SMG 2240.9

FDA Staff Manual Guides, Volume III - General Administration

Administrative Services - Office Services

Publications and Multimedia Clearances

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1. Purpose

This Staff Manual Guide (SMG) is revised to reflect changes in the Food and Drug Administration (FDA) requirements for clearance (review and approval) and responsibility for managing, developing, and approving applications for design, development, and distribution of written and web-based publications, multimedia materials (such as videos), exhibits, and other external audience-focused communications messages.

This guide updates the required FDA strategic communication process for review and clearance of agency staff-developed and supporting contractor-developed written and web-based publications, multimedia materials (such as videos), exhibits and other audience-focused communications messages intended for internal or external distribution. These communications are subject to internal FDA Office of External Affairs (OEA) review and clearance and may be subject to review by the Office of the Assistant Secretary for Public Affairs (ASPA) as well.

2. Background

ASPA requires that communication products described in section 5, developed by HHS agencies, follow the strategic communication planning (SCP) process.

The SCP process is designed to proactively develop and disseminate content and is used by communicators, program staff, Contracting Officer Representatives (CORs), Program and Project Managers (P/PMs), and supporting contractors to create a consistent approach for planning. Each communications project team must submit a strategic communication plan for review and approval through the OEA.

ASPA, in collaboration with HHS agencies, developed the Strategic Communication Planning (SCP) platform. The SCP platform is a web-based application that supports the development of strategic communication plans for content. The SCP platform is where the SCP project team submits its strategic communication plan for clearance of audience-focused communications messages.

Each FDA component office needs to have its own SCP project team who will work with OEA. The SCP project team coordinates with the communications manager(s) within its own component office. In addition, OEA sets certain standards for visual identity including the use of logos, colors, font, and other visual criteria. The visual identity requirements shall be distributed to SCP project teams upon request. Adherence to the VI program is required in all FDA internal and external communications materials. The organizational components involved and category of products subject to HHS/ASPA review and clearance are defined in Definitions. The policy that specifies criteria for submission is found in Item 5.B.

3. Definitions

A. FDA Component: In general, an FDA Component is any part of the FDA organization that is separately established as an organizational entity by law, regulation, the Secretary, or an official who has been delegated authority; and has formally assigned functions and an approved Standard Administrative Code (SAC) and title. For example, an FDA component may be the Office of External Affairs (known as agency manager, agency submitter, or agency public affairs/communications manager); or may be FDA component SCP project teams that initiate strategic communication plans and may include Offices that report to: the Office of the Commissioner, the Office of Operations, Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Biologics Review and Research, Center for Devices and Radiological Health, Center for Tobacco Products, National Center for Toxicological Research, and Office of Regulatory Affairs.

B. Publications: The agency and or the department must be identified in all printed information, including but not limited to books, periodicals, pamphlets, brochures, newsletters, reports, circulars, posters, flyers, and fact sheets. Excepted from Departmental requirements for having both FDA

and HHS identification are FDA publications that are developed for internal and administrative use, such as employee memos and journal articles, as well as speeches, news releases, and other items that may be exempted in writing by ASPA. News releases are subject to separate clearance procedures and must be submitted to OEA's Office of Media Affairs (OMA).

C. Periodical: Any publication issued annually or more often with a format, content, and purpose consistent in nature. This also includes any publication that is reprinted due to a need for substantial revisions.

D. Reprint: Any published document essentially unchanged from the previous printing.

E. Revision: Any published document with text and/or graphic changes since the previous printing or web posting.

F. Multimedia: Content that uses a combination of different visual and aural content. Multimedia may include a combination of text, audio, still images, animation, video, infographics, or interactive content. Multimedia is usually recorded and played, displayed, or accessed by information content processing devices, such as computerized and electronic devices, but can also be part of a live performance. Multimedia devices are electronic media devices used to store and experience multimedia content. Multimedia is distinguished from mixed media in fine art; by including audio, for example, it has a broader scope. The term "rich media" is synonymous for interactive multimedia, such as webcasts that feature interaction.

G. Exhibit: Any display, device, or structure designed to inform or educate any audience.

H. Employee-Related Materials: All magazines, newsletters, fact sheets, and publications such as guides, introductions to the various components of the department, awards materials, training materials, handbooks, and internal posters.

