

POLICY AND PROCEDURES

OFFICE OF THE CENTER DIRECTOR

Sharing Nonpublic Information With Federal Government Departments and Agencies

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PURPOSE

This MAPP describes the procedures in the FDA Center for Drug Evaluation and Research (CDER) for handling requests for nonpublic information from other federal government organizations.

BACKGROUND

Federal government departments and agencies outside of the Department of Health and Human Services (HHS) (e.g., Department of Justice, Federal Trade Commission, Internal Revenue Service, Securities and Exchange Commission) routinely request nonpublic information from CDER. This MAPP has been created to ensure that CDER responds appropriately to those requests.

POLICY

- Official CDER records otherwise exempt from public disclosure may be disclosed to other federal government departments and agencies outside of HHS under the procedures outlined in this MAPP. These procedures are to be used for documentary and verbal disclosures of nonpublic information.
 - Certain officials in FDA's Office of Regulatory Affairs (ORA) have the delegated authority to disclose official records and information under 21 CFR § 20.85.
 - The requesting federal government department or agency must provide written assurances to ORA that the requesting agency will not further disclose the information without prior written approval. ORA will consider whether the disclosure of information is warranted for each individual request and will specifically authorize the release in writing.
 - The requesting federal government department or agency must provide written assurances that the requests are not overly broad or unduly burdensome (e.g., they must be specific and limited as to time and subject matter relevant to the inquiry).
 - CDER may not share trade secret information with federal government agencies outside of HHS unless the holder of the trade secret consents in writing.
 - CDER may share confidential commercial information under 21 CFR § 20.85 with a federal government department or agency because such disclosure is not considered a public disclosure.
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RESPONSIBILITIES

Office of Regulatory Affairs

- The Associate Commissioner for Regulatory Affairs (ACRA) must authorize disclosure of nonpublic records and information to other federal agencies. The ACRA has designated the authority to determine whether to disclose official records and information to the Director and Deputy Director, Office of Strategic **Planning and Operational Policy**.
 - The Testimony Specialists, Office of Strategic **Planning and Operational Policy in ORA, will review the requests. If they determine that any request is overly broad or unduly burdensome, ORA will confer with the requesting agency to attempt to limit the scope. They will then communicate the agreed-upon scope of the request with the office with custody of the records.**
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- With respect to requests for verbal disclosures in informal and formal interviews, it is CDER's strong preference that (1) efforts be taken to ensure that, in the first instance, questions be posed in a written format in lieu of interviews, and (2) if interviews are to take place, they be conducted at one time, rather than sequentially, to avoid time-consuming undue burden. The Testimony Specialists, ORA's Office of Strategic **Planning and Operational Policy**, will confer with the requesting agency to limit the number of sequential interviews.

Executive Operations Staff, Office of Executive Programs, CDER

- The Executive Operations Staff (EOS) in the Office of Executive Programs is the central point of contact within CDER for coordinating responses to requests from other federal government departments and agencies.
- EOS will forward any questions as to whether a document needs to be redacted to the CDER Office of Regulatory Policy, Division of Information Disclosure Policy (ORP/DIDP) for a determination.
- EOS will discuss with ORP/DIDP the disclosure of predecisional information and potential investigative records.
- EOS will discuss with ORP/DIDP the need to obtain sponsor consent for release of trade secret information to a non-HHS agency.

Division of Information Disclosure Policy, CDER Office of Regulatory Policy

- When necessary, ORP/DIDP is responsible for redacting any nonpublic documents prior to release from CDER.

CDER Staff

- CDER staff will notify EOS of any outside agency requests for nonpublic information. EOS's email address is CDEREXSEC@cder.fda.gov.

Upon request, CDER staff will provide all appropriate materials to the EOS liaison.

Office of Chief Counsel (OCC)

- With respect to verbal disclosures of nonpublic information -- for example, verbal questioning not under oath -- OCC will take primary responsibility for preparing and accompanying CDER personnel before and during formal and informal witness interviews

PROCEDURES

1. The requesting federal government department or agency should submit a written request (on the requester's letterhead) for nonpublic information (see Attachment 1). The request should be sent to:

Division of Information Disclosure Policy, Office of Regulatory Affairs, FDA
ORAInfoShare@fda.hhs.gov

This request should include the type of records and/or information requested and the purpose for which the information is requested. It should include a written statement that the requester will protect the confidentiality of the nonpublic records and not further disclose the information without written permission from FDA, or in the case of nonpublic information, the permission of the holder, and it should provide written assurances that the requests have been reviewed by the requester, and they are not overly broad or unduly burdensome. (See Attachment 1).

