INFORMATION TECHNOLOGY

Posting Documents on the External World Wide Web Site

CONTENTS

PURPOSE This MAPP outlines the responsibilities and procedures for Center for Drug Evaluation and Research staff for submitting items for posting on the external World Wide Web (WWW) site.

REFERENCES

- "HHS Use of the Internet," U.S. Department of Health and Human Services, April 1996 (DRAFT).
- "Policy for Internet Information Dissemination Using the World Wide Web," U.S. Food and Drug Administration, Office of Public Affairs, March 1996 (DRAFT).

DEFINITIONS

- **Originator.** A CDER staff member or organizational unit who wishes to post a document on the WWW. The originator of the document should be the individual who is responsible for clearing or issuing the document for final publication and is responsible for the content of the document. See

Attachment B for examples of originators.

- **Webmaster.** The individual or organizational unit who physically maintains the CDER web site.

POLICY

- Only final versions of documents that have received proper clearance may be posted on the WWW.

- Public FDA material or material releasable under FOI must be used whenever possible. Use of links to material on other FDA servers is preferred over developing new documents.

- Only information that is disclosable to the public will be placed on the CDER web site. No information will be included on the CDER web site that is covered by the Privacy Act or exempt under the Freedom of Information Act.

- Clearance procedures that are currently in place for the Center and Agency for issuing hard copies of documents must be followed. Procedures outlined in this MAPP do not supersede clearance procedure requirements specified in other guidance documents or regulations (e.g., guidance documents should be cleared in accord with MAPP 4000.2; speeches should be cleared in accord with MAPP 4510.2; approval letters should be cleared through the Office/Division Director).

- The CDER web site will include the following four main categories:

  1. **About CDER** - Examples of documents that will be located in this category are: mission statement, organizational charts, history of CDER, personnel listings, careers at CDER, telephone listings.

  2. **What's Happening** - Examples of documents that will be located in this category are: meeting information (notices, agendas, minutes), upcoming events, publications (e.g., *News Along the Pike*).

  3. **Drug Information** - Examples of documents that will be located in this category are: drug approval letters, approved final printed labeling, the Orange Book, Drug and Device Product Approval List, Drug Quality Reporting System Forms, Data Standards Manual, MedWatch Reporting Forms, National Drug Code Directory, Phase 4 Post-Approval Research List (purged copy), Inactive Ingredient

Guide (purged copy).

4. **Regulatory Guidance** - Examples of documents that will be located in this category are: MAPPs, guidance documents, relevant Federal Register documents, excerpts from the Code of Federal Regulations, the Food Drug and Cosmetic Act.

- Individual organizational units that want to have their own home page must develop and maintain their home page as a subpage to the CDER web site. Additionally, the organizational unit must coordinate their subpage with the CDER Webmaster.

- In general, the documents will be posted using the following priority:

1. drug approval information (e.g., approval letters, approved final printed labeling, "FDA Drug and Device Product Approvals")

2. time sensitive material, e.g., notice of upcoming public meetings, workshops, seminars, etc. (agendas and minutes)

3. guidance documents and MAPPs

4. communications (e.g., speeches, minutes of meetings)

5. other publications (e.g., Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) and supplements)

6. Federal Register documents

7. general information (e.g., telephone directory, personnel listings)

- The recommended file format for submitting documents to be posted on the CDER web site is hypertext markup language (HTML). However, other formats will be accepted (e.g., Adobe Acrobat, WordPerfect, Microsoft Word, and ASCII text).

External Links

- External links will only be established with other sites that contain appropriate and reliable information.

- External links should be established with other pertinent and appropriate

U.S. government organizations.

- External links with non-U.S. government organizations should be pre-approved by the Information Technology Coordinating Committee (ITCC).

- All external links will be terminated in one year unless the link is reviewed by the originator for appropriateness and reliability of information.

- The following message will appear regarding all external links when accessed by the user:

Attention

You are now exiting the Center for Drug Evaluation and Research Web Server.

