OFFICE OF THE CENTER DIRECTOR

SHARING NONPUBLIC INFORMATION WITH FEDERAL GOVERNMENT OFFICIALS

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PURPOSE

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

BACKGROUND

- Government agencies outside of the FDA (e.g., 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.

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)).

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

POLICY

- Official CDER records otherwise exempt from public disclosure can be disclosed to other federal government departments and agencies under the procedures outlined in this MAPP. These procedures are to be used for verbal as well as documentary disclosures of nonpublic information.
- The requesting federal government agency must provide written assurances to FDA's Office of Regulatory Affairs (ORA) that the requesting agency will not further disclose the information. ORA will consider whether the disclosure of information is warranted for each individual request and will specifically authorize the release in writing.
- CDER may not share trade secret information with federal government agencies outside the Department of Health and Human Services (DHHS) unless the holder of the trade secret consents in writing.

- CDER can share confidential commercial information under 21 CFR 20.85 with a federal government agency because such disclosure is not considered a public disclosure.

RESPONSIBILITIES

Office of Regulatory Affairs

- The Associate Commissioner for Regulatory Affairs must authorize disclosure of nonpublic records and information to other federal agencies. The Associate Commissioner for Regulatory Affairs has designated the authority to determine whether to disclose official records and information to (1) the Director and Deputy Director, Office of Enforcement, and (2) the Director, Division of Compliance Policy, Office of Enforcement.

Executive Operations Staff (EOS), Office of Executive Programs, CDER

- The Executive Operations Staff (EOS) (HFD-006) in the Office of Executive Programs is the central point of contact within CDER for coordinating responses to requests from other federal government officials.

- Questions as to whether a document needs to be redacted will be forwarded by EOS to the Division of Information Disclosure Policy (DIDP) for a determination. Documents will be redacted, if necessary.

- Disclosure of predecisional information and potential investigative records will be discussed with DIDP.

- EOS will obtain sponsor consent for release of trade secret information to a non-DHHS agency.

Division of Information Disclosure Policy, CDER Office of Regulatory Policy

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

CDER Staff

- CDER staff will notify the EOS of any outside agency requests for nonpublic information. The phone number for the EOS is 301-594-6779, the facsimile number is 301-594-5493, and the email address is CDEREXSEC@cder.fda.gov (CDEREXSEC).

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

PROCEDURES

1. The requesting government official should submit a written request (on the requestor's letterhead) for nonpublic information (see Attachment A). The request should be sent to:

Director, Division of Compliance Policy
Office of Regulatory Affairs (HFC-230)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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 confidential commercial information, the permission of the holder.

2. ORA will review the request and prepare a memorandum to CDER providing authorization to disclose nonpublic information to the requestor (see Attachment B).

3. The Director of the Executive Operations Staff will assign a liaison to coordinate the request for nonpublic information. Once the information has been consolidated, it will be forwarded to the DIDP for redaction, if necessary. The EOS liaison will then forward the documents along with a transmittal letter to the requester, stating that the enclosed documents may contain nonpublic information and must not be disclosed without further authorization (see Attachment C). EOS will send a copy of the transmittal letter to the Office of Regulatory Affairs, Division of Compliance Policy. This letter will include a list of the documents disclosed. Executive Operations Staff will maintain in its files a copy of all material sent.

   CDER Offices/Divisions receiving outside government agency requests for nonpublic information should forward the requests to the CDER Executive Operations Staff (HFD-006) for processing.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

Attachment A

SAMPLE LETTER REQUESTING NONPUBLIC INFORMATION

(ON REQUESTER'S LETTERHEAD)

Director, Office of Enforcement
Office of Regulatory Affairs
c/o Director, Division of Compliance Policy (HFC-100)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

To Whom It May Concern:

The _____ *(title of federal government agency)* would like the following nonpublic information under 21 CFR 20.85 *(list the type of records/information requested, including the firm and/or product name(s)).*

The purpose for which the information is requested is

The records will only be used for the following official activity: _____. *(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 and/or information will be used only for the stated purposes, and will not be further disclosed without the written permission of the Food and Drug Administration.

I understand that 21 U.S.C. 331(j) of the Federal Food, Drug, and Cosmetic Act prohibits disclosure of trade secret information outside of the Department of Health and Human Services.

If you have any questions, please contact me at *(indicate address, telephone number and facsimile number).*

Sincerely,

Name and Title of Requester

Attachment B

SAMPLE MEMORANDUM

MEMORANDUM

DATE:

FROM: Director, Division of Compliance Policy, Office of Enforcement (HFC-230)

SUBJECT: Request for Authorization to Disclose Food and Drug Administration Records or Information Exempt from Public Disclosure to *(name of requester)*

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

In accordance with 21 CFR 5.23 and 21 CFR 20.85, the Director, Office of Enforcement Policy, Office of the Center Director, Center for Drug Evaluation and Research (CDER), and any other employees in CDER whom you believe to be appropriate are authorized to disclose nonpublic information and/or records regarding *(identify the records).* This information may be disclosed to *(name, agency, address, and telephone number of requester).*

This authorization does not include information prohibited from disclosure by 21 U.S.C. 331(j); therefore, you cannot release any trade secret information to the requestor. 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 the Office of Chief Counsel before granting the interview.

Any information provided to the *(name of agency)*, as authorized above, may be transmitted to them directly. Please send a copy of the outgoing transmittal letter to HFC-230. This letter should include a list of the documents disclosed.

Director, Division of Compliance Policy
Office of Enforcement

Attachment C

SAMPLE LETTER TRANSMITTING NONPUBLIC CONFIDENTIAL COMMERCIAL 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)* 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