
POLICY AND PROCEDURES

OFFICE OF COMMUNICATIONS

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

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PURPOSE

This MAPP establishes policies and procedures for developing and publishing digital content for the Drugs external Web site. This MAPP also sets standards for ensuring the Drugs 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 Drugs Web site.

POLICY

Design of New Web Pages Sections, and Multimedia: CDER staff who want to develop new or substantially revise Web components (pages, sections, images, and applications), must contact the Office of Communications' (OCOMM) Division of Digital and Online Communications (DDOC) at the conceptual planning stage. DDOC will help plan, design, develop, test, and disseminate the content. This includes staff who employ contractor support for any web components.

Web Content Coordination: All human-drug-related content developed for the Drugs Web site and other multimedia will be coordinated through DDOC to ensure the following requirements are met:

- ☐ Content complies with all applicable laws, regulations, policies, standards, and procedures, including 508 compliance, Federal Plain Language requirements, and FDA visual identity requirements.
- ☐ Content is created using current best web development practices.
- ☐ Content is compatible with the overall FDA Web information architecture.
- ☐ Content is coordinated with other Departments, Agencies, and CDER Web projects.
- ☐ Content design features work as expected as demonstrated through usability testing.
- ☐ Links to existing pages and applications work.
- ☐ Video production is appropriate in terms of content and length.
- ☐ Content has an appropriate life-cycle schedule for review, updating, and expiration.
- ☐ FDA security requirements are met.
- ☐ Offices and divisions are responsible for their own internal clearance process.
- ☐ Only documents, videos, or multimedia materials that have received final, proper clearances will be sent to DDOC for publishing on the Drugs Web site and other digital media.
- ☐ Only information that is disclosable to the public will be published on the Drugs 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 Drugs Web site. ☐ Current Department, Agency, and Center clearance procedures for publications, presentations, and other documentation must be followed. Content that appears to make a new policy statement will be cleared through CDER's Office of Regulatory Policy.
- ☐ OCOMM will coordinate clearance for video and multimedia productions representing the Center through all production phases.

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- ☐ Content already published will be significantly changed only at the request of an office director, division director, branch chief, or his/her designee.
 - ☐ Content that has been removed from [fda.gov](https://www.fda.gov/about-fda/about-website/fdagov-archive) will be available at an FDA archive web site, <https://www.fda.gov/about-fda/about-website/fdagov-archive>.

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.

RESPONSIBILITIES

Web content creators are responsible for:

- ☐ Assuring the accuracy, currency, and quality of information.
- ☐ Reviewing the information at least every two years for currency and accuracy.
- ☐ Providing DDOC with updated versions of information and documents.
- ☐ Identifying content that can be removed from the web site. This content will be available through the FDA Archive.
- ☐ Coordinating and obtaining internal clearance and publishing approval from senior management. In some cases, approval must be obtained through the CDER Director of Regulatory Policy, FDA regulatory counsel, and HHS Web staff.
- ☐ Assuring compliance with all applicable CDER MAPPs and Staff Manual Guides (SMGs) for clearing documents.
- ☐ Working with DDOC to make sure content is 508 compliant.
- ☐ Assuring that any policy implications are consistent with CDER and FDA regulatory policy.
- ☐ Assuring that all content is disclosable to the public.
- ☐ Assuring that requirements for plain language are met, and the language is appropriate for the intended audience.

DDOC staff is responsible for:

- ☐ Working with CDER staff to develop digital content and Web applications.
- ☐ Assuring compliance with all web and digital-related laws, regulations, policies, and standards.
- ☐ Using current standard operating procedures (SOPs) and best practices from HHS, FDA, CDER, IT, and other sources to develop digital, web content, and applications.
- ☐ Ensuring the Web site features work appropriately.
- ☐ Ensuring content has no editorial comments or mark-up.