2. ORA will review the request and prepare a memorandum to CDER providing authorization to disclose nonpublic information to the requester (see Attachment 2).
3. The Director of CDER's EOS will assign a liaison to coordinate the request for nonpublic information. Once the liaison consolidates the information, they will forward it to ORP/DIDP for redaction, if necessary. ORP/DIDP will provide the liaison with the redacted documents. The EOS liaison will then add a statement about confidentiality and disclosure to all documents to be shared with other federal government organizations. If applicable, the liaison will discuss with ORP/DIDP the release of predecisional information, investigative records, or trade secret information.

Steps to add required statement in header for PDF files:

- Tools > Pages > Header & Footer > Add Header & Footer > Select Arial 8-point text, red.
 - Copy the following statement in "Center Header Text" box in red font: OFFICIAL UNITED STATES FOOD AND DRUG ADMINISTRATION (U.S. FDA) DOCUMENTS SUBJECT TO CONFIDENTIALITY ARRANGEMENT; DO NOT DISCLOSE WITHOUT WRITTEN PERMISSION OF U.S. FDA OR INFORMATION OWNER.
 - Adjust top margin as needed to avoid interference with other text.
4. The EOS liaison will then forward the redacted documents along with a transmittal letter to the requester (unless ORP/DIDP instructs the EOS liaison to send documents to OCC or the Testimony Specialists) stating that the enclosed documents may contain nonpublic information and must not be disclosed without further authorization (see Attachment 3).

5. EOS will send a copy of the transmittal letter to the Division of Information Disclosure Policy, ORA.¹ This letter will include a list of the documents disclosed. EOS will maintain in its files a copy of all materials sent.

CDER Offices/Divisions receiving outside federal government agency requests for nonpublic information should forward the requests to CDER's EOS (CDEREXSEC@cder.fda.gov) for processing.

REFERENCES

- 21 CFR § 5.23, Disclosure of Official Records
- 21 CFR § 20.85, Disclosure to Other Federal Government Departments and Agencies
- 21 CFR § 20.61, Trade Secrets and Commercial or Financial Information Which is Privileged or Confidential
- FDA Regulatory Procedures Manual, August 1997

DEFINITIONS

- **Confidential Commercial Information:** Valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs (21 CFR § 20.61(b)).
- **Trade Secret:** Any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process (21 CFR § 20.61(a)).

EFFECTIVE DATE

- This MAPP is effective upon date of publication.

MANUAL OF POLICIES AND PROCEDURES

CENTER FOR DRUG EVALUATION AND RESEARCH

MAPP 4112.2 Rev. 1

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
5/9/02	n/a	Initial issuance
10/27/22	1	Minor edits. Added references.

ATTACHMENT 1: Sample Letter Requesting Nonpublic Information

(ON REQUESTER'S LETTERHEAD)

Director, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs
c/o Testimony Specialist
ORAInfoShare@fda.hhs.gov

The YOUR AGENCY'S NAME AND OFFICE requests access to the following nonpublic information (list the type of records/information requested, including the firm and/or product name and the relevant timeframe) _____ pursuant to 21 CFR § 20.85: LIST THE INFORMATION YOU ARE REQUESTING IN DETAIL, AS WELL AS THE RELEVANT TIMEFRAME. (Requests for all documents, or all communications relating to a product/firm, are usually overly broad and can result in processing delays).

The purpose for which the information is requested is to assist in the STATE THE NATURE OF YOUR INTEREST. The records will be used only for the following authorized activity: STATE THE ACTIVITY, and state that this information is limited to STATE TIMEFRAME and RELEVANT SUBJECT MATTER. (In addition, indicate whether the request for information is the result of an ongoing investigation, and if so, give the details.)

