## Office of Regulatory Policy

# SUBMITTING NON-FOIA REQUESTS FOR DOCUMENT COLLECTION AND REDACTION TO CDER'S DIVISION OF INFORMATION DISCLOSURE POLICY (DIDP)

**CONTENTS**



## PURPOSE

- This MAPP establishes the policies and procedures for forwarding non-Freedom of Information Act (FOIA) requests for collection and redaction of documents to the Office of Regulatory Policy (ORP) Division of Information Disclosure Policy (DIDP) (formerly FOI Staff).

  Some examples of non-FOIA requests for document redaction include advisory committee meeting packages, drug advertising information, and warning letters. Requests can also come from foreign and/or state governments, other federal agencies, or Congress. This MAPP does not include procedures for submitting redaction requests for NDA or ANDA approval packages; those are described in MAPP 4520.1, Communicating Drug Approval Information.

## BACKGROUND

- Although much of the workload in DIDP is from FOIA requests, Center and Agency staff routinely ask DIDP to collect and/or redact documents.

- Because of the volume of requests and DIDP resource limitations, CDER must establish work priorities so that DIDP can respond efficiently to non-FOIA requests for disclosure. Accordingly, the Center is establishing this MAPP for tracking and prioritizing requests for DIDP document collection and/or redaction.

## REFERENCES

- Freedom of Information Act (FOIA) (5 U.S.C. section 552)

- 21 CFR 5.23, Disclosure of Official Records
- 21 CFR part 20, Public Information
- FDA/Office of Regulatory Affairs (ORA) *Regulatory Procedures Manual*
- ORA *Information Disclosure Manual*

## POLICY

- All requests sent to DIDP (HFD-013) for response must be in writing and must be accompanied by a DIDP Tracking Information Form. They can be mailed, faxed, E-mailed, or hand carried to the DIDP Project Manager.

## RESPONSIBILITIES AND PROCEDURES

- **Originators of requests will:**

**1.** Complete the Project Information section of the DIDP Tracking Information Form (see Attachment A). [NOTE: This form is available electronically on the CDER Intranet (http://cdernet.orp)]. Include in the Project Description the reason for the proposed document disclosure.

**2.** Contact the Director of DIDP for concurrence on priority due dates. Priority due dates should be requested based on the impact of disclosure on the protection of the public health.

**3.** Mail, fax, E-mail, or hand carry the completed form with the material to be reviewed and any pertinent background information to the DIDP Project Manager.

- **Director of DIDP will:**

  **1.** Review and approve, as appropriate depending on workload and deadlines, all requests for priority review for redaction.

  **2.** Ensure that all non-FOIA requests are handled according to applicable regulations and procedures (e.g., 21 CFR 5.23, 21 CFR part 20, the FDA/ORA *Regulatory Procedures Manual,* and the ORA *Information Disclosure Manual*).

  **3.** Meet periodically with DIDP staff to discuss and adjust priorities for DIDP work. When necessary, the due dates will be modified through coordination and agreement between DIDP and the requester, based on current DIDP priorities.

- **DIDP Project Manager will:**

  **1.** Inform appropriate FDA and/or CDER offices of the receipt of the request.

**2.** Enter the appropriate information into the tracking system.

**3.** Fill in the Tracking Numbers section on the DIDP Tracking Information Form and forward to the DIDP Lead.

**4.** Maintain the tracking system and provide regular reports to the Director of ORP, the Director of DIDP, and DIDP staff.

**5.** Ensure that originators of requests and DIDP staff are aware of due dates.

**6.** After receiving completed package from DIDP Lead, send hard copy of request and response back to the requester.

**7.** Archive all DIDP Tracking Information Forms and any other information relevant to the request.

- **DIDP Lead will:**

**1.** Ensure that all requests are accompanied by a DIDP Tracking Information Form and that the DIDP Project Manager is aware of the request.

**2.** Ensure that all procedures are in compliance with applicable regulations and procedures (e.g., 21 CFR 5.23, 21 CFR part 20, the FDA/ORA *Regulatory Procedures Manual*, and the ORA *Information Disclosure Manual*).

**3.** Review and respond to the request, consulting with originator of requests as appropriate.

**4.** Enter the action taken and date completed on the DIDP Tracking Information Form and then return the form and the request to the DIDP Project Manager.

## EFFECTIVE DATE

This MAPP is effective upon date of publication.

**CENTER FOR DRUG EVALUATION AND RESEARCH**
**DIDP TRACKING INFORMATION FORM**

**TRACKING NUMBERS – ENTERED BY DIDP PROJECT MANAGER**

| **Non-FOI Tracking No.** | **GC COMIS No.** | **Other** |
|---|---|---|
| | | |

**PROJECT INFORMATION – ENTERED BY REQUESTER**

**CONTACT PERSON** **PHONE NO.** **FAX NO.**

**DATE SENT TO DIDP**

**STANDARD REQUEST**_____ **PRIORITY REQUEST (include date requested)**_____
Note: All priority requests should have a requested due date. Those requesting a priority due date must get approval from the Director, DIDP, prior to submitting the request to DIDP. Refer to MAPP 4170.2.

**PROJECT DESCRIPTION**
Note: Include the reason for proposed disclosure.

**PROJECT TYPE (circle one or more than one)**

- Subpoena
- Document Certification
- Advisory Committee Meeting Materials
- Congressional
- Privacy Act
- Manuscript
- Foreign Government (e.g., Australia, Canada)
- Federal Government (e.g., HCFA, NIH, SEC)
- State/City Government (e.g., Maryland, Dallas)
- Enforcement (e.g., Warning Letter, Untitled Letter)
- Enforcement Litigation
- Defensive Litigation
- CDER Action (e.g.,publications, speeches)
- Other (describe):_____
  _____
  _____
  _____

**REQUESTED ACTION (circle one)**

- Search, Review, Redact
- Other (describe):
- Opinion
- Prepare to Post

**REQUESTER'S SIGNATURE**

**DIDP INFORMATION – ENTERED BY DIDP DIRECTOR AND DIDP LEAD**

| **DATE RECEIVED** | **DIDP DUE DATE** (Provided by DIDP Director) | **DATE COMPLETED** |
|---|---|---|
| **ASSIGNED LEAD** | **ACTION TAKEN BY DIDP** | |
| **DIDP SIGNATURE** | • *Completely Responded*<br>• *Partially Responded*<br>• *Other (describe):*_____ | |