
POLICY AND PROCEDURES

OFFICE OF COMMUNICATIONS

**CDER CLEARANCE OF FDA-RELATED ARTICLES, SPEECHES, AND
OTHER PUBLICATIONS**

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PURPOSE

- This MAPP establishes the policies and procedures for CDER employees to follow when clearing FDA-related¹ articles and speeches² intended for public dissemination. This MAPP supplements the policies and procedures set forth in FDA Staff Manual Guide (SMG) 2126.3, Review of FDA-Related Articles and Speeches.

BACKGROUND

- CDER employees are encouraged, with immediate supervisory concurrence, to speak at conferences and publish articles in professional journals or lay publications on topics related to the work of CDER or on subjects in their areas of expertise.
- Section 713 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) directs FDA to “establish and make publicly available clear written policies to implement and govern the timely submission, review, clearance, and disclaimer requirements for articles.”

¹ Articles or presentations that are not FDA-related and not part of an employee's official duties are not subject to CDER clearance.

² This MAPP describes the process for clearing the *content* of speeches and presentations. Procedures for managing, tracking and funding invitations to speak from outside entities can be found in MAPP 4510.1.

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- FDA developed SMG 2126.3 — Review of FDA-Related Articles and Speeches (effective February 2, 2011), which implements section 713 of the FD&C Act and extends the policy to speeches and other oral presentations. SMG 2126.3 provides for each Center to develop written policies that may supplement and expand upon this policy to meet their specific needs.
 - This MAPP revision supplements SMG 2126.3 and updates CDER policies and procedures for the clearance of FDA-related articles and speeches that are undertaken as assigned work.³
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POLICY

- FDA-related articles and speeches prepared by CDER employees, either as part of assigned work or as an outside activity (non-assigned), and intended for audiences outside the Agency are considered sensitive and require review and clearance by a designated clearing official. Examples of materials that must be cleared include, but are not limited to, speeches, articles, monographs, slide presentations, books, films, exhibits, and posters.⁴
- FDA-related web postings by employees to social networking sites, such as blogs, may be considered official communications when done in an official capacity or when posted using government networks or a government-issued email address, and require appropriate clearance facilitated by the Office of Communications. Clearance is not required if the post is not FDA-related and the author does not disclose his or her FDA affiliation. If there is a question regarding the content of a posting to a social networking site, consult with your supervisor.
- The determination of whether an article or speech is undertaken as assigned or non-assigned work must be made by the clearing official prior to the beginning of any work. The clearing official, in consultation with the author, may consider work on an FDA-related article or speech done outside of work hours to be assigned work.⁵
- An FDA-related article or speech written as non-assigned work is subject to the policies and procedures for review and clearance set forth in SMG 2126.3, including prior approval for the work as an outside activity. Non-public information may not be used for the preparation of work done as an outside activity.
- FDA-related articles and speeches prepared as assigned work will be reviewed and cleared following procedures described in this MAPP.
- The director of each office shall be the responsible clearing official for all articles and speeches developed by CDER employees. Office directors may delegate clearance responsibilities, determine the review sequence for each type of communication, the appropriate approval mechanisms, and the documentation required for clearance. Articles and speeches prepared by office and super office

³ If a CDER employee undertakes an FDA-related article or speech that is not part of his or her assigned work, it will be considered an “outside activity,” subject to the requirements for outside activities.

⁴ This MAPP does not apply to presentations or background materials prepared for presentation to an advisory committee. Such presentations are subject to existing procedures for clearance.

⁵ For example, if an employee writes a review article for professional development outside of work hours, the clearing official may choose to consider that assigned work, without requiring an outside activity approval.

directors do not need further clearance, but should be shared with their supervisor, as appropriate.