I certify that the ACTIVITY is authorized by law, that the records or information will be used only for the stated purpose and will not be disclosed outside YOUR AGENCY AND OFFICE without the prior written permission of the Food and Drug Administration or other holder of the nonpublic information. I also certify that disclosure within YOUR AGENCY will be limited to the specific purpose stated above, and that I will provide a copy of this letter to any person(s) with whom I share the nonpublic information. I further certify that I have reviewed the requests, and they are specific and limited as to time and subject matter relevant to the investigation and are not overly broad or unduly burdensome.

I understand that 21 U.S.C. § 331 of the Federal Food, Drug, and Cosmetic Act prohibits disclosure of trade secret information outside the Department of Health and Human Services. If you have any questions, please contact PROVIDE NAME AND CONTACT INFORMATION.

Sincerely,

YOUR SIGNATURE LINE

cc: RECOMMEND INSERTING NAME OF YOUR FDA CONTACT, IF ANY.

ATTACHMENT 2: Sample Memorandum

MEMORANDUM

DATE:

FROM: Director, Office of Strategic Planning and Operational Policy (OSPOP), Office of Regulatory Affairs

SUBJECT: Authorization to Disclose Food and Drug Administration Records or Information Exempt from Public Disclosure to *(name of federal government official and associated agency)*

TO: Executive Operations Staff, Office of Executive Programs, Center for Drug Evaluation and Research (HFD-006)

In accordance with Title 21, Code of Federal Regulations, 21 CFR § 20.85 you, or any other employee(s) of CDER, are authorized to disclose nonpublic records and/or information to (INSERT REQUESTER'S NAME). (REQUESTER NAME AND AGENCY) is requesting the following records or information: (INSERT TYPES OF RECORDS/INFORMATION).

The purpose for which the information is requested: _____.
The records will be used only for the following authorized activity:

_____.

You may share the information with the (INSERT AGENCY) official who signed the letter requesting nonpublic information or their designee. If you share non-public information, please advise the requester that they may not further disclose such information except with my written permission with anyone outside of those listed in the (DATE) _____ request and nondisclosure agreement.

Please note that this authorization does not include information prohibited from disclosure by law, e.g., trade secrets [18 U.S.C. 1905; 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j))]. Therefore, you cannot release any trade secret information to the requester without the sponsor's/owner's authorization. If you are unsure if certain information in the responsive records constitutes trade secret information, please contact the FOI Officer in your Center or the FOI Staff (HFI-35) to request an opinion. If you disclose nonpublic records, please advise the requesters that they may not further disclose such records, except with the written permission of the FDA.

If you are requested to provide a statement (deposition), you should contact (TESTIMONY SPECIALIST NAME) since a deposition is testimony and, as such, it is not covered by 21 CFR §

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20.85. Rather, testimony requires my approval pursuant to 21 CFR § 20.1, and the (AGENCY NAME) must submit a written request conforming to that regulation.

You may directly transmit any information provided to the (AGENCY NAME), as authorized above. Please send a copy of the outgoing transmittal letter and a summary of the agency information released to the Division of Information Disclosure Policy, Office of Strategic Planning and Operational Policy (OSPOP).

If you have any additional questions about these procedures or policy, please contact (TESTIMONY SPECIALIST NAME) at (PHONE NUMBER).

Director,
Office of Strategic Planning and Operational Policy
Office of Regulatory Affairs
U.S. Food and Drug Administration

ATTACHMENT 3: Sample Letter Transmitting Nonpublic Information

FOR OFFICIAL USE ONLY

(Date)

(Name and address of federal government agency requester)

Dear _____:

The letter responds to your _____(DATE) request for information from the Food and Drug Administration (FDA). I am enclosing the following document(s), which contain (INSERT ONE: CONFIDENTIAL COMMERCIAL, TRADE SECRET, PRIVACY, DELIBERATIVE PROCESS) information.

(INSERT TITLE OF NONPUBLIC DOCUMENT)

This nonpublic information is provided for official use only and should be used according to the written assurance to protect confidentiality of the information that your agency provided on _____, and 21 CFR § 20.85, which requires that the requesting federal government agency maintain the confidentiality of this material until FDA provides written permission for disclosure of the nonpublic information.

If you have any questions, please contact me at (INSERT ADDRESS, PHONE NUMBER, OR ELECTRONIC MAIL ADDRESS).

Sincerely,

Signature of CDER EOS Liaison