OFFICE OF THE CENTER DIRECTOR

CDER/FDA PRESS OFFICE INTERACTIONS IN THE PREPARATION AND CLEARANCE OF WRITTEN DOCUMENTS FOR THE PUBLIC

CONTENTS

PURPOSE

- This MAPP describes CDER's policies and procedures for working with the Press Office in the preparation and clearance of Talk Papers, Press Releases, and other written documents (e.g., Questions and Answers (Q&As), Notes to Correspondents, Statements) for distribution to the public.

DEFINITIONS

Type Of Document	Content	Level of Clearance	Prepared by	Audience	Disseminated by
Press Release	General information in plain language about a particular subject of current interest; may contain quotes from Agency personnel; issued on HHS letterhead	Department	Press Office Staff	General Public	Press Office & FDA Website
Talk Paper	More detailed information in plain language about a particular topic to help guide Agency staff in responding to questions on the topic; actively disseminated to the media; subject to change as more information becomes available	Agency	Press Office Staff	General Public	Press Office & FDA Website

Type Of Document	Content	Level of Clearance	Prepared by	Audience	Disseminated by
Note to Correspondents	Provides media with information about upcoming event or activity	Agency	Press Office Staff	Media	Press Office & FDA Website
Public Health Advisory	Information about an important public health issue in plain language	Center	Center Program Staff	General Public	CDER Website & MedWatch
Science/Issue Paper	Detailed scientific information about a particular topic	Center	Center Program Staff	Scientific Community	CDER Website
Statements	Short declaration to respond to a breaking situation when a quick response is needed	Department	Press Office Staff	Media	Press Office
Q&As	For internal use – Designed to help FDA staff answer anticipated questions from the media and public	Agency	Press Office Staff	Agency staff	Internal use Only
Frequently Asked Questions (FAQs)	For external use – Anticipated questions and answers to a particular issue	Center	Drug Informa-tion Staff	General Public	CDER Website

POLICY

- Any final action that will affect a significant number of people will generate public or press interest. These actions may include, but are not limited to, approval of a new molecular entity, approval of a new product for a serious or life threatening condition, an important regulation that has published, or a new policy decision. Staff should be sensitive to identifying issues that could generate public or press interest and follow the procedures described below.

- The Executive Projects Team (EPT) (HFD-006) in the Office of the Center Director is the central point of contact within CDER to coordinate responses on matters of significant public or press interest. EPT works with CDER staff to identify any current or upcoming issues or actions that may warrant a Press Release, Talk Paper, or other documents intended for distribution to the public, and will communicate this information to the Press Office and other appropriate staff.

PROCEDURES

- When an issue is identified as potentially generating public or press interest, the program office should identify a spokesperson to work with the EPT staff and the Press Office to handle inquiries about the product or issue. The spokesperson must be readily available to answer questions at the time of initial press interest and usually for 1 to 2 days after information is distributed to the public. This availability may include being pulled from previously scheduled meetings for brief periods to respond to inquiries from the press.

Deciding whether a public document is needed

- If an issue is identified as potentially generating public or press interest, the program office should determine whether a public document should be prepared explaining the Center's or Agency's position. CDER Staff should contact the EPT to inform them of any upcoming or current issues or actions that may warrant a Press Release, Talk Paper, or other public document, or to consult with them regarding whether preparation of such a document is warranted. The phone number for the EPT is 301-594-6779, the facsimile number is 301-594-5493, and the e-mail address is CDEREXSEC@cder.fda.gov(CDEREXSEC).

Deciding on the Type of Document

- Once an item of interest is identified, the lead program contact for the issue will notify the EPT liaison that a document needs to be prepared.

- The EPT liaison will notify the Press Office and Division of Drug Information that there is an item of interest and a document needs to be prepared.

- The Press Office, EPT liaison, and the program office will decide on the type of document to be prepared and the appropriate contacts for preparing the document.

Press Release, Talk Paper, Note to Correspondents, Statements, and Q&As

- The Press Office contact initially will work directly with the program staff responsible for the product and/or issue to draft the document.

- The Press Office contact will coordinate the drafting of the document with the Chief of the Project Management Staff (CPMS) in the review division, the Associate Director for Regulatory Affairs (ADRA) in the Office of Drug Evaluation (ODE), or other designated division/ODE contacts. The Press Office will ask the EPT liaison to identify the appropriate points of contact for documents concerning other parts of CDER.

- After a draft document is written, the Press Office will begin the clearance process by preparing a copy of the Press Office/CDER Final Document Clearance Form (Attachment A) and forwarding the document with the form to the program office contact who helped prepare the draft for clearance. In most cases, the clearance process will begin at the Division staff level. The document will then be forwarded by the program to the next level of clearance (i.e., forward through the chain of command) and finally to the Division Director.