- Articles or speeches must not include any non-public information.
- FDA-related articles or speeches, which may have significant policy implications, must accurately represent official FDA policy to be cleared. If a clearing official has reviewed the document and determined that it is inconsistent with FDA's official policy, the required disclaimer must be included, as discussed below.
- If articles or speeches result from research involving human subjects that is conducted, funded, or sponsored by FDA, there must be documentation that the underlying research was approved by FDA's Research Involving Human Subjects Committee, FDA's Institutional Review Board.
- The process for review and clearance of articles and speeches should take no more than 30 days, unless the CDER employee and clearing official agree that an alternate time frame for clearance should apply.⁶ Unless an alternate timeline is agreed to, articles or speeches that are not reviewed within 30 days may be published, but must include the appropriate disclaimer⁷ (See Attachment II).
- FDA-related articles and speeches with co-authors from more than one CDER office must obtain clearance from each office. These parallel reviews can be conducted simultaneously and should be coordinated by the lead author.
- All articles or speeches forwarded for clearance describing research performed with FDA resources must be supported by appropriate documentation of the underlying primary data and observations.⁸ The author should follow the criteria put forth in the records management policy.⁹

*Disclaimers*¹⁰

- If a clearing official determines that an article is in accordance with FDA policy, no disclaimer is needed. However, the clearing official or the employee may decide to use the standard FDA disclaimer to emphasize that the views expressed in the article do not necessarily represent the official views or policies of the Agency. The standard disclaimer may also be used when writing or speaking about a scientific area where no FDA policy has been established or determined, as long as the establishment of new policy is not inferred.
- For cleared articles where a disclaimer is included by the author or clearing official, the following standard disclaimer language (Disclaimer 1) must be used:

“This [article/speech/other publication] reflects the views of the author and should not be construed to represent FDA’s views or policies.”

⁶ This may be especially appropriate for review of slide presentations, posters, or abstracts, which often involve short timelines and take less time to review. Alternatively, the clearance official's workload may make a longer clearance time optimal.

⁷ The employee must ensure that the article or speech does not contain any non-public information (see Definitions, and Attachment I).

⁸ SMG 9001.1, Scientific Integrity at FDA.

⁹ SMG 3291.1, Records Management Policy.

¹⁰ See Attachment II, Disclaimer Determination Chart.

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- If the clearing official has reviewed and determined that the article contains statements or conclusions that are not consistent with FDA policy, a different disclaimer (Disclaimer 2) is required:
“This [article/speech/other publication] has been reviewed by FDA and determined not to be consistent with the Agency’s views or policies. It reflects only the views and opinions of the author.”
 - Although FDA cannot mandate where a disclaimer is placed, the FDA employee should request that the disclaimer be placed in a prominent position on the first page of the article.
 - If a disclaimer is required and the publisher does not print disclaimers, it can only publish the article without the employee’s FDA title, affiliation, and address (email or U.S. Mail).
 - Non-federal employees who are working at FDA through a fellowship program, internship program, Intergovernmental Personnel Act assignment, volunteer program, or other arrangement must follow the policies, responsibilities, and procedures outlined in this MAPP.
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RESPONSIBILITIES

The FDA employee will:

- Discuss with his/her immediate supervisor whether an FDA-related article or speech will be done as assigned or non-assigned work before any work has begun. If it is decided the work will be non-assigned, the employee will request approval to write the article or present the speech as an outside activity. Approval must be received prior to beginning work on the article, and the review and clearance policies and procedures set forth in SMG 2126.3 must be followed.
- Ensure that underlying data supporting the article or speech are retained and available for review.
- Clear supporting data with the vendor, as required, when data owned by a vendor are used in an article or speech, (i.e., IMS Health).
- Coordinate any required reviews for clearance if authors are from multiple offices (if employee is the lead author).
- Provide any FDA-related article or speech prepared as part of assigned or non-assigned work to the appropriate clearing official for review no less than 30 days before pursuing its publication. This applies to all FDA-related articles, even if the article will not contain the employee’s FDA title, affiliation, or contact information.
- Keep the immediate supervisor apprised of substantive changes to the FDA approved version necessitated by required revisions or if the paper will be submitted or published by another journal.

The office director will:

- Act as the clearing official for articles developed within the office. Office directors may, at their discretion, delegate this responsibility.

