OFFICE OF REGULATORY POLICY

Litigation Document Control Procedures in the Division of Information Disclosure Policy

CONTENTS

PURPOSE

- This MAPP outlines consistent procedures for gathering, organizing, and producing documents in response to subpoenas and lawsuits involving the Center for Drug Evaluation and Research (CDER).

BACKGROUND

- The Division of Information Disclosure Policy (DIDP) is responsible for responding to FOIA requests for documents regarding pharmaceuticals. DIDP also gathers, reviews, and redacts documents released under subpoenas and in lawsuits. Subpoenas and lawsuits that involve large numbers of documents are very labor intensive and require consistent document management procedures. This MAPP delineates the responsibilities and procedures within DIDP for retrieving, organizing, and producing documents responsive to subpoenas and lawsuits.

REFERENCES

- Freedom of Information Act, 5 U.S.C. section 552

DEFINITIONS

- **b(4):** FOIA Exemption 4, which protects from disclosure "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential." (5 U.S.C. 552(b)(4))

- **b(5):** FOIA Exemption 5, which protects from disclosure certain "interagency or intra-agency memorandums or letters." (5 U.S.C. 552(b)(5))

- **Bates Number:** A number with a three-letter prefix printed or placed on each page of responsive documents. Bates numbers provide reference points in the document production and facilitate organization of the documents (e.g., DOC000001, DOC000002, DOC000003).

- **Search Request:** An official request by DIDP to the divisions and offices in FDA for documents that may potentially be responsive to a subpoena or lawsuit. See Attachment 2.

- **True Duplicate:** A duplicate of another document, with no markings or differences of any kind that distinguish it in any way from the original.

POLICY

- DIDP's goal is to produce documents in response to subpoenas and lawsuits in a timely, accurate, and efficient fashion. To facilitate this process, DIDP is implementing procedures on how to retrieve, organize, redact, index, and produce documents.

- DIDP can employ contractors to assist in the production of documents in response to subpoenas and lawsuits. A contractor can assume the role of Consumer Safety Officer (CSO) or Regulatory Counsel as described in this MAPP.

RESPONSIBILITIES

The Director of DIDP will:

- Generally supervise the DIDP responses to subpoenas and lawsuits. The Director will coordinate responses with the Office of Chief Counsel (OCC) and DIDP staff. The Director is ultimately responsible for ensuring the proper implementation of Center and Agency policies and procedures.

The Team Leader for Litigation will:

- Generally coordinate the retrieval, organization, review, and ultimate production of the documents. The Team Leader for Litigation will keep the Director, DIDP, apprised of the status of litigation projects and will consult with the Litigation Paralegal, CSO, Regulatory Counsel, and other staff members assigned to the project to ensure that responsibilities and procedures are followed properly.

The Litigation Paralegal will:

- Generally manage and keep track of the documents in each project, making sure that all necessary procedures are followed. The Litigation Paralegal will participate in retrieving and organizing the documents, creating the model index, writing the indexing rules, preparing the index, Bates-numbering the documents, and ensuring that the production of documents is executed in a timely, accurate, and efficient manner.

The Consumer Safety Officer or Regulatory Counsel will:

- Review the documents to determine what can be released, partially released, or withheld, and make redactions as appropriate.
- Prepare and update the document index to reflect decisions and reasons for releasing, partially releasing, and withholding documents.

PROCEDURES

A. Gathering Documents

The Director of DIDP will:

- Consult with the Office of Chief Counsel (OCC) as appropriate.
- Send search requests to the appropriate offices and/or individuals within the Agency (see Attachment 2 for a sample search request).

The Team Leader for Litigation will:

- Consult with the Director, DIDP, and OCC as appropriate.

- Advise the Litigation Paralegal on the scope of the subpoena or lawsuit, and give instructions on drafting the search request.

The Litigation Paralegal will:

- Consult with the Team Leader for Litigation in reviewing the subpoena or lawsuit.

- Draft the search request and forward it to the Director, DIDP, through the Litigation Team Leader, for signature (see Attachment 2 for a sample search request).

- Describe in the search request the types of documents requested, ask for a preliminary e-mail response indicating receipt and disposition of the request, and specify the date by which all documents must be submitted to DIDP. Explain that if the office or individual does not have responsive material, that office must submit to DIDP by the specified date an e-mail or memo stating that fact.

- As documents are received, keep a checklist of who has responded, with a brief description of the material provided by each person or office.

- One week before the due date, send a reminder to those who have not responded to the initial request and determine whether an extension is necessary.

B. Organizing Documents

The Litigation Paralegal will:

- Make copies of any documents that are the Agency's original documents. The copies are designated "Set A — Working Copy." If the offices or individuals already have provided copies of the Agency's original documents, rather than the originals themselves, then the copies provided by the offices or individuals are designated "Set A — Working Copy," and there is no need to make another copy. If the offices or individuals provide voluminous amounts of material, including original volumes of a new drug application (NDA) or an abbreviated new drug application (ANDA), copy only those pages responsive to the request. If documents are in electronic format, make electronic copies of the documents and save the copies with "Set A" in the filename.

- Store the original documents (if originals are provided instead of copies) in boxes and label the boxes "Originals" with a brief description of the contents. Usually, such documents are NDA or ANDA files. However, if the original documents are not NDA or ANDA files, they may be returned to the originating office, if appropriate.

- Review Set A to make sure the documents are responsive to the request for information. Segregate all nonresponsive documents from Set A and label them "Nonresponsive." They are not indexed or released.

- Sort Set A according to date, and then within categories (e.g., e-mails, correspondence, meeting minutes, personal notes, telecons, reports). Keep attachments together and remove and shred true duplicates.

- Place Set A in boxes in a neat and organized manner. Number the boxes, and label them with a brief description of the contents. Set A will be used for indexing and redacting.

- Bates-number set A.

- Consult with the Director, DIDP, and OCC on the information to be included in the document index.

- Consult with the Director, DIDP, and OCC to determine the reasons and authorities for withholding that may apply. The authorities for redacting and withholding documents can come from several sources, including the Freedom of Information Act; the Privacy Act; the Trade Secrets Act; the Federal Food, Drug, and Cosmetic Act; Agency regulations; and Department of Health and Human Services regulations. For subpoenas, the authorities for redacting and withholding documents are the Federal Rules of Civil Procedure (Rule 45).

- Write the rules for indexing the documents, incorporating decisions made in conjunction with the Director, DIDP, and OCC. The model rules for indexing in Attachment 3 may be amended, as appropriate, following consultation with the Director, DIDP, and OCC.

- Create a model document index using Microsoft Access or Microsoft Excel. The index will include information related to the release, redaction, and withholding of documents. Attachment 4 shows the basic format of the model index, which may be amended, as appropriate, following consultation with the Director, DIDP, and OCC.

- Distribute the indexing rules and model index to all individuals who will index the documents.

- Index the documents or monitor the indexing to ensure that it is done correctly. After a small number of documents are indexed, an initial review should be conducted. If several people are doing the indexing, additional reviews should be done periodically to make sure the index is consistent.

- When the index is