I. Administrative Materials: These include department and agency or center operation division catalogs and manuals (except those of a purely technical nature and those whose distribution is limited to within the department).

J. FDA Office of External Affairs (OEA): The office responsible for providing FDA clearance of strategic communication plans and the agency administrator for the platform where communication plans are developed by the FDA component.

K. Strategic Communications Platform: The SCP platform (web-based application) allows project teams to build a lean strategic plan where a target

audience is clearly defined, the target audience is aligned with dissemination plan, an efficient and effective distribution plan is described, goals for target audiences are specified numerically, there is a succinct plan for measuring goals and outcomes, key messages are clearly defined and validated with testing, collaborators identified and consulted, and a post product release evaluation of the plan documents “plan vs. what was achieved.” The platform allows team comments between one another, upload of draft and final product as well as statements of work, and drives clearance for approval at agency and departmental levels with e-mail integration.

L. Script/Storyboard: Usually refers to a two-column representation of a presentation on standard portrait sized paper, one column representing what you see (video, text, identification of performer, graphics, illustrations, animation, charts, graphs), and one column representing what you hear (voice, music, sound effects)

M. Staff Manual Guide (SMG): The FDA Staff Manual Guides (SMGs) are the agency directives that document organizations and functions; delegations of authority; and administrative and program policies, responsibilities and procedures.

N. Visual Identity Program (VI): FDA’s required, agency-wide visual identity for internal and external communications and the foundation for employee and public recognition, preference and loyalty. A consistent visual identity allows people to instantly recognize a communication product as being from the FDA. Over time, with consistent use, the visual identity allows people to associate the FDA's core values with that look and feel. A universally applied visual identity can help to promote trust in the agency's communications products, and therefore trust in our messaging.

4. Acronyms

A. OEA: Office of External Affairs.

B. Operating Divisions (OPDIVs): HHS Operating Division (FDA, NIH, CDC, IHS, etc.).

C. RFI/RFP: Request for Information / Request for Proposal.

D. SCP: Abbreviation for Strategic Communication Planning.

5. Policy

A. It is FDA policy to develop strategic communications programs to meet the needs of the agency’s regulatory responsibilities and the information needs of technical audiences, other agencies, the public, industry, and other

stakeholders. It is also FDA policy to encourage prompt dissemination of technical and program information resulting from the work of agency grants and contracts relating to consumer protection and industry regulations.

B. Strategic Communication Planning Process Decision List

The "What's in and What's Out" of message types will help agency communicators and issue experts decide whether an SCP submission is necessary. Your SCP project team will submit one strategic communication plan for clearance of an audience-focused communications message. If you have a series of message that are similar in development, you may request submission as a series.

What's In*	What's Out
Newsworthy	Course materials (such as conference presentations) for internal/external training
Controversial	Press releases and press materials
New information	Printed and online training marketing materials
Public campaigns	Recalls and notifications
Fact sheets	Webinars for internal audiences
Brochures, posters, exhibits, reports	Talking points
PSAs, Videos, B-Roll	Statements
Webinars for external audiences	Key messages and questions and answers (KMQA) documents
	Podcasts

*All materials are subject to HHS and agency-wide Visual Identity Program requirements

C. Criteria for SCP Submission to ASPA: When filling out the web-based communications plan at https://stratcomm.hhs.gov/. The criteria for determining whether the SCP has an FDA internal or an additional ASPA review is under the "Review Criteria" tab in the SCP platform. Any one of the following criteria would automatically require ASPA review if:

1. It is Newsworthy - (e.g., this issue has received coverage from major news outlets, you plan to promote widely to the press, there is significant reporter interest in the issue)

2. It contains New Information- (e.g., a change in policy, a substantial new research finding or development, a new campaign or program)

3. The subject/content is Controversial - (e.g., has received interest from

Congress, subject of investigations, issue raised significant criticism by advocacy groups or associations, involves pending legislation, has received widespread or critical media attention)

4. It is a Public Education Campaign: (e.g., a coordinated set of materials designed to inform or persuade an audience to take action and/or adopt a behavior about a specific public health/human services issue such as www.millionhearts.hhs.gov)

D. SCP project teams should address the following questions when completing the SCP communications plan:

1. Target Audience clearly defined: Has the audience for whom the content is targeted been narrowly defined?

2. Target Audience aligned with Distribution Plan: Have the demographics of the target audience been considered – that is, how its members behave and are influenced – when describing the distribution of your product?