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- At their discretion, delegate responsibility to a supervisor or team lead to decide whether a planned article or speech will be prepared by the employee as assigned or non-assigned work.
 - Develop and disseminate additional office-specific procedures, if needed, that describe how various types of FDA-related articles or speeches authored or coauthored by office personnel are to be cleared.¹¹ Additional office-specific procedures must meet minimal requirements of this MAPP and can:
 - Define each type of communication (e.g., slides, abstracts, manuscripts)
 - Identify the review chain for each type of communication
 - Identify the clearing official for each type of communication and indicate the clearing official's level of authority in the review process
 - Identify the type of approval mechanism required for each type (e.g., an office may elect to allow a clearing official to review and approve slides via email)
 - Identify specific requirements for documenting clearance (e.g., *CDER Clearance Request for Articles, Speeches, and Other Publications*)

The clearing official will:

- Complete clearance review to determine if an article or speech (1) contains non-public information and (2) has significant policy implications, within 30 days of receipt, unless an alternate time frame is agreed upon. Clearing officials will make reasonable efforts to accommodate meeting and publication deadlines.
- Provide clearance decision and, if appropriate, written comments to the employee and discuss with the employee suggested or required changes.
- Determine if disclaimer 1 or 2 is required or appropriate if a disclaimer is not already included.

PROCEDURES

Review of FDA-Related Articles or Speeches that are Assigned Work

Procedures for review and clearance of FDA-related articles and speeches that are assigned work are described below. Prior to an employee beginning work on any article or speech, the clearing official, in consultation with the employee, must determine that the article or speech will be assigned work.

Prior to submission for review

- Before submitting an article or speech materials for clearance, CDER employees are authorized and encouraged to obtain peer and technical review and evaluation from any component of the Center or elsewhere in the Agency that has relevant expertise

¹¹ The office-specific clearance procedures should be flexible to account for the realities of preparing oral and written communications, bearing in mind that the purpose of the procedures is to help the clearing official become aware of what is being written and/or presented by FDA employees and to provide necessary input.

(e.g., statistical review of a medical paper containing statistical material or having statistical implications).

- Should the employee elect to include Disclaimer 1, this should be added to the article or speech prior to submission for clearance.
- If the article addresses subjects that ordinarily fall within the purview of another office or center, the employee and supervisor should work to ensure that those other offices are identified and have an opportunity to review and provide comments.
- The CDER employee needs to determine that the article or speech does not contain any non-public information in the article or speech. Also, the CDER employee should determine if there are any policy implications.

Review

- CDER authors should submit their article or speech for review following procedures developed in this MAPP, in addition to any office-specific procedures that may exist. Should those procedures require use of a clearance sheet, use FDA form *CDER Clearance Request for Articles, Speeches, and Other Publications* (see Attachment III).
- If the topic of an article or speech is a CDER-regulated product, the employee and clearing official are expected to make the review division primarily responsible for that product aware of the content. Similarly, if the topic of the article or speech is sensitive because it discusses evolving policy that is pre-decisional, or policies or issues that are the subject of pending litigation, CDER's Office of Regulatory Policy (ORP) should be notified. ORP should review the document and determine if Office of Chief Counsel review is warranted. ORP's review may occur concurrently with that of the clearing official.
- The clearing official will review the article or speech to determine if it contains any non-public information (see Attachment I) or has significant policy implications that are at odds with current FDA policy.
- Should the employee or clearing official have questions about whether an article or speech contains non-public information, the clearing official should seek guidance from the director of the Division of Information Disclosure Policy in ORP.
- The clearing official provides feedback to the employee, identifying non-public information to be removed, or suggesting modifications to statements that are contrary to FDA policy.
- Once an article or speech is free of non-public information and statements and its conclusions conform to FDA policy, the clearing official clears the article. Clearance is documented according to the office-specific procedures. If a clearance form is used, the clearing official signs and returns the clearance form and the article or speech to the employee for submission or presentation. The employee will retain a record of the signed clearance form with the cleared version of the article or speech.
- If, after review of an article or speech, an employee and clearing official cannot agree about the findings, conclusions, or policy implications set forth in the FDA-assigned article, the clearing official documents that the article or speech is not cleared. The employee may only publish the article with Disclaimer 2.

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- If the article has not been reviewed or cleared within 30 days, unless an alternate time frame has been agreed to, the employee may publish the article with Disclaimer 1.

Review of Non-Assigned FDA-Related Articles and Speeches

- Review of a non-assigned FDA-related article or speech done as an outside activity should be reviewed using the procedures described in SMG 2621.3.

