA of planned action according to contact information available on the CPG information page on the FDA intranet
 - (2) Works in conjunction with collaborating offices in developing a new or revised CPG, a withdrawal, and the associated *FR* notice.
 - (3) Manages collaborative consults with Office of Chief Counsel
 - (4) For new CPGs, contacts ORA for document numbering
- b. Staff in collaborating offices keep their respective management informed of progress.
- c. The originating office submits the CPG and *FR* collaborative drafts for review.

C. Reviewing a CPG and *FR* Notice.

- 1. The originating office sends a pre-clearance review request and instructions to the collaborating offices for staff-level reviews (also known as “staff clearance”).

A collaborating office manages its internal review process in order to return relevant, authoritative, non-conflicting, consistent, and consolidated comments to the originating office.

After examining the comments, the originating office works to resolve differences. In some cases, the originating office may repeat the collaboration and review stages. Use the following decision-making roles to help resolve differences:

- a. The originating office is the lead for:
 - (1) Interpretation of regulation and policy (with OCC consultation as appropriate)
 - (2) Regulatory and scientific issues related to the compliance policy
 - (3) Regulatory action guidance
- b. ORA is the lead for:
 - (1) Policy analysis of regulatory guidance
 - (2) ORA operational issues that may be impacted by the CPG
 - (3) Numbering and formatting requirements
 - (4) Accessibility requirements and web posting

The originating office prepares the reconciled CPG and *FR* notice for clearance.

D. Clearing a CPG and *Federal Register* Notice.

NOTE: The originating office uses FRDTS, or its successor system, to obtain clearances; if there is no FR notice due to CPG correction, the originating office uses clearance form [FDA 2306, Clearance Record](#).

1. **Concurrence:** The originating office obtains management concurrence from the appropriate clearing officials prior to forwarding the CPG and associated *FR* notice for final guidance approvals and posting. The appropriate officials are:
 - a. For ORA, the ORA Assistant Commissioner for Compliance Policy provides the concurrence signature even if multiple ORA offices are collaborators.
 - b. For other non-ORA collaborating offices, the concurrence signature is established in the office’s internal procedures.
2. **Final approval:** The originating office determines the final approval signature based on their procedures for guidances and *FR* documents.

E. Issuing or Withdrawing a CPG.

1. **Posting**

- a. The originating office, using contact information available in the FDA intranet “CPG/CPGM Resources” page, coordinates with ORA in advance of the planned action date on posting—or removing—appropriate CPG documents and information.
- b. The originating office provides ORA an editable electronic version of the cleared Draft CPG or Final CPG with anticipated action dates entered on first page, and, as appropriate, on the last page.
- c. In synchronization with the issuance of the *FR* notice, ORA, according to internal procedures for editing the [CPG internet page](#):

Makes changes to	For Draft CPG	For Final CPG	For Withdrawn CPG
CPG internet page revision/update history	Add update	Add update	Add update
Document on internet	Post in new URL	Add issue date and post	Remove
CPG internet page chapter lists	n/a	Edit listing as needed	Remove listing

2. **Notification**

- a. The *FR* notice and the [CPG internet page](#)’s Revision/Update section provide notice to FDA stakeholders. At their discretion, the originating office may highlight CPG changes on its own internet pages.
- b. The originating office is encouraged to use an email transmittal to notify internal staff of CPG changes (see FDA intranet “CPGM & CPG Resources” page for a transmittal template). Collaborating offices may send internal transmittals.

3. Feedback

- a. GGP regulations provide mechanisms for FDA stakeholders to provide input and participate in the CPG process (reference 21 CFR 110.115(f) & (g)).
- b. Originating offices are encouraged to maintain a documented process by which FDA staff may comment internally on final CPGs and a procedure for evaluating and acting on both internal and external comments to ensure CPGs are current and clear.

5. RECORDS.

- A. The originating office follows record management policies and procedures for draft, final, superseded, and withdrawn guidance documents and associated *FR* Notices.
- B. For convenience, ORA will maintain a copy of the editable version of the CPG at the originating office's request.

Note: For CPGs, apply FDA programmatic record control schedule file code 1200.

6. AMENDMENT OF THIS STAFF MANUAL GUIDE.

A CPG originating office, as defined in this SMG, may edit this SMG and the issue the revision without full agency clearance in limited circumstances. (FDA SMGs [3280.1](#) and [3280.2](#) describe SMG management.)

- 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, CPG governance agreements (for example, a multi-office council that will approve CPGs)
- 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 a notation in §9. Document History of this SMG
 - Does not change this SMG's effective date
 - Informs non-affected centers and offices of the edits

7. SUPPORTING INFORMATION.

A. Background.

In 1968, the FDA Bureau of Compliance began issuing compliance policies as Administrative Guidelines. In 1972, the responsibility for the Guidelines was assigned the Office of the Executive Director of Regional Operations (EDRO). In 1980, the Administrative Guidelines were compiled into and replaced by the Compliance Policy Guides manual which was referenced in the regulation for advisory opinions. After reorganization in 1984, the Office of Regulatory Affairs became responsible for publishing

the CPG manual. In 1998, the CPG manual was reorganized in current chapters and sections, replacing previous numbering system based on the FDA SMGs. In 2000, the agency published the final rule for good guidance practices and subsequently determined applicability to CPGs.