3. Efficient and Effective Distribution Plan: Are you using the best distribution channels for this target audience?

4. Goals for Target Audience specified – numbers: How many people and organizations are in your target audience?

5. Plan for measuring goals & outcomes: How will you collect measurements for reach, awareness, utilization, understanding and behavior goals?

6. Key messages clearly defined and validated with testing: Is your message clearly articulated using language appropriate for your target audience?

7. Collaborators identified and consulted: Have you notified other stakeholders inside HHS and confirmed their alignment with your plans?

E. If questions arise during submission, your agency administrator will be available to assist you and train new submitters as requested.

6. Responsibilities

A. ASPA is responsible for maintaining the department-wide SCP platform, https://stratcomm.hhs.gov and for reviewing communication plans submitted to them by OEA.

B. Associate Commissioners, Assistant Commissioners, Center Directors, Regional Food and Drug Directors, and District Directors are responsible for adherence to the SCP processes and procedures described herein. Associate Commissioners and Center Directors have the authority to clear, for policy purposes and technical accuracy, audience-focused communications messages intended solely for technical and scientific audiences.

C. The Associate Commissioner for External Affairs or designee, as designated and required by HHS, is responsible for the development and issuance of FDA clearance procedures described in this guide, and for clearance of FDA publications, multimedia materials, exhibits, and materials prepared under public affairs and communications service contracts.

D. Each FDA component is responsible for initiating an SCP submission as defined herein and is responsible for maintaining necessary acquisition files and records of covered content in accordance with agency records management practices.

E. SCP Roles:

1. Agency manager, agency submitter, agency public affairs/communications manager, or OC/PA Review. These are users who can:

    a. Submit strategic communication plans to ASPA.

    b. Provide guidance and training for users with support from ASPA.

    c. Add/delete users on the system.

    d. Determine whether a strategic communication plan can be internally cleared or requires ASPA or review; also can return to project team for editing.

2. SCP project team. Members of the team:

    a. Develop SCP with guidance from OEA's Office of Editorial and Creative Services (agency managers).

    b. Can edit or provide comments and concur/nonconcur to stages of project in an SCP.

    c. Can be internal agency or external HHS personnel.

    d. Can designate a lead or Point of Contact that will submit SCP to

agency manager. All team members must be mindful of clearance timeframes.

e. Can create notifications to send to some or all SCP project team members.

f. Resubmit to OC/PA Review (agency manager) after making edits required by ASPA or agency manager.

g. Submit all final draft communications products covered by this guide to OEA for review and approval prior to release or distribution.

h. Complete the project evaluation within the SCP platform which is a critical component in the lifecycle of the audience-directed communication product.

F. Publication or Multimedia Preparation and Review: The publication or multimedia clearance begins when a publication or multimedia product is in the planning/concept stage, or phase one.

In phase one of the clearance, the Commissioner for External Affairs or designee within OEA is responsible for reviewing within ten days of the submission, messaging, and adherence to the Visual Identity requirements. OEA will determine whether a review is required by ASPA, or if the SCP Communications Plan (SCP) will be reviewed within the agency only (internal review). Thus, an SCP project team should develop the SCP early in the process (phase one), indicate the cost and the concept, so that FDA and ASPA can notify the team to proceed, modify, or terminate the project.

In the second and final phase of clearance, the Associate Commissioner for External Affairs or designee will require clearance of the attached final manuscript, “rough” cut and/or final multimedia product, or design. Prints and revisions that are to be printed and distributed by the agency or a component must be included in this second phase of the process as well. All communications products covered by this guide must be reviewed by OEA prior to release or distribution.

7. Media-Applicable

A. Publications: Clearance for publications begins with completion of a strategic communication plan submission in the SCP platform at https://stratcomm.hhs.gov/. This is the first phase of the SCP development process. This includes the project, manuscript, budget, and other SCP content that must be submitted into the platform. At this point, a preliminary signoff is obtained so that production can commence. When completed with production, or at the second and final phase, the final manuscript including

all graphics must be submitted and the file or representation of final audience-focused communications message will be attached to the submission in SCP. The SCP platform will provide e-mail notifications to the originator indicating a need for modification, if necessary. Please note that required changes may require additional time, resources, or budget, as applicable. In case of file size issues, or any other problems with the SCP platform, please contact OEA.