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- ☐ Ensuring that FDA has received permission to publish copyrighted material
 - ☐ Ensuring that content is not published before approval from the content provider.
 - ☐ Working with web content providers to make the content 508 compliant.
 - ☐ Ensuring that new topical pages or substantially updated content is reviewed and edited by a DDOC staff member to make sure content follows best practices for web design.
 - ☐ Ensuring the content approver has received the necessary clearances and approvals.
 - ☐ Coding the content and publishing it according to best practices ☐ Informing the content creator and other interested staff when content has been published to the Web.
 - ☐ Maintaining the Drugs Web site for accuracy and timeliness of information.
 - ☐ Maintaining the Drug Web site for consistent look and feel.
 - ☐ Acts as a liaison with requestor and OMA on clearance for video and multimedia productions

DDOC 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 Drugs 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 sections and applications are coordinated appropriately.
- ☐ Working with CDER program and DDOC 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.

PROCEDURES

The Development Process for Web Content

To publish new sections of the Drugs Web site, significant new pages or updates, office/division directors, or their designees will submit a web request ticket. DDOC staff will review and confirm the following information:

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- ☐ Instructions are clear and all content to be published is provided.
 - ☐ A date to publish the content is provided.
 - ☐ Whether or not the content provider wants to review a draft before publishing.
 - ☐ A date for the content provider to review the content for update or archiving.
 - ☐ Metadata for the content is complete.

The Development Process for Multimedia, including Videos and Webinars

Offices will work with DDOC to create multimedia content. The accuracy of the content will be guaranteed by the originating office.. DDOC 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 DDOC.
- ☐ 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, DDOC will arrange for captioning. For videos, the video creator will arrange for captioning.
- ☐ Webinar content will be developed and cleared in the originating office or division.

Writing of Web Content

Web site content will be accurate and concise. It will reflect current science and Agency policies. All material written for fda.gov must be in plain language according to the Plain Writing Act of 2010, and at a reading level or comprehension level appropriate for its specific audience. Content published on the Drugs 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 Drugs 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 and PowerPoint files will be converted to HTML or PDF for posting. PDF Files will be submitted as non-scanned files.

Removal of Web Content

- ☐ Content that has not been updated or reviewed two years after the original publish date will be reviewed for removal (expired) from the web site. Expired content can be accessed on FDA.gov Archive. Some content, such as guidances, MAPPs, and user fee-related information are exempt from removal.

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 graphics to be posted on the Drugs Web site are JPG, PNG, GIF, and PDF.
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REFERENCES

1. FDA, 2000, Staff Manual Guide 3215.1 Web Program Operations
 2. FDA, 2017, Staff Manual Guide 3215.2 Archiving and Unpublishing Web Content Policy
 3. FDA, 2014, Staff Manual Guide 2020 FDA Quality System Framework for Internal Activities
 4. FDA, 2013, Center for Drug Evaluation and Research, MAPP 4510.2; Clearance of FDA-Related Articles, Speeches, and Other Publications
 5. Americans With Disabilities Act (ADA) 1990, Section 508 Requirements and Responsibilities
 6. Website Policies
 7. Plain Language Guidelines
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DEFINITIONS

Content creators - Subject matter experts that supply final, cleared new or substantially revised web content for digital or web publishing. Content creators are responsible for ensuring that content is periodically reviewed and updated, as needed.

Plain language – Follows the [Plain Writing Act of 2010](#) guidelines so audiences can understand communications the first time they read or hear it.

Section 508 of the Americans with Disabilities Act (ADA) of 1990 - Section 508 requires Federal web information to be accessible to people with disabilities, including employees and members of the public.

