
POLICY AND PROCEDURES

OFFICE OF COMMUNICATIONS

Criteria for Developing and Publishing Digital Content on the CDER External Web Site

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PURPOSE

This MAPP establishes policies and procedures for developing and publishing digital content for the CDER external Web site (www.fda.gov/Drugs/default.htm). This MAPP also sets standards for ensuring the CDER Web site is periodically reviewed for currency, accuracy, and consistency with Agency and Department policies.

BACKGROUND

This MAPP outlines the criteria that must be met when developing and publishing content on the CDER Web site.

POLICY

Design of New Web Pages and Sites - CDER staff who want to develop new or substantially revise Web components (pages, sites, and applications) and staff who employ contractor support for any Web components will contact the Office of Communications’ (OCOMM) Division of Online Communications (DOC) at the conceptual planning stage. DOC will help plan, design, test, and implement the pages.

Web Content Coordination - All human-drug-related content developed for the CDER Web site will be coordinated through DOC to ensure:

- Compliance with all applicable laws, regulations, policies, standards, and procedures, including 508 compliance and Federal Plain Language requirements.
- Compatibility with the overall FDA Web information architecture.
- Coordination with other Departments, Agencies, and CDER Web projects.
- Usability testing to make sure Web features work as expected, if appropriate.
- Appropriate linking to existing pages and applications.
- Appropriate content and length for video production.
- Development of an appropriate review life-cycle.
- Updating or archiving of existing pages.
- Procurement of necessary clearances and approvals.
- Clearance - Only final versions of documents, videos, or multimedia materials that have received proper clearances will be posted on the CDER Web site. A version is considered to be “final” when an office director, division director, branch chief, or his/her designee sends a confirmatory email to DOC.
- Only information that is allowed to be disclosed to the public will be placed on the CDER Web site. Information that is exempt from disclosure, under either the Privacy Act or the Freedom of Information Act (FOIA), will not be posted on the CDER Web site.
- Current Department, Agency, and Center clearance procedures for publications, speeches, and other documentation will be followed. Content that appears to make a policy statement will be cleared through CDER’s Office of Regulatory Policy.
- OCOMM will provide and coordinate clearance for video and multimedia productions representing the Center through all production phases.
- Copyrighted material may be published only with permission from the copyright holder. The CDER Web page will state that permission has been obtained along with the copyright holder’s name and the date the permission was obtained.
- Content already published will be changed only at the request of an office director, division director, branch chief, or his/her designee.
- For transparency, information is rarely removed from the CDER Web site except for Freedom of Information Act (FOIA) documents. Exceptions will be approved by CDER’s Office of Regulatory Policy (ORP), or a CDER office director or designee.

Translated Materials - All CDER Web information will be created first in an English language version. OCOMM will translate materials to Spanish through a translation language specialist to ensure that the translations are accurate and culturally sensitive to the targeted audience.

Content Distribution - All content files intended for distribution on a third-party Web site will be cleared through OCOMM. A content plan must be discussed and developed in conjunction with OCOMM before any content is placed on a third-party site.

RESPONSIBILITIES

Web content creators are responsible for:

- Assuring the accuracy, currency, and quality of information.
- Periodically reviewing the information for currency and accuracy, and updating it as needed.
- Providing DOC with updated versions of information and documents.
- Obtaining clearance and publishing approval from management at the next highest organizational layer. For example, if the material is developed within a division, it will be approved through the next highest level. In some cases, approval may be obtained through the super office level, the level of the CDER Executive Committee, or CDER policy staff.
- Working with DOC to make sure content can be made 508 compliant.

The content approver is responsible for:

- Designating any program contacts and program content managers for the project.
- Assuring the accuracy and currency of the content.
- Assuring that any policy implications are consistent with CDER and FDA regulatory policy.
- Assuring compliance with all applicable CDER MAPPs and Staff Manual Guides (SMGs) for clearing documents.
- Assuring that all content is able to be disclosed to the public.
- Assuring that the language appears appropriate for the intended audience.

DOC staff is responsible for:

- Working with CDER staff to develop content and Web applications.
- Assuring compliance with all laws, regulations, policies, standards, and Web best practices.