B. Multimedia: Clearance for multimedia products begin with completion of an SCP submission in the SCP platform at https://stratcomm.hhs.gov/. This is the first phase of the SCP development process. This includes the project, including an audiovisual script/storyboard, budget, and other SCP criteria must be submitted in SCP. At this point, a preliminary signoff is obtained so that production can commence. When completed with production, or at the second and final phase, the final script and final multimedia product must be submitted, and the file or representation of final audience-focused communications message will be attached to the submission in SCP. The SCP platform will provide e-mail notifications to the originator indicating a need for modification, if necessary. In case of file size issues, or any other problems with the SCP platform, please contact OEA or the SCP Help Desk at scphelpdesk@hhs.gov.

C. Exhibits: Clearance for exhibits begin with completion of an SCP submission in the SCP platform at https://stratcomm.hhs.gov/. This is the first phase of the SCP development process. This includes the project, including mock-up or concept draft, budget, and other SCP criteria must be submitted in SCP. At this point, a preliminary signoff is obtained so that production can commence. When completed with production, or at the second and final phase, the final product must be submitted, and the file or representation of final audience-focused communications message will be attached to the submission in SCP. The SCP platform will provide e-mail notifications to the originator indicating a need for modification, if necessary. In case of file size issues, or any other problems with the SCP platform, please contact OEA or the SCP Help Desk at scphelpdesk@hhs.gov.

8. Procedures

A. The SCP Platform

1. The SCP platform can be found at https://stratcomm.hhs.gov. Only registered users can access the system. An employee may become a registered user by contacting their SCP agency manager within OEA or the SCP Help Desk at scphelpdesk@hhs.gov. Provide your name, agency/office; e-mail address; center/division/institute; phone number, and PIV number (10-digit number personal identifier number found on the back side of the HHS ID).

2. Prior to submitting a strategic communication plan and content for ASPA review, users must:

    a. Complete all required fields of the SCP platform;

    b. Identify collaborators both inside and outside HHS and receive their concurrence;

    c. Obtain review and approval from their designated HHS agency and office communications and public affairs officials.

3. The SCP platform provides a mechanism for users to submit a strategic communication plan to their approving officials to document their approval of the plan. Upon approval by the designated approving officials, SCP agency managers can submit the plan to ASPA for review (SCP agency managers are the only SCP users who have access to submit communication plans to ASPA).

4. Depending on the topic, complexity of the content and circumstances involving other activities and events throughout HHS, review of a submission may take several weeks to ensure appropriate Office of the Secretary/ASPA review.

B. Submitting Content for agency and ASPA Review

1. The originating office completes the SCP submission. The SCP, phase one, is submitted into the SCP platform, https://stratcomm.hhs.gov/, by the SCP project team. The originating office is responsible for appropriate office or center clearance, including review by relevant subject matter experts, cross-agency work groups, and other interested parties throughout FDA. Centers and offices are encouraged to seek OCC clearance as appropriate The project team will recommend internal agency review or, based on criteria, recommend ASPA approval, or higher approval such as OMB, White House, etc.

2. Once the SCP is submitted to the agency manager, the completed SCP submission is available to the Associate Commissioner for External Affairs, or designee for review/approval at the agency level.

3. The agency manager or ASPA will inform the POC listed in the SCP of the need for modification, approval, or disapproval of a submission, and/or the SCP platform will notify the submitter directly. The agency manager may return the SCP to the project team as agreed to by the Team. An SCP may go through multiple reviews for phase one concept and content clearance (if all is ready for internal clearance or submission

to ASPA, the agency manager will typically take 5-10 business days to clear and notify the SCP project team).

4. Depending on the topic, complexity of the content and circumstances involving other activities and events throughout HHS, ASPA review of a submission may take several weeks to ensure appropriate OS/ASPA review. ASPA will enter their comments and either sign-off on the plan or ask for additional information prior to complete sign-off. The agency manager will receive the ASPA notification and return the submission as cleared or not cleared, requiring further action.