- The Division Director will review the document, revise it as needed, identify a proposed CDER spokesperson, and sign the clearance form. The Division will then send the document with the clearance form to the Office for clearance.

- The Office Director will review the document, revise as needed, approve the proposed spokesperson, and sign the clearance form. The Office will then send the document with the clearance form to the EPT liaison. The Office is responsible for deciding when Office staff will discuss revisions with the Division. Any discussions between the Office and the Division should be completed before the document is forwarded to the EPT liaison.

- The EPT liaison will get Center clearance, including the Director of the Office of Pharmaceutical Science, the Office of Review Management, and/or the Office of Regulatory Policy, as needed, and will forward the document with the signed clearance form to the Press Office.

- If the Press Office makes revisions other than minor editorial changes in the document after it has been cleared by the Center, the Press Office will return the document to the EPT liaison to coordinate further clearance.

- In all cases, the EPT staff member handling the document will notify the Press Office contact and appropriate CDER staff when the document is cleared by the Center.

- When the document receives final clearance, the Press Office will notify the EPT liaison. The EPT liaison will distribute copies of the cleared document to the involved Center staff.

Public Health Advisory and Science/Issue Papers

- After drafting the document, the program staff will begin the clearance process by preparing a copy of the Press Office/CDER Final Document Clearance Form (Attachment A) and forwarding it to their supervisor for clearance. The document will then be forwarded by the supervisor to the next level of clearance (i.e., forward through the chain of command) and finally to the Division Director.

- The Division Director will review the document, revise it as needed, identify a proposed CDER spokesperson, and sign the clearance form. The Division will then send the document with the clearance form to the Office for clearance.

- The Office Director will review the document, revise as needed, approve the proposed spokesperson, and sign the clearance form. The Office will then send the document with the clearance form to the EPT liaison. The Office is

responsible for deciding when Office staff will discuss revisions with the Division. Any discussions between the Office and the Division should be completed before the document is forwarded to the EPT liaison.

- The EPT liaison will get Center clearance, including the Director of the Office of Pharmaceutical Science, the Office of Review Management, and/or the Office of Regulatory Policy, as needed.

- In all cases, the EPT staff member handling the document will notify the Press Office, Division of Drug Information, and other Agency staff, as appropriate, when the document is cleared by the Center and ready for dissemination.

FAQs

- The Division of Drug Information (DDI) will draft FAQs in collaboration with the program staff.

- After the FAQs have been drafted, the DDI will begin the clearance process by preparing a copy of the Press Office/CDER Final Document Clearance Form (Attachment A) and forwarding the document with the form to the director of the program office that helped prepare the draft. In most cases, the clearance process will begin at the division staff level. The document will then be forwarded by the program to the next level of clearance (i.e., forward through the chain of command) and finally to the Division Director.

- The Division Director will review the document, revise it as needed, identify a proposed CDER spokesperson, and sign the clearance form. The Division will then send the document with the clearance form to the Office for clearance.

- The Office Director will review the document, revise as needed, approve the proposed spokesperson, and sign the clearance form. The Office will then send the document with the clearance form to the EPT liaison. The Office is responsible for deciding when Office staff will discuss revisions with the Division. Any discussions between the Office and the Division should be completed before the document is forwarded to the EPT liaison.

- The EPT liaison will get Center clearance, including the Director of the Office of Pharmaceutical Science, the Office of Review Management, and/or the Office of Regulatory Policy, as needed.

- In all cases, the EPT staff member handling the document will notify the Press Office, Division of Drug Information, and other Agency staff, as appropriate, when the document is cleared by the Center and ready for dissemination.

Dispute resolution

- If a CDER office and the Press Office cannot agree on the wording for a document, the Executive Projects Team (EPT) staff member handling the document should be contacted to coordinate a Center-level decision. Generally, the responsible EPT staff member will be the EPT liaison working with that office.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

Attachment A:

PRESS OFFICE/CDER
FINAL DOCUMENT CLEARANCE

DUE DATE _____

DATE

PRESS OFFICE CONTACT _____ **Phone** _____

EXECUTIVE PROJECTS TEAM CONTACT _____ **Phone** _____

TYPE OF CORRESPONDENCE ____ **TALK PAPER** ____ **PRESS RELEASE**

____ **OTHER**

TITLE: _____

CDER SPOKESPERSON
TITLE
TELEPHONE NO
FAX NO
EMAIL

ACTION

	FINAL CLEARANCE (SIGNATURE)	**DATE**
DIVISION _____	_____	
OFFICE _____	_____	
CDER **HFD-006** _____ **Exec Sec Ofc**		
CDER **HFD-001** _____ **(Director)**	_____	

COMMENTS