POLICY AND PROCEDURES

OFFICE OF COMMUNICATIONS

Criteria for Developing and Publishing Digital Content on the Drugs External Website

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PURPOSE

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

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 website and other multimedia are coordinated through DDOC to ensure the following requirements are met:

- FDA security 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.
- Only information that is disclosable to the public will be published on the Drugs website. 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 website.
- Current Department, Agency, and Center clearance procedures for publications, presentations, and other documentation are followed. Content that appears to make a new policy statement will be cleared through CDER's Office of Regulatory Policy.
- 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.
- Content has an appropriate life-cycle schedule for review, updating, and expiration.
- Offices and divisions are responsible for their own internal clearance process.
- Content removed from fda.gov is available at an FDA archive website. More information about FDA.gov archive is available at https://www.fda.gov/about-fda/about-website/fdagov-archive.
- Content already published will be significantly changed only at the request of an office director, division director, branch chief, or designee.

- OCOMM coordinates clearance for video and multimedia productions representing the Center through all production phases.
- Only documents, videos, or multimedia materials that have received final, proper clearances will be sent to DDOC for publishing on the Drugs website and other digital media.
- Video production is appropriate in terms of content and length.

Translated materials

All CDER web information is created first in an English language version. OCOMM translates selected materials into other languages when appropriate using a translation language specialist, to ensure that the translations are accurate and culturally sensitive to the targeted audience.

RESPONSIBILITIES

Web content creators

- Assuring that all content is disclosable to the public.
- Assuring the accuracy, currency, and quality of information.
- Complying with section 508 to provide accessible information.
- 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.
- Reviewing the information at least every two years for currency and accuracy.
- Providing DDOC with updated versions of information and documents.
- Identifying content to be removed from the website. This content will be available through the FDA Archive.
- Assuring compliance with all applicable CDER MAPPs and Staff Manual Guides (SMGs) for clearing documents.
- Assuring all policy implications are consistent with CDER and FDA regulatory policy.
- Assuring that requirements for plain language are met, and the language is appropriate for the intended audience.

DDOC staff

- 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 Health and Human Services (HHS), Food and Drug Administration (FDA), CDER, define IT here – Information Technology?? (IT), and other sources to develop digital, web content, and applications.
- Ensuring the website features work appropriately.
- Ensuring content has no editorial comments or mark-up.
- 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 owners to provide guidance on making content section 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 website for accuracy and timeliness of information.
- Maintaining the Drug website for consistent look and feel.
- Acts as a liaison with requestor and define OMA here (OMA) on clearance for video and multimedia productions.

DDOC Division Director

- Overseeing all work to ensure that it supports the public health mission of the Center.
- Maintaining a strategic view of the Drugs website 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

Development process for web content
To publish new sections of the Drugs website, significant new pages or updates, office or division directors, or their designees submit a web request ticket. DDOC staff reviews and confirms the following information:

- 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.

Development Process for Multimedia, including Videos and Webinars
Offices work with DDOC to create multimedia content. The accuracy of the content is guaranteed by the originating office. DDOC provides 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, are done in consultation with DDOC.
- OCOMM requires concept clearances from HHS. If approved, OCOMM provides guidance, consultation, and clearance of the production elements (e.g., story board, scripts, rough cuts, and final versions of the product.)
- Video and multimedia are 508 compliant and contain captioning which is the responsibility of the content owner.
- Webinar content is developed and cleared in the originating office or division.

Writing of web content
Website content is 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 website will follow FDA Website Style Guide.

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

- The recommended file formats for submitting documents to be posted on the Drugs website are hypertext markup language (HTML), Microsoft Word, Portable Document Format (PDF) (commonly known by Information is written with the most important information — who, what, where, when, and (sometimes) why — appearing in the first paragraph.
- Content stays on message and will be stated simply and clearly.
- Information is grouped in manageable portions with frequent subheads to make it easier to scan the content.

the brand name Adobe Acrobat), and Microsoft PowerPoint. Microsoft Word and PowerPoint files are converted to HTML or PDF for posting. PDF Files are 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 (unpublished) from the website.
- 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 add to or reinforce content of the text. Graphics and photographs are in the public domain or permission to republish is obtained in writing from the owner.
- All graphics and photographs 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 website are JPG, PNG, GIF, and PDF.

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 posted on FDA.gov: Website Policies
7. Plain Writing Act of 2010.

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
03/1/2020	Rev. 1	New work request submission procedure and archiving expired Web pages.
1/13/23	n/a	Typographical errors corrected, per P. Buckman's direction.
7/21/25	Rev. 2	Formatted content and minor editorial changes. For both attachments, removed the graphic and inserted text equivalents.

ATTACHMENT I: Guide for publishing Content on FDA.gov

1. Web content creator produces content.

2. Does the content creator need to have content cleared at a higher level?

    a. Yes
        i. Sends to content approver to make sure it's accurate and can be disclosed to the public.

        ii. Web content approver clears the content and returns to content creator.

        iii. Go to step 3.

    b. **No** – go to step 3.

3. Content creator **submits a ticket to DDOC** with final 508 compliant content and publishing instructions, including where and when to publish. If required, content creator also requests to view the draft page before DDOC publishes it.

4. DDOC creates a new webpage or edits an existing webpage with content.

    a. If requested, DDOC sends draft to content owner for review.

5. DDOC makes final edits to webpage, if needed.

6. DDOC publishes content when given approval by content creator.

7. DDOC closes the request which notifies the content creator the content is live.

8. DDOC adds a link to "What's New Related to Drugs" webpage for newly published webpages or notable edits unless the web content creator requests not to have it on the What's New page.

Done

ATTACHMENT II: Posting Multimedia Content on the CDER WebSite

1. Content creator obtains director approval for the project.
2. Content creator meets with DDOC to discuss the project.
3. DDOC sends concept approval forms and supporting material to content creator.
4. Content creator submits concept approval forms to DDOC.
5. OCOMM reviews and clears project concept.
6. DDOC forwards project concept to FDA Office of External Affairs for clearance. OEA determines if HHS approval is needed.
7. Once concept is cleared by FDA/HHS, content creator can solicit contract proposals for video and/or scripting services if necessary.
8. Content creator obtains office approval for the script and sends to DDOC.
9. OCOMM reviews script and submits to FDA Office of External Affairs/HHS for clearance.
10. Approved script with any edits/changes is sent back to the originating office to produce a rough-cut video.
11. Once produced, the submitting office obtains division and office clearance for the rough-cut video.
12. The rough-cut is viewed by OCOMM.
13. Are there any major changes?
    a. **Yes** – OCOMM highlights any major concerns or necessary changes; returns rough-cut to originating office for edits. Go to step 11.
    b. **No** – go to step 14.
14. OCOMM clears rough-cut and submits to FDA/HHS for review.
15. Once FDA/HHS clearance is obtained, any comments/edits to the rough-cut are used to produce the final video.
16. DDOC notifies originating office of additional information needed to post final video.
17. Originating office submits CDER web production ticket. DDOC works with OEA to upload final video for public viewing.

Done