MEMORANDUM OF AGREEMENT BETWEEN THE FOOD AND DRUG ADMINISTRATION (FDA) AND THE NATIONAL TREASURY EMPLOYEES UNION (NTEU) CONCERNING THE FDA'S STAFF MANUAL GUIDE REGARDING FDA RELATED ARTICLES AND SPEECHES

The FDA encourages employees to share information that may benefit the public health by both giving speeches and publishing articles in scientific or professional journals or other publications. NTEU and FDA recognize that when an article or speech by an FDA employee contains FDA-related material, FDA has an interest in ensuring that nonpublic information is not disclosed and 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 determinations, views, or positions. Furthermore, the parties recognize that the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et. seq) requires the 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. To this end, the FDA has established a Staff Manual Guide (SMG) titled "Review of FDA-Related Articles and Speeches." The purpose of the SMG is to establish general procedures for FDA staff to follow when publishing articles or delivering speeches that are FDA related, whether the articles or speeches are assigned work or outside activities. The parties have negotiated over the impact and implementation of the SMG and agree as follows:

1. The parties agree that the SMG/publication policy applies to any current employee, including staff fellows, at FDA who plans to publish or present an FDA-related article or speech and is not intended to restrict employees' rights, including the First Amendment right to free speech, than is currently allowed by law, rule, regulation and/or the collective bargaining agreement.

2. Centers will implement and follow the general requirements and procedures set forth in the SMG/publication policy. Centers may supplement and expand upon this SMG/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 the SMG. However, in the event that Center(s) supplement or expand this SMG/policy in a manner that has more than a *de minimis* impact on the conditions of employment of employees, consistent with law, rule, regulation and/or collective bargaining agreement the Center(s) must give NTEU notice and an opportunity to bargain.

3. An FDA–Related Article or Speech is defined as 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 that (1) relies on or discusses data that was only available to the author through his or her employment at FDA, or (2) discusses products or matters within FDA's jurisdiction; or (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.

4. Non-public information is information that is 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. Assigned work is defined as a project that is conducted as part of the employee's official duties. FDA-Related 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. If during the review and clearance process 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 the FDA, the employee may still opt to pursue publishing the article or presenting the speech as a non-assigned article or speech providing that he or she follows the procedures and uses a disclaimer to emphasize that the views expressed in the non-assigned article or speech do not necessarily represent the official views or policies of the agency.

6. Articles or speeches that flow from assigned work but were not undertaken as part of the employee's official duties are not assigned work. The following procedures apply to all non-assigned FDA-related articles and speeches.

   a. An FDA-related article or speech that is not part of an employee's assigned work, is considered to be an "outside activity," subject to the requirements for outside activities consistent with the HHS-NTEU consolidated collective bargaining agreement and law, rule, and regulation.

   b. 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 disclaimer below. The disclaimer must be prominently displayed as part of its published form, and for speeches the employee must preface his or her remarks with the disclaimer and prominently include it in any written materials provided as part of the speech.

   c. The following is the disclaimer: "This article/speech/presentation/book/chapter reflects the views of the author and should not be construed to represent FDA's views or policies."

   d. All Employees must provide any non-assigned but FDA-related articles or speeches to his or her supervisor (or other designated official) for review no less than thirty calendar days before the article is submitted for publication or before presenting the speech. This 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. If the full text of the speech is not available, the employee may submit slides or other written materials that have been prepared in advance of the speech. At a minimum, the topic to be discussed and an outline of the key points the employee plans to make must be submitted for review. The article cannot be submitted or the speech made until either the review is complete or the 30 day review period has expired.

e. Employees should ensure that articles and speeches do not contain any nonpublic information. The employee's supervisor will review the article or speech to identify nonpublic information and potential major concerns regarding the accuracy of the information or the manner in which information is presented.

f. Within 30 calendar days of the submission, the supervisor must provide, in writing, any changes the supervisor deems necessary to protect nonpublic information. The supervisor 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 in the non-assigned FDA-related article or speech and for its substantive content, including its accuracy.

g. 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 with the 30 calendar days review period.

h. 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 or speech (its overall quality, scientific accuracy, and/or legal conclusions), but the SMG/policy does not require in-depth review and all reviews must be conducted within the 30 calendar days review period.

i. After the 30 calendar days review period expires, the employee may then submit the article for publication, or make the presentation, with the required disclaimer.

j. In addition, during the 30 calendar days review period, the supervisor and the employee may mutually agree 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 by sending written notification to his or her supervisor (e.g., e-mail notification).

7. The FDA will provide employees, upon request, a list of the laws governing disclosure or requiring confidentiality, including the Federal Food, Drug, and Cosmetic Act, the Freedom of Information Act, the Trade Secrets Act and FDA's implementing regulations.

8. FDA will distribute a copy of the SMG/publication policy, and this MOU to employees prior to implementation of the policy.

9. FDA and NTEU will conduct joint 7114 meetings with employees prior to the implementation of the SMG/publication policy to explain the policy and this MOU, and to answer employees' questions. The joint 7114 meetings will occur no later than fifteen days after execution of this MOU.

10. If FDA is unable to answer any question(s) at the meeting, then FDA will distribute written answers to employees' questions via broadcast e-mail within 10 days of the meeting

11. FDA will issue to employees an annual message reminding them of the policy and this MOU.

12. Employees will be granted two hours of administrative leave to review the publication policy, the FAQs, this MOU, the CBA and relevant laws, rules and/or regulations.

13. In addition, the union will be granted 2 hours of official time to meet with employees to discuss the publication policy, this MOU, and/or all pertinent laws, rules and/or regulations related to the Publication Policy each year the policy is in effect. Employees will also be granted up to 2 hours of official time to meet with NTEU to discuss the same each year the policy is in effect.

14. FDA agrees to develop and provide to employees appropriate training concerning the publication policy consistent with the parties' Collective Bargaining Agreement within 90 days of the date the policy is first implemented.

15. FDA agrees to provide NTEU with pre-decisional input concerning the training.

16. Each year the publication policy is in effect, FDA and NTEU will meet, as deemed necessary by either FDA or NTEU, to discuss issues that have arisen concerning the policy, including the effectiveness of training provided to employees concerning the policy. The parties will jointly assess the effectiveness of this initiative during the life of this agreement. FDA will provide National NTEU with all information not otherwise prohibited from disclosure by law, rule, or regulation it obtains concerning the policy, including its effectiveness, violations, actions taken to address the violations and any other pertinent information.

17. Should the FDA propose to change the publication policy (Staff Manual Guide: Review of FDA-Related Articles and Speeches, it will provide NTEU notice and an opportunity to bargain consistent with law, rule, regulation and/or the collective bargaining agreement.

18. This MOU will become effective the date the last signature below is executed, and will expire three years from the effective date.

Sharon Quinn Harris 12-9-10

Sharon Quinn Harris, NTEU
National Negotiator — Date

RJ Abbott 12-9-2010

Russell Abbott, FDA
Deputy Commissioner for Administration — Date