5. When the distribution date has arrived, the SCP is then available to all members of the SCP platform, including those members of the SCP platform outside of FDA, for purposes of collaboration.

6. The Evaluation of the SCP is a critical component in the lifecycle of the audience-directed communication product as described in the SCP. When the SCP is approved it will designate specific frequency for evaluation of the SCP to determine whether the goals of the SCP were met/not met, so that the project team can modify its planning, study its estimates of impact, and track its ongoing communications strategy for this particular SCP.

7. Strategic Communication Planning is designed for program staff, including CORs and their servicing contractors, to create a consistent approach for strategic planning of agency audience-focused communications messages. Strategy reflected in a Strategic Communications Plan (SCP) should cascade from department to agency (found at https://stratcomm.hhs.gov/, Resources Tab, Strategic Alignment and Budgeting) to a project team SCP. This is the first phase of the SCP development process. This includes the project, including script, budget, and other SCP criteria that must be submitted in SCP.

   At this point, a preliminary signoff is obtained so that production can commence. When completed with production, or at the second and final phase, the final script and final multimedia product must be submitted, and the file or representation of final audience-focused communications message will be attached to the submission in SCP.

   The SCP platform will provide e-mail notifications to the originator indicating a need for modification, if necessary. In case of file size issues, or any other problems with the SCP platform, please contact OEA or the SCP Help Desk at scphelpdesk@hhs.gov.

   The SCP includes the key elements in communications planning and execution – all FDA Component-developed RFIs and solicitation should

address how these elements will be developed as part of the project:

a. Strategic Alignment – the purpose for this communication product including how it helps advance the Department and agency/office strategic goals.

b. Target Audience – the demographics, sociographics and psychographics of the people or organizations expected to change as a result of the communications.

c. Field Analysis - what the target audience needs, building on what's already available to meet these needs, and potential collaborators.

d. Goals – specific, measurable outcomes expected as a result of the communications products.

e. Content and Distribution – the content approach and distribution methods effective for the specified target audience.

f. Evaluation – a plan for when and how outcomes and impact will be measured, including sharing best practices and lessons learned, and flexibility for mid-course corrections.

Finally, the work submitted in an SCP should strategically align with FDA SMG 2240.9. This SMG is a requirement for creation, promotion, dissemination and evaluation of audience-focused communications messages.

9. Technical Support

SCP Technical Support – scphelpdesk@hhs.gov

10. Clearance Timetable

Review Steps	Responsibilities
Phase one review:	OEA is responsible for reviewing the submission within ten days. Note that more time may be required for extremely long or complex submissions. OEA will advise if that is the case.

Review Steps	Responsibilities
ASPA review:	OEA will determine whether a review is required by ASPA, or if the SCP will be reviewed within the agency only (internal review). Depending on the topic, complexity of the content and circumstances involving other activities and events throughout HHS, ASPA review of a submission can take several weeks. ASPA may recommend that other agencies or entities review the submission; this review is the responsibility of the originating office or center.
Preliminary signoff:	Video submissions must be in three phases: concept, script/storyboard and rough cut. Exhibits, print and electronic publication submissions must be in two phases: mock-up or concept draft and final product. An SCP may go through multiple reviews for phase one concept and content clearance. Once a preliminary signoff is obtained, production can commence. The agency manager will receive the ASPA notification and return the submission as cleared or not cleared within ten days. This will require further action from the submitter within 10 business days.
Phase two review:	In the final phase of clearance, the Associate Commissioner for External Affairs or designee will require clearance of the attached final manuscript, “rough” cut and/or final multimedia product, or design. Prints and revisions that are to be printed and distributed by the agency or a component must be included in this second phase of the process as well. This phase of review can take up to two weeks or more.

11. **Effective Date**

The effective date of this guide is July 15, 2016.

12. Document History – SMG 2240.9, "Publications and Multimedia Clearances"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	07/15/2016	N/A	OC/OEA	Kathleen Quinn, Deputy Director of Operations, OEA
Change	07/25/2023	Sect. 1-8, 10	OC/OEA	Heidi Rebello, Deputy Associate Commissioner, OEA
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