REFERENCES

- FDA, 2011, Staff Manual Guide 2126.3. Review of FDA-Related Articles and Speeches.
- FDA, 2009, Center for Drug Evaluation and Research, MAPP 7700.2 Rev. 1; Review and Conduct of Human Subject Research.
- 5 CFR, §5501.106, Outside Employment and other Outside Activities, 2005.
- 5 CFR, §2635.703, Use of Nonpublic Information, 2009.
- 21 CFR, §20.60, Applicability of Exemptions, 2010.
- FDA, 2013, Center for Drug Evaluation and Research, MAPP 4510.1; CDER Authorization and Tracking of Outside Speaker Clearance.
- GPO, 2010, United States Code. Federal Food, Drug, and Cosmetic Act, Sec. 713.

DEFINITIONS

- **Assigned Work.** For purposes of this MAPP, assigned work is a project that is conducted as part of the employee's official duties. An article that flows from assigned work but was not undertaken as part of the employee's official duties is not assigned work (non-assigned work) and is considered an outside activity and requires the appropriate permissions, as per SMG 2126.3.
- **Clearing Official.** The person responsible for approving content of articles to be published. The clearing official for all articles is the office director, but the office director may delegate this responsibility.
- **Clearance Review.** The process of reviewing an article or speech to determine if it is (1) free of any non-public information and (2) in conformance with current FDA policy. The article or speech may only be considered "cleared" by the clearing official if conditions 1 and 2 are met.

The super office directors should make sure conditions 1 and 2 are met when they author an article, speech, or publication. No additional clearance is needed but the article should be shared with their supervisor, as appropriate.

- **Disclaimer 1.** For articles, speeches, or other publications that have been cleared by the clearing official or designee, the following statement, while not required, may be included:

“This [article/speech/other publication] reflects the views of the author and should not be construed to represent FDA’s views or policies.”

This disclaimer applies to both assigned and non-assigned work that is FDA-related.

- **Disclaimer 2.** For articles, speeches, or other publications that have not been approved because they contain statements or conclusions that are not consistent with FDA Policy, the following disclaimer must be included:

“This [article/speech/other publication] has been reviewed by FDA and determined not to be consistent with the Agency’s views or policies. It reflects only the views and opinions of the author.”

This disclaimer applies to both assigned and non-assigned work that is FDA-related.

- **Employee.** For the purposes of this MAPP, in addition to federal employees, the term employee also refers to non-federal employees who are working at FDA through a fellowship program, internship program, Intergovernmental Personnel Act assignment, volunteer program, or other arrangement.
- **FDA-Related Article or Speech.** Any article, poster, abstract, book, book chapter, presentation, or published writing written (or co-written) by an FDA employee that (1) relies on or discusses data or information that were only available to the employee through his or her employment at FDA (i.e., nonpublic information); (2) discusses products or matters within FDA’s jurisdiction; (3) discusses or analyzes an FDA program, policy, regulation, action, or initiative; or (4) could reasonably be perceived to reflect FDA’s approach to issues within its jurisdiction.
- **Non-assigned work.** When an FDA employee is working on a manuscript as a non-assigned publication and undertaking the work as an approved outside activity, he or she is essentially writing as a member of the general public. Therefore, work done as an outside activity may only utilize public information. For example, a paper that requires analysis of subject level data from INDs, NDAs, or BLAs relies on non-public information and therefore could not be undertaken as an outside activity.
- **Nonpublic Information.** Information exempt from disclosure under 5 U.S.C. 552 or otherwise protected from disclosure by statute, executive order, or regulation; information that has been designated as confidential by the Agency; or information that has not actually been disseminated to the public and is not available to the public upon request (5 CFR 2635.703(b)). Among the laws and regulations governing disclosure or requiring confidentiality are the Federal Food, Drug, and Cosmetic Act (e.g., 21 U.S.C. 331(j)), the Freedom of Information Act, the Trade Secrets Act, and the Privacy Act, and FDA’s implementing regulations (e.g., 21 CFR part 20).

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
11/07/95	Initial	n/a
1/26/99	Rev. 1	Minor changes. Minor formatting change.
10/22/13	Rev. 2	Revisions were made to the Purpose, Background, Policy sections. The Responsibilities and Procedures were made into separate sections and revisions were made. Added a References section. Moved the Definitions section. Inserted Attachment I

Attachment I: Use of public and non-public information

Non-Assigned Work – When an FDA employee is working on a manuscript as a non-assigned publication and undertaking the work as an outside activity, he or she is essentially writing as a member of the general public. Therefore, work done as an outside activity may only utilize public information. For example, a paper that requires analysis of subject level data from INDs, NDAs, or BLAs relies on non-public information and therefore could not be undertaken as an outside activity.

Assigned Work – When an FDA employee is working as a representative of FDA, the author takes the following steps to ensure the article or speech does not contain any non-public information:

1. Identify sources for all information relied on while preparing the work.
2. Present source notes to the supervisor or clearing officials.

To facilitate the supervisor's review of an employee's article or speech, the following is general guidance on public and nonpublic information:

Public Information:

- Information found on FDA's Internet site or other Internet site.
- Information obtained in response to a Freedom of Information Act (FOIA) request. If an employee would like to request FDA records to assist in preparing a speech or article, the instructions for submitting a FOIA request are on FDA's Internet site.
- Published literature/scientific journal articles.

Non-public Information:

Some FDA records are not disclosable to the public. When records are disclosable because, for example, they relate to an approved application, certain information in the records may be non-public and is redacted before the records are publicly disclosed. The most common types of information that are usually non-public are:

- Information about unapproved products
- Information relating to or from pending or unapproved applications
- Information relating to pending or unapproved product indications, strengths, dosage forms, etc.
- Information from investigational new drug applications (INDs) that has not been used by FDA in deciding to approve an application or supplemental application
- Applicant/sponsor datasets
- Manufacturing process information
- Manufacturing quality control information
- Product formulation information not in the approved product labeling
- Production volumes, sales distribution, and other similar business information
- Information obtained by FDA under a contract that limits further disclosure of the information, such as drug use vendor data (e.g., Verispan, IMS)
- Information for which the release would constitute an unwarranted invasion of personal privacy.

Attachment II: Disclaimer Determination Chart

Is the Work Assigned or Non-Assigned?	Was Clearance Granted?	Is a Disclaimer Required?
Assigned Work	Clearance Granted	No, but clearing official or CDER employee may opt to include disclaimer 1.
Assigned Work	Review not completed within specified timeframe.	Yes, disclaimer 1 must be included.
Assigned Work	Clearance Denied	Yes, disclaimer 2 must be included.
Non-assigned Work that is FDA-related or identifies the employee's FDA affiliation or address	Clearance Granted	Yes. If cleared in accordance with SMG 2126.3, disclaimer 1 applies.
Non-assigned work that is FDA-related or identifies the employee's FDA affiliation or address	Review not completed within specified timeframe.	Yes, disclaimer 1 must be included.
Non-assigned Work that is FDA-related or identifies the employee's FDA affiliation or address	Clearance Denied	Yes, disclaimer 2 must be included.

Attachment III: CDER Clearance Request for Articles, Speeches, and Other Publications

The writable PDF CDER clearance form is attached to this MAPP. Click the paper clip icon, called “Attachments: View file attachments,” on the left side of this PDF document. Then select the document called ‘Clearance Requests For Articles, Speeches, and Other Publications.’ The data file management instructions are listed below.

Export file data

You can save the information in a completed PDF form as a data file in another file format. Later, you can reuse the data to fill in the form again or another form with the same fields and field names.

In Acrobat, open the completed form file.

Choose Tools > Forms > More Form Options > Manage Form Data > Export Data.

In the Export Form Data As dialog box, select the format in which you want to save the form data (FDF, XFDF, XML, or TXT). Then select a location and filename, and click Save.

Note: Some file formats are available only for specific types of PDF forms, depending on how the form was created.

Merge exported data files to a spreadsheet

If you want to compile data from forms that are not already in a data set, use the following process.

Choose Tools > Forms > More Form Options > Manage Form Data > Merge Data Files into Spreadsheet.

In the Export Data from Multiple Forms dialog box, click Add Files.

In the Select file Containing Form Data dialog box, select a file format option in File of Type option (Acrobat Form Data Files or All Files). Then locate the form files that you want to merge into the spreadsheet, select them, and click Open.

Repeat the previous step to add form data files that are in other locations, as needed.

Click Export. Then select a folder and filename for the spreadsheet, and click Save.

In the Export Progress dialog box, click either View File Now to open the spreadsheet file or Close Dialog to return to Acrobat.

Note: When returned forms are in a response file, the most efficient way to export the information into a spreadsheet is to use the Export Data button in the left navigation panel for the PDF Portfolio response file.