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- Coordinating and ensuring internal clearance, including from the CDER Director of Regulatory Policy, FDA regulatory counsel, FDA Web management staff, and the HHS Web management staff, if needed.
 - Ensuring the Web site features work appropriately.
 - Ensuring content has no editorial comments or mark-up.
 - Ensuring that FDA has received permission to publish copyrighted material included in Web content and documenting the permission.
 - Making the content 508 compliant.
 - Ensuring that new topical pages or substantially updated content is reviewed and edited, if necessary, by a DOC staff member.
 - Ensuring the content has received the necessary clearances and approvals.
 - Coding the document and publishing it as quickly as possible.
 - Informing the content creator and other interested staff when content has been posted to the Web.
 - Archiving a copy of the final signature page or clearance record.
 - Maintaining the CDER Web site for accuracy and timeliness of information.
 - Providing and coordinating clearance for video and multimedia productions through the various production phases.

DOC Division Director is responsible for:

- Overseeing all work to ensure that it supports the public health mission of the Center.
- Maintaining a strategic view of the CDER Web site and its interrelationships with other parts of the Agency, the Department, and other government organizations.
- Providing overall editorial control of content and links to assure message consistency and appropriate language and style.
- Working with Web management staff in the FDA Office of the Commissioner's Office of External Affairs and the Internet/Intranet Support Services Group in the Chief Information Officer's Office of Business Enterprise Solutions to ensure all substantive new sites and applications are coordinated appropriately.
- Working with CDER program and DOC staff to set overall priorities and resolve any issues.
- Developing additional policies and guidances as necessary.
- Reviewing new content and applications to ensure site quality and that all approvals have been received.

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- Responding to initial requests to publish or update content and coordinating with DOC deputy director or designee on execution.
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PROCEDURES

The Approval Process for Web Pages

To publish new sections of the CDER Web site, significant new pages, or a Web application, office directors, division directors, branch chiefs, or their designees will communicate with the Director of DOC through email. DOC will review and confirm the following information:

- The name of the content creator.
- The requested date the content will be published on the Web site.
- A date for the content provider to review the content for update, if appropriate.
- A description of the content or application (optional).

The Approval Process for Multimedia

Offices will work with DOC to create multimedia content. The accuracy of the content will be decided on by the originating office, content creators, and content approvers. DOC will provide guidance and clearance over the creative elements of production to ensure CDER is presenting a high-quality product.

- All video and multimedia planning, through all phases of production, will be done in consultation with DOC.
- OCOMM requires concept clearances from HHS. If approved, OCOMM will provide guidance, consultation, and clearance of the production elements (e.g., story board, scripts, rough cuts, and final versions of the product.)
- Video and multimedia will be 508 compliant and contain captioning. For webinars, DOC will arrange for captioning. For videos, the video creator will arrange for captioning.

Writing of Web Content

Web site content will be accurate and concise. It will reflect current science and Agency policies. All material written for or posted to the CDER Web should be in plain English and at a reading level or comprehension level appropriate for its specific audience. Content displayed on the CDER Web will follow *FDA Website Style Guide* and the *CDER Style Guide*.

Information should be written with the most important information — who, what, where, when, and (sometimes) why — appearing in the first paragraph. Content will stay on message and will be stated simply and clearly. Information will be grouped in manageable portions with frequent subheads to make it easier to scan the content.

External links will be established only with other sites that contain appropriate and reliable information as per OMB, HHS, and FDA policies, i.e., links to government Web sites and specific organizations. Links to commercial Web sites will receive special review.

The recommended file formats for submitting documents to be posted on the CDER Web site are hypertext markup language (HTML), Microsoft Word, Portable Document Format (PDF) (commonly known by the brand name Adobe Acrobat), and Microsoft PowerPoint. Microsoft Word documents will be converted to HTML or PDF for posting.

Removal of Web Content

- To remove content from the Web site, the Director of DOC or designee will receive approval via email from an office director, division director, branch chief, or his/her designee.

