TRAINING AND COMMUNICATIONS

Clearance of Speeches, Articles, and Other Communication Materials

CONTENTS

PURPOSE This mapp establishes the policy and procedures by which communication materials are cleared.

BACKGROUND

- CDER staff are frequently asked to speak at public meetings on topics related to the work of CDER. CDER staff also publish articles in journals on subjects in their areas of expertise. These activities are considered potentially sensitive and require prior clearance. Many of the topics involve CDER policies and issues that affect staff from more than one division and for which the Center is responsible.

- CDER management wishes to ensure that the information disseminated at public meetings and in written publications is consistent with CDER policies. To achieve this objective, this mapp describes procedures for clearing speeches and articles for publication.

DEFINITIONS

Clearing Official is that person responsible for approving the content of the material to be presented. These Officials are:

- For materials describing policies that affect more than one Division (CDER policy communications) in one of the following disciplines: (i) chemistry/microbiology; (ii) medical/clinical; (iii) pharmacology/toxicology; (iv) project management; (v) research;

vi) information technology; vii) compliance:

1. Chemistry/Microbiology: Chair(s) of the Chemistry, Manufacturing and Controls Coordinating Committee (CMCCC);

2. Medical/Clinical (including statistical analyses of clinical trials): Chair(s) of the Medical Policy Coordinating Committee (MPCC);

3. Pharmacology/Toxicology: Chair(s) of the Pharmacology and Toxicology Coordinating Committee (PTCC);

4. Project Management: Chair(s) of the Project Management Coordinating Committee (PMCC);

5. Information Technology: Chair(s) of the Information Technology Coordinating Committee (ITCC);

6. Research: Chair(s) of the Research Coordinating Committee (RCC);

7. Compliance: Chair(s) of the Compliance Coordinating Committee (CCC).

- For requests to speak or represent the Center on topics that affect only one Division or that do not fall within the purview of a coordinating committee or one of its subcommittees/technical committees: appropriate Division Directors and Office Directors are the clearing officials. Office Directors may designate some or all Division Directors as clearing officials for all or for specific categories of communications.

- Office Directors, Deputy Directors and Associate Directors are their own clearing officials.

CDER Policy Speeches: Presentations at meetings or workshops on topics that involve new or evolving CDER policies or issues that affect the work of more than one division, such as chemistry stability policy, general requirements for clinical trials, or broad pharmacology/toxicology policy (e.g., the need for carcinogenicity data for drugs used for chronic conditions). CDER Policy speeches are distinct from policy or informational speeches that involve the work of a single division such as a discussion of appropriate study endpoints or analyses for a particular class of drugs.

POLICY

- Communications by CDER staff to audiences outside the Agency that bear on the work of the Center are considered sensitive and require a policy clearance review. Examples of materials that must be cleared include, but are not limited to, speeches, articles, monographs, slide presentations, books, films, exhibits, and poster session materials.

- This policy applies to all communication materials concerning FDA programs, policies or

activities whether or not prepared or presented as an official responsibility on official time using official resources unless they meet the requirements described in the next paragraph.

- Communications that are not subject to clearance, regardless of whether they deal with topics bearing on the work of CDER or the Agency, are those materials that meet the definition of "personal activities" stated in the CDER MAPP *Outside Activities* (Mapp 4641.3), or if they are the product of approved outside activities, as defined in that mapp. A disclaimer shall be used, however, if the speech or publication prepared as an outside activity or personal activity, pertains to FDA programs or policy.[1]

- The usual clearance procedure is described below, but it must be used flexibly to account for the realities of preparing oral communications bearing in mind the policy's purpose to enable the clearing official to become aware of the essentials of what is being said and to provide necessary input on policy, scientific quality, need for further consultations, and any other steps needed to assure a high quality and accurate presentation.

- When there is more than one author on a communication material and the material does not fall within the pruview of a coordinating committee, each author must clear the material through their division and office directors.

RESPONSIBILITIES AND PROCEDURES

Speakers or authors:

- If a speaker, obtain proper authorization in accordance with MAPP 4510.1;

- Before submitting the communications materials for clearance, ensure that they are of high journalistic quality and that to the best of your knowledge, the scientific, technical and policy statements are correct and consistent with CDER and Agency policies. It is important that the originator be sensitive to and aware of the degree to which any oral or written presentation by an individual associated with the Agency affects public and professional perceptions of the quality of the Agency and its work. The originator is authorized and encouraged to obtain peer and technical review and evaluation from any component of the Center or elsewhere in the Agency having relevant expertise (e.g., statistical review of a medical paper containing statistical material or having statistical implications).