B. References.

1. 21 CFR 10.85, Advisory opinions
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=10.85>
2. 21 CFR 10.115, Good guidance practices
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=10.115>
3. Clearance Record, FDA 2306
<https://www.fda.gov/media/145710/download>
4. FDA SMG 3280.2, FDA Program Directives System
<https://www.fda.gov/media/81730/download>
5. FDA external web page containing CPG Revision/Update information and links to CPG chapter lists: “Manual of Compliance Policy Guides”
<http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/default.htm>.

NOTE: FDA staff will find additional resources for contacts and guidance procedures 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 CPG and any accompanying *FR* notice. ORA is a collaborating office; OCC may be a collaborating office. Other collaborating offices may be in the same or different centers or super-offices as the originating office.
2. **Compliance Policy Guide (CPG)** – A statement of agency compliance policy to FDA staff that provides interpretation of FDA statutory or regulatory requirements.
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); a limited revision that does affect content of the CPG.
4. **Draft CPG** – Draft guidance with a specific public comment period according to GGPs; a Draft CPG is not incorporated into the CPG manual.
5. **Final CPG** – Final guidance incorporated into the CPG manual.
6. **Issue** – Providing a Draft or Final CPG to the public via electronic means.
7. **Originating office** – FDA office with functional responsibilities for regulatory programs that leads the development of a new or revised CPG or a CPG withdrawal in that program area.

- 8. **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).
- 9. **Revision** – Action to change a CPG.
- 10. **Withdrawal** – Action to remove a CPG from the CPG manual.

8. EFFECTIVE DATE.

07/01/2016

- Originating offices format new CPGs—those initiated after the effective date of this SMG—according to the requirements of this SMG and FDA guidance procedures.
- Originating offices reformat existing CPGs according to requirements of this SMG and FDA guidance practices when revising the CPG.

9. DOCUMENT HISTORY. SMG 7100.0, Management of the FDA Compliance Policy Guides Manual

STATUS (Initial, Revision, Cancel)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIALS
Initial	6/20/2016	Transmittal	ORA Ofc. of Policy and Risk Management	Kate Bent, Assistant Commissioner for Compliance Policy

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ATTACHMENT A – CPG Format and Content

The format for Draft and Final CPGs must be consistent with agency templates for guidance documents. The CPG/CPGM Resource intranet page contains, as available, links to guidance templates. Include the following CPG-specific content information in addition to the standard guidance content.

A. Title areas:

The Draft or Final CPG is identified as follows

“Compliance Policy Guide
CPG Sec. [Instruction: Insert CPG number, if available, and title]”
and
“Guidance for FDA Staff”

B. Sections

I. Introduction:

The purpose of this Compliance Policy Guide is to provide guidance to FDA staff on. . . *[Add information on the CPG topic, including whom or what the guidance does not address if applicable; if this is a revision of a previously issued final CPG, explain briefly how the revised CPG differs from the previous version (do not duplicate information on policy changes to be supplied in the Background.)]*

[At the end of the Introduction, include standard guidance language from approved template related to the standing of a guidance document, such as not legally enforceable ; describes current thinking; use of the word 'should.']

II. Background:

[Add background relating to the compliance policy established in the CPG. For example, provide information about the problem or situation associated with the policy. If the compliance policy was previously stated in a publicly available document, cite that source. When the CPG changes an existing policy, indicate the superseded policy and the reason for the change.]

III. Policy:

[Include a clear and concise statement of the current FDA compliance policy and the limitations or exceptions, if any, to that policy.]

IV. Regulatory Action Guidance:

[Provide guidance to FDA staff on application of the compliance policy for making regulatory decisions relating to domestic products and products offered for import. Include criteria for direct reference authority, when applicable (see the [FDA Regulatory Procedures Manual](#) for information on direct reference).]

V. Specimen Charges (as appropriate):

[As appropriate to the subject matter, add specimen charges for the domestic and import violations associated with the compliance policy see the [Regulatory Procedures Manual](#), Exhibit 5.3 and Chapter 9 for examples].]

Domestic Seizure: *[State the applicable adulteration, misbranding, or other charge. Use an example of the language that should be used for stating the applicable violation of the FD&C Act in the U. S. Attorney seizure referral letter. If product seizure is not recommended, provide an explanation or alternative action.]*

Import Refusal: *[State the violation of section 801 or other applicable section of the FD&C Act. Use example language that provides the applicable violation of the FD&C Act that should be referenced in OASIS.]*

C. Document history

[At the end of the CPG text, add the applicable issued or revised date of the Final CPG in either mm/yyyy or mm/dd/yy format, for example:

Issued: 10/2001

Revised: 08/2007 (format), 04/2009

Retain earlier issued and revised dates when adding new changes. Use the date corresponding to either the FR date, or the internet posting date if no FR notice is used.]

[end Attachment A]