Graphics and Photographs

- All graphics and photographs used on the public site will add to or reinforce content of the text. Graphics and photographs will be in the public domain or permission to republish will be obtained in writing from the owner.
- All graphics and photographs will include alternative text in the HTML code to describe the graphic or photograph, to be 508 compliant.
- The recommended file formats for submitting documents to be posted on the CDER Web site are HTML, Microsoft Word, Microsoft PowerPoint, Microsoft Excel, and PDF. Microsoft Word documents will be converted to HTML or PDF for posting. PDF Files will be submitted as non-scanned files.

Posting Non-advisory Committee Meeting Presentations

- Following a presentation at any CDER public forum, the presenter will provide an electronic copy of the PowerPoint presentation to DOC for posting.
- For presentations that are part of an FDA-sponsored or co-sponsored event where CDER wants to post all the presentations related to that event, presentations must be sent to cderpresentations@fda.hhs.gov. Posting and timing instructions must be included.
- For presentations too large to email, the presenter will upload the presentation on the FDA transfer drive (for example, the x-drive) into a folder designated for the presentation. The presenter should notify DOC at cderpresentations@fda.hhs.gov to indicate that the presentation has been uploaded.
- DOC will ensure all presentations are 508 compliant.

- Within three days following the 508 compliance process, DOC will post the presentations on the meeting page. DOC will create a link to the presentation page or managed list on the:
 - “CDER Presentations Library” page:
<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm074833.htm>
 - CDER “What’s New” page:
<http://www.fda.gov/Drugs/NewsEvents/ucm130958.htm>
 - DOC will let the program office know when the presentations are on the site.
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REFERENCES

1. FDA, 2000, Staff Manual Guide 3215.1 Web Program Operations
 2. FDA, 2008, Staff Manual Guide 3215.2 Web Content Archiving Policy
 3. FDA, 2006, Staff Manual Guide 2020 FDA Quality System Framework for Internal Activities
 4. FDA, 2011, Center for Drug Evaluation and Research, MAPP 7600.2; CDER Informatics Governance Process
 5. FDA, 2005, Center for Drug Evaluation and Research, MAPP 4000.2; Developing and Issuing Guidance
 6. FDA, 1999, Center for Drug Evaluation and Research, MAPP 4510.2; Clearance of Speeches, Articles, and Other Communication Material
 7. FDA/CDER, 2012, CDER Style Guide
 8. NARA, 2003, Records Management Handbook
 9. Americans With Disabilities Act (ADA) 1990, Section 508.
 10. FDA Website Style Guide, Version 11.03
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DEFINITIONS

Content approvers - Subject matter experts outside of DOC who provide final clearance of new or substantially revised Web pages, Web sites, and Web applications. Content approvers are division directors, at a minimum. Depending on the sensitivity of the content, approval may be provided at the office or super office level, or from the CDER Executive Committee. DOC will consult with content creators to make these determinations. Content approvers designate program contacts and program content managers for their respective divisions, offices, or staffs. In some cases, the content approvers, content creators, and program content managers are the same person.

Content creators - CDER staff outside of DOC who are the subject matter experts for a Web page or Web area, and who are intimately familiar with the information content and/or data in the databases that supply content posted in that Web area. Content creators are responsible for ensuring that content is periodically reviewed and updated, as needed.

Plain language - communication an audience can understand the first time it is read or heard.

Program content managers - Intermediaries between Web content creators and the CDER Web Management staff. Program content managers liaise with the CDER Web management staff and work with them to conceptualize, design, and create Web pages and applications. Not all offices and divisions use content managers. Program content managers will be designated by content approvers.

Program contacts - Liaisons between content creators and DOC. They interact with DOC to request changes to existing pages, to furnish updated organizational information, and to coordinate the clearance process. It is common for one person to serve as both the program contact and the program content manager. Program content managers will be designated by content approvers.

Section 508 of the Americans with Disabilities Act (ADA) of 1990 - This Act establishes requirements for electronic and information technology developed, maintained, procured, or used by the Federal government. Section 508 requires Federal electronic and information technology to be accessible to people with disabilities, including employees and members of the public.