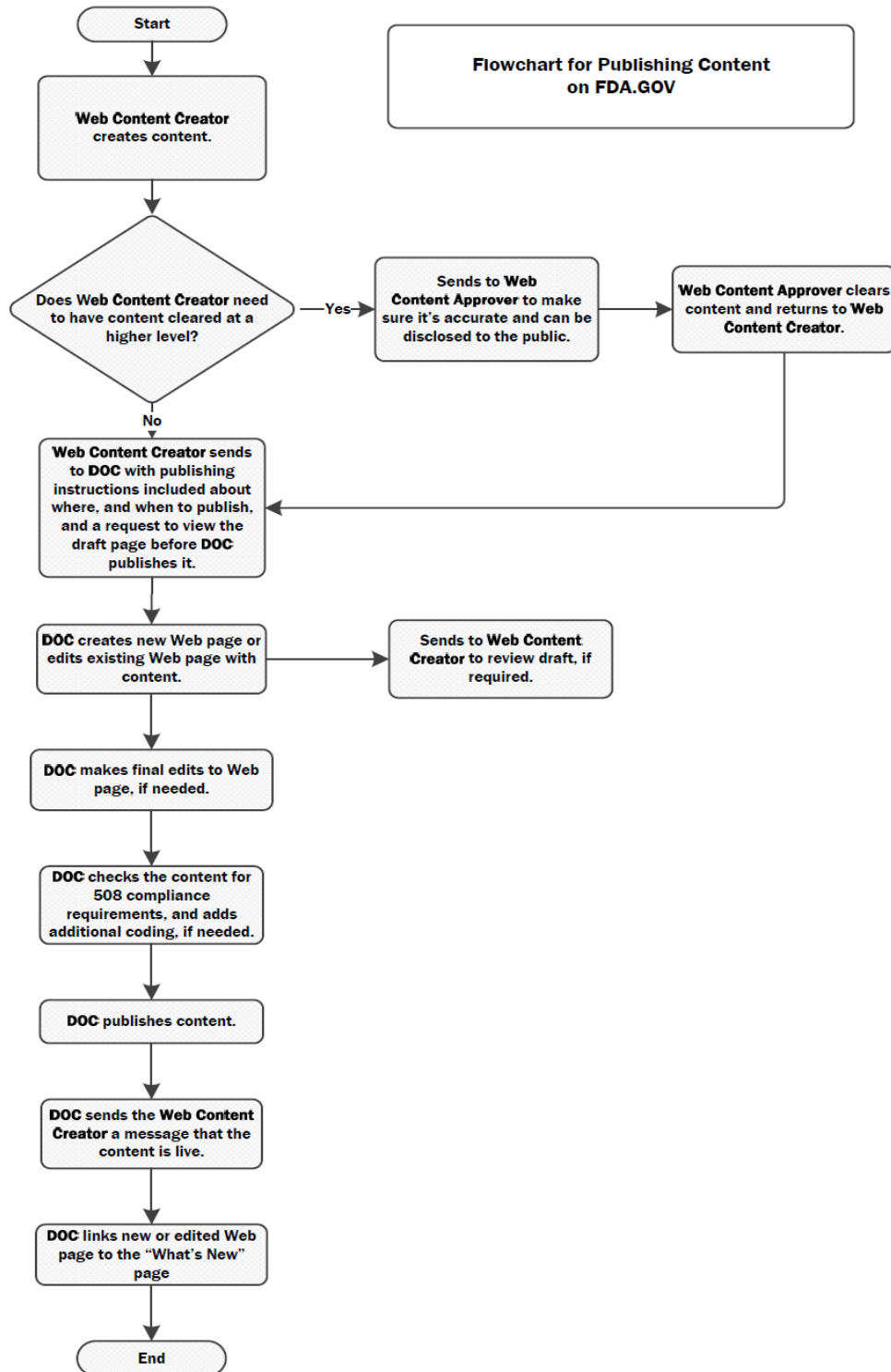
EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
12/26/12	Initial	n/a
07/13/2017	1	New work request submission procedure and archiving expired Web pages.

ATTACHMENT I Publishing Digital Content on the Drugs Web Site Chart



ATTACHMENT II Posting Multimedia Content on the CDER Web Site