You will be entering a site that contains information that is NOT controlled by CDER.
Thank you for visiting the Center for Drug Evaluation and Research.
We hope your visit was useful and informative.

RESPONSIBILITIES AND PROCEDURES

Originators are responsible for:

- assuring the content, timeliness, and quality of information;

- obtaining approval from the ITCC for establishing an external link to a non-U.S. government organization;

- reviewing the document or external link periodically for timeliness and appropriateness and reliability of information;

- providing the Webmaster with updated versions of documents;

- clearly indicating the following information on a Web Posting Request (WPR) form (see Attachment A);

    1. individual responsible for the material (e-mail address), i.e., “Information Contact Person”

    2. date of publication or issuance of the document

3. date the document will expire, if appropriate

4. document file format

5. document information (title, description);

- forwarding the following to the Webmaster;

  1. a completed WPR form

  2. an electronic copy of the document

  3. a copy of the clearance record or final signature page

- assuring compliance with all applicable MAPPs for clearing documents; and,

- assuring that all product specific documents (e.g., approval letters) have been cleared by the Freedom of Information Staff for dissemination to the public.

The Webmaster is responsible for:

- immediately logging in the request;

- posting the document **as quickly as** possible using the priorities established in the POLICY section;

- assuring that documents that are posted on the WWW have received proper clearance, i.e., by maintaining a copy of the final signature page or clearance record;

- maintaining the CDER web site;

- maintaining a database of all posted documents and documents to be posted on the CDER web site;

- informing originator of the deletion of a document and/or link 30 calendar days before the expiration of a link or document;

- informing the originator when the document is posted; and,

- informing the FDA Internet Work Group (through its FDAWEB listserv) when new documents of potential interest to other parts of the Agency are posted.

The ITCC is responsible for:

approving all non-U.S. government external links.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

Attachment A

WEB POSTING REQUEST FORM

ORIGINATOR NAME:	**MAILCODE:**
	TELEPHONE #:
	E-MAIL ADDRESS:
THIS REQUEST IS FOR: **____ ADDING A NEW DOCUMENT** **____ UPDATING A DOCUMENT** **____ REMOVING A DOCUMENT** **____ CREATING AN EXTERNAL LINK (URL:_____)**	
DOCUMENT TITLE:	
BRIEF DESCRIPTION:	
DOCUMENT FILE FORMAT (e.g.,WordPerfect, HTML) :	
ELECTRONIC FILE NAME (i.e., location on x drive):	
DATE OF PUBLICATION OR ISSUANCE OF DOCUMENT IN PRINTED FORM:	
EXPIRATION DATE OF DOCUMENT (if appropriate):	
INDIVIDUAL RESPONSIBLE FOR THE MATERIAL:	**MAILCODE:**
	TELEPHONE #:
	E-MAIL ADDRESS:
SUBMIT THE COMPLETED FORM TO THE CDER WEBMASTER (HFD-200) WITH THE FOLLOWING: **1. AN ELECTRONIC COPY OF THE DOCUMENT** **2. A COPY OF THE CLEARANCE RECORD OR SIGNATURE PAGE**	

X:\WWW\WPRFORM.WPD

Attachment B

EXAMPLES OF ORIGINATORS

Type of Document	Originator
Approved Drug Products with Therapeutic Equivalence Evaluations	Director, Division of Drug Information Resources (DDIR)
Approved final printed labeling	Project Manager/Consumer Safety Officer
Drug and Device Product Approvals List	Director, DDIR
Drug approval letters	Project Manager/Consumer Safety Officer
Federal Register documents	Associate Director for Policy
Guidance documents	Associate Director for Policy
Manual of Policies and Procedures	Associate Director for Policy
Meeting information (announcements, agendas, minutes)	Meeting Coordinator
Personnel listings	Director, Office of Management
Telephone directories	Director, Office of Management