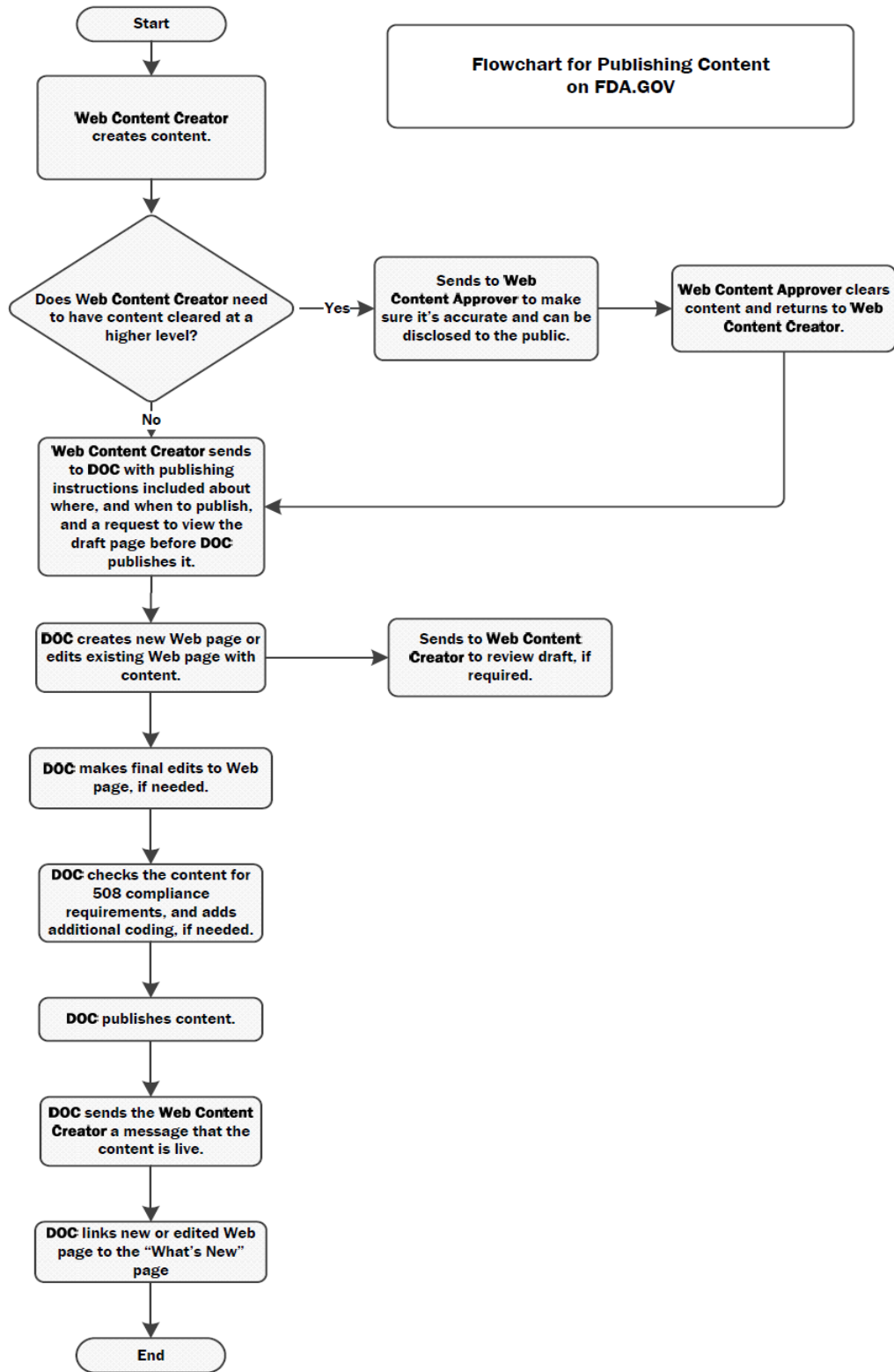
EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
12/26/12	Initial	n/a

ATTACHMENT I – Publishing Digital Content on the CDER Web Site Chart



ATTACHMENT II – Posting Multimedia Content on the CDER Web Site Chart

