

SMG 2126.3

FDA STAFF MANUAL GUIDES, VOLUME III – GENERAL ADMINISTRATION

EXTERNAL RELATIONS

REVIEW OF FDA-RELATED ARTICLES AND SPEECHES

Effective Date: 02/02/2011

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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 4A.), whether the articles or speeches are assigned work or outside activities.

2. POLICY

- A. FDA encourages employees 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 employee undertakes an FDA-related article or speech that is not part of his or her assigned work (*see* “Definitions” in section 4.A below), it is considered to be an “outside activity,” subject to the requirements for outside activities (*see* section 7.B.2 below).
- C. FDA further encourages employees 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 employee 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 employee’s office or Center 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 employee'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 employee's official duties. Articles or speeches that flow from assigned work but were not undertaken as part of the employee'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 employee: (1) that relies on or discusses data or information that was only available to the author through his or her employment 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. Center(s).** One or more of FDA's Office of the Commissioner, Office of Regulatory Affairs, Center for Food Safety and Applied Nutrition, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Center for Veterinary Medicine, Center for Tobacco Products, and National Center for Toxicological Research.
- D. Employee.** Any (1) current employee at FDA or (2) staff fellow at FDA who plans to publish or present an FDA-related article or speech.
- E. Supervisor.** The FDA employee's direct supervisor or some other official designated by the employee's Center 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 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

Centers will implement and follow the general requirements and procedures set forth in this policy. Centers 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 Center may specify that some designated official other than the employee’s supervisor be responsible for conducting the review required by this SMG. Unless supplemented by the SOPs in an employee’s Center, however, the policy and procedures set forth in Section 7 of this document apply, as written, to any FDA-related article or speech authored or presented by that employee. If an article or presentation involves multiple FDA employees, 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 Center or the agency and on a schedule to be determined by the employee and the supervisor. The time limits given below (in section 7.B.) do not apply to assigned work.

If, during the review and clearance process of an FDA-assigned article or speech, an employee and his or her Center do not agree about the findings, conclusions, or policy implications set forth in the FDA-assigned article or speech, or if the Center determines that the article or speech is not appropriate as an official communication by FDA, the employee may still opt to pursue publishing the article or presenting the speech as a non-assigned FDA-related article or speech providing that he or she follows the procedures in section 7.B below (including use of a disclaimer as required in section 7.B.11).

Even in the case of an FDA-related article or speech that is assigned work, the supervisor and/or the employee 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. An employee must provide any FDA-related article or speech that was not part of the employee's assigned work to his or her 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 employee's FDA 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 employee 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 employee 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. An employee writing an article or preparing a speech that is not part of his or her 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 Employees should submit any "Request for Approval of Outside Activity" to their supervisor as early as possible.
3. An employee should ensure that the article or speech does not contain any nonpublic information before providing it to the supervisor for review.
4. The employee'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

¹ Under 5 CFR 5501.106(d), an 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 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).

comments may also include suggested revisions for the employee's consideration with respect to accuracy and the presentation of information. The employee, however, retains the responsibility for both protecting nonpublic information and for the substantive content of the article or speech, including its accuracy.

6. The employee 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 Centers, the employee and supervisor should work together to ensure that those other Centers are identified and have an opportunity to review and provide comments within the 30-day review period, as well.
8. If time and employee resources permit, or if the content raises specific issues, the supervisor (and other employees or Centers, 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 employee may then submit the article for publication, or make the presentation, in all cases with the required disclaimer (as described below). Even if the employee has not received comments from the supervisor, the employee is responsible for ensuring that he or she complies 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 employee may mutually decide that the employee will complete or finalize the publication or speech as assigned work rather than an outside activity. In that event, the employee 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 his or her 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 the following disclaimer when published or presented: "This [article/speech/presentation/ book chapter] reflects the views of the author and should not be construed to represent FDA's views or policies." The disclaimer must be prominently displayed as part of its published or presented form. For a non-assigned FDA-related speech, the employee 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 February 2, 2011.

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

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	01/25/2011	N/a	OC/OCS	Jesse L. Goodman, M.D., M.P.H., Chief Scientist and Deputy Commissioner for Science and Public Health