- Submit two hard copies of the materials accompanied by a "Communication Clearance Request" form (Attachment A) to the appropriate Clearing Official at least two weeks

[1] See FDA Staff Manual Guide 3118.3, Supplementary Procedures Regarding Standards of Conduct - Outside Activities, Section 3(b) and Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR Part 2635.807.

before the scheduled presentation or requested date by publisher. *Note: This form is available on the shared drive at x:\ocd\form\clearreq.*

In addition, the originator should indicate the location of the electronic file. Generally, these files should be filed in the common shared drive (i.e., x-drive) under the relevant directory. Materials should be provided at least two weeks before the material will be delivered, but shorter times can be negotiated with the clearing official. The materials should be the most fully developed that will be used (i.e., a complete talk that is to be used, slides if they are to be the basis for the talk), but even an abstract or outline is useful two weeks ahead, with the more detailed document to follow. For written communications, the document to be submitted for publication should be provided.

- May appeal within 2 working days the decision of the Clearing Official to the Coordinating Committee chair(s) for discipline-specific requests or the Clearing Official's supervisor for non-discipline specific requests, if he/she disagrees.

- Will maintain a hard copy and an electronic copy of the cleared material for at least two years.

Clearing Officials and Appeals Officials:

- Will review the materials submitted by staff members for conformance with established CDER and Agency policy and accuracy of technical and scientific information, if appropriate. Evaluation of scientific or technical aspects is a responsibility of the Clearing Official insofar as the content and/or style reflect upon the quality of the Center's work. The Clearing Official may consult with the author or may seek consultation with other experts on technical questions, scientific matters or policy issues, as appropriate.

- The Clearing Official may refuse to clear the material if it is not of high journalistic quality or does not accurately reflect current policies. The Clearing Official need not rewrite nor spend large amounts of time making comments on it. If it is not of high journalistic quality, it should be returned to the originator. The clearing official may request greater detail on some or all parts of the submission.

- May require the inclusion of a disclaimer in an item submitted for clearance whether related or unrelated to the employee's official duties. Such disclaimers shall be in accord with Section 73.735-705 of the HHS Standards of Conduct, 45 CFR Part 73, Subpart G and will read as follows: "This [article, book,speech, etc.] was [written, edited, prepared] by [employee's name] in his/her private capacity. No official support or endorsement by the Food and Drug Administration is intended or should be inferred."

- Signify the clearance decision on the "Communication Clearance Request" form (Attachment A).

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- Forward one signed copy to the originator within 10 working days of receiving the request for clearance and, for discipline-specific materials, send a second signed copy, including the cleared material, to the Executive Secretary of the appropriate coordinating committee for electronic filing.

- Upon appeal for clearance from originator, will reply within two working days.

EFFECTIVE DATE

This mapp is effective upon date of publication.

Attachment A

CENTER FOR DRUG EVALUATION AND RESEARCH
COMMUNICATION CLEARANCE REQUEST

REQUESTS SHOULD BE SUBMITTED IN DUPLICATE TO THE APPROPRIATE CLEARING OFFICIAL

PART I - TO BE COMPLETED BY ORIGINATOR OF REQUEST

NAME:	**DATE:**
OFFICE/DIVISION (HFD #):	**TELEPHONE NUMBER:**
COORDINATING COMMITTEE REQUESTING CLEARANCE FROM (if appropriate):	

PUBLICATIONS (*Attach full text of material*)	**OR PERSONAL DELIVERY**
TYPE OF PUBLICATION (e.g., Journal, Book, etc.)	**TYPE OF MEETING:**
SPONSORING ORGANIZATION:	**SPONSORING ORGANIZATION:**
TITLE OF PUBLICATION:	**TITLE OF PRESENTATION:**
DEADLINE DATE FOR SUBMISSION:	**DEADLINE DATE FOR SUBMISSION:**
PROPOSED DATE OF PUBLICATION:	**MEETING DATE:**
LOCATION OF ELECTRONIC FILE (i.e., Name of file in x drive):	
ADDITIONAL COMMENTS:	

PART II - TO BE COMPLETED BY CLEARING OFFICIAL(S)

CONCURRENCE:

MATERIAL CLEARED: _____**YES** _____**NO** **CLEARING OFFICIALS SIGNATURE/DATE:**

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ADDITIONAL COMMENTS:

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