SMG 2126.3

FDA Staff Manual Guides, Volume III – General Administration

External Relations

Review of FDA-Related Articles and Speeches

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1. Purpose

The purpose of this Staff Manual Guide (SMG) is to provide general procedures for FDA staff to follow when publishing articles or delivering speeches that are FDA related (as defined below in section 3.A), whether the articles or speeches are assigned work or outside activities.

2. Policy

A. FDA encourages FDA staff to share information that may benefit the public health by giving speeches and publishing articles in scientific or professional journals or other publications.

B. If an FDA staff member undertakes an FDA-related article or speech that is not part of their assigned work (*see* "Definitions" in section 3.A below), it is considered to be an "outside activity," subject to the requirements for outside activities (*see* "Responsibilities and Procedures" in section 6.B.2 below).

C. FDA further encourages FDA staff to consult with their supervisors to determine whether an FDA-related article or speech that is not assigned work, where appropriate in content area, may potentially be conducted as a work assignment.

D. When an article or speech by an FDA staff member contains FDA-related material, FDA has an interest in ensuring (1) that nonpublic information (as defined below) is not disclosed and (2) that supervisors within an FDA staff member's Center, Office, or Program have an opportunity to provide feedback on the content of the article or speech for consideration before it is published. If articles or speeches are not part of the FDA staff member's assigned work, FDA also has an interest in ensuring that

they are not incorrectly construed to represent official FDA determinations, views, or positions.

E. All timeframe references are to **calendar days.**

3. Definitions

A. Assigned Work. For purposes of the SMG, assigned work is a project that is conducted as part of the FDA staff member's official duties. Articles or speeches that flow from assigned work but were not undertaken as part of the FDA staff member's official duties are not assigned work.

B. FDA-Related Article or Speech. Any article, poster, abstract, book, book chapter, published writing, presentation, or speech written or presented (or co-written or co-presented) by an FDA staff member: (1) that relies on or discusses data or information that was only available to the author through their role at FDA, or (2) that discusses products or matters within FDA's jurisdiction, or (3) that discusses or analyzes an FDA program, policy, regulation, action or initiative, or (4) that could reasonably be perceived to reflect FDA's approach to issues within its jurisdiction.

C. COP(s). One or more of the Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Center for Drug Evaluation and Research, Center for Tobacco Products, Center for Veterinary Medicine, Human Foods Program, National Center for Toxicological Research, Office of the Commissioner, Office of Inspections and Investigations, and Oncology Center of Excellence**.**

D. FDA Staff or FDA Staff Member(s). Any FDA employee, political appointee, contractor, fellow, trainee, or any other individual at the agency who plans to publish or present an FDA-related article or speech.

E. Supervisor. The FDA staff member's direct supervisor or other official(s) designated by the staff member's COP to review FDA-related articles or speeches.

F. 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 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, as well as FDA's implementing regulations (e.g., 21 CFR part 20).

4. Background

Section 713 of the Federal Food, Drug and Cosmetic Act, which was added by section 1101 of the Food and Drug Administration Amendments Act of 2007, directs FDA to "establish and make publicly available clear written policies to implement [section 713] and govern the timely submission, review, clearance, and disclaimer requirements for articles." An "article" is defined as "a paper, poster, abstract, book, book chapter, or other published writing." Section 713 imposes a 30-day time limit on the agency's review of articles intended for publication. This SMG implements section 713 of the Act but also extends to speeches and other oral presentations.

5. Application

COPs and FDA staff will implement and follow the general requirements and procedures set forth in this policy. COPs may supplement and expand upon this policy to meet their specific needs through issuance of written standard operating procedures (SOPs), so long as those SOPs do not conflict with the general principles set forth in this SMG. For example, a COP may specify that official(s) other than the FDA staff's supervisor are responsible for conducting the review required by this SMG. Unless supplemented by the SOPs in an FDA staff member's COP, however, the responsibilities and procedures set forth in section 6 of this document apply, as written, to any FDA-related article or speech authored or presented by that FDA staff member. If an article or presentation involves multiple FDA staff, all are subject to these procedures.

6. Responsibilities and Procedures

A. FDA-Assigned Articles or Speeches

Articles or speeches that are assigned work will be reviewed and cleared through the standard supervisory channels established by the COPs and on a schedule to be determined by the FDA staff member and the supervisor. The time limits given in section 6.B.1 do not apply to assigned work.

For articles done as assigned work, FDA staff must use PubTracker (https://pubtracker.fda.gov/), the agency's centralized publications management application, as the designated platform to track and document review and clearance. FDA staff upload draft articles to PubTracker and follow a guided workflow that includes providing authorship information, identifying associated research projects, completing compliance checklists related to both the articles themselves and any underlying research, and ensuring review and clearance of articles before publication.

If, during the review and clearance process of an FDA-assigned article or speech, an FDA staff member and their COP do not agree about the findings, conclusions, or policy implications set forth in the FDA-assigned article or speech, or if the COP determines that the article or speech is not appropriate as an official communication

by FDA, the FDA staff member may still opt to pursue publishing the article or presenting the speech as a non-assigned FDA-related article or speech provided that they follow the procedures in section 6.B (including use of a disclaimer as required in section 6.B.11).

Even in the case of an FDA-related article or speech that is assigned work, the supervisor and/or the FDA staff member may decide to use a disclaimer to emphasize that the views expressed in the article or speech do not necessarily represent the official views or policies of the agency (*see* 21 CFR 10.85 (k)).

B. Non-Assigned but FDA-Related Articles or Speeches

1. FDA staff must provide any FDA-related article or speech that was not part of their assigned work to their supervisor (or other designated official) for review no less than thirty (30) days before pursuing publication of the FDA-related article or presenting the FDA-related speech. This responsibility applies even if the article or speech will not contain the FDA staff member's title, affiliation or contact information. In the case of a speech, if the full text of the speech is prepared in advance, it must be submitted to the supervisor. Alternatively, if the full text of the speech is not available, the FDA staff member may submit slides or any other written materials that have been prepared in advance of the speech. At a minimum for any speech or other oral presentation (e.g., an appearance on a panel of experts at a conference), the topic to be discussed and an outline of the key points the FDA staff member plans to make must be submitted for review. The FDA-related article may not be submitted for publication, nor may the speech or other oral presentation be made, until after the review is completed or the 30-day period for review has expired, whichever occurs first.

2. FDA staff writing an article or preparing a speech that is not part of their assigned work must comply with statutes and regulations that apply to any outside activity. Of note, submission, review and approval of a "Request for Approval of Outside Activity" (form HHS-520) is a separate and distinct requirement from the process under this SMG for reviewing an FDA-related article or speech that was not undertaken as assigned work.[1] FDA staff should submit any "Request for Approval of Outside Activity" to their supervisor as early as possible.

3. FDA staff should ensure that the article or speech does not contain any nonpublic information before providing it to the supervisor for review.

[1] Under 5 CFR 5501.106(d), an FDA employee must obtain written approval before, among other things, engaging in teaching, speaking, writing, or editing that deals in significant part with (1) a current or recent assignment of the FDA employee's or (2) the agency's ongoing or announced activities, programs, or operations. Another example of a regulation that could apply is 5 CFR 2635.807(a) (prohibiting, *inter alia*, an FDA employee from receiving compensation from any source other than the government for teaching, speaking, writing, or editing under certain circumstances).

4. The FDA staff member's supervisor will review the FDA-related article or speech to identify: (1) nonpublic information and (2) potential major concerns regarding the accuracy of the information or the manner in which information is presented.

5. Within the 30 days following submission of the non-assigned FDA-related article or speech, the supervisor must provide in writing any changes the supervisor notes that are necessary to protect nonpublic information. These comments may also include suggested revisions for the FDA staff member's consideration with respect to accuracy and the presentation of information. FDA staff, however, retains the responsibility for both protecting nonpublic information and for the substantive content of the article or speech, including its accuracy.

6. FDA staff must make any specific changes needed to prevent disclosure of nonpublic information.

7. If the article addresses subjects that ordinarily fall within the purview of other COPs, the FDA staff member and supervisor should work together to ensure that those other COPs are identified and have an opportunity to review and provide comments within the 30-day review period, as well.

8. If time and FDA staff resources permit, or if the content raises specific issues, the supervisor (and other FDA staff or COPs, as applicable) may choose to conduct a more detailed evaluation and provide comments regarding the article, e.g., its overall quality, scientific accuracy, and/or legal conclusions, but this SMG does not require in-depth review of the article for those purposes, and all review must be conducted within the 30-day review period.

9. After allowing 30 days for the supervisory review, the FDA staff member may then submit the article for publication, or make the presentation, in all cases with the required disclaimer (see section 6.B.11). Even if the FDA staff member has not received comments from the supervisor, the FDA staff member is responsible for ensuring that they comply with all legal and ethical requirements, including the duty to protect nonpublic information from public disclosure.

10. During the 30-day review period, the supervisor and FDA staff member may mutually decide that the FDA staff member will complete or finalize the publication or speech as assigned work rather than an outside activity. In that event, the FDA staff member may decide to withdraw the article from the 30-day review process for non-assigned FDA-related articles or speeches by submission of a written notification (e.g., an e-mail) to their supervisor.

11. All non-assigned FDA-related articles or speeches (including those that began as assigned work but were not completed or finalized as assigned work) **must** include a disclaimer when published or presented.

- If the supervisor (on their own or in collaboration with others in their COP or elsewhere in the agency) determines that the non-assigned article or speech does not align with the views of the agency from the perspective of policy, science, or law, the supervisor must require the following disclaimer:

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

- The supervisor and the FDA staff member planning to publish a non-assigned article or speech may otherwise work together during the 30-day review period to develop an appropriate disclaimer. The supervisor may opt to require the following disclaimer:

  "FDA has not cleared this [article/speech/other publication]. It reflects the views of the author and should not be construed to represent FDA's views or policies."

- If the FDA staff member does not receive comments (related to major concerns) back from the supervisor during the 30-day review period, the FDA-related article or speech must include the following disclaimer:

  "FDA has not cleared this [article/speech/other publication]. It reflects the views of the author and should not be construed to represent FDA's views or policies."

12. The required disclaimer must be prominently displayed as part of the article or speech in its published or presented form. For a non-assigned FDA-related speech, the FDA staff member must preface his or her substantive remarks with the disclaimer and prominently include the disclaimer in any written materials provided as part of the speech.

7. Effective Date

The guide is effective August 06, 2026.

8. Document History – SMG 2126.3, Review of FDA-Related Articles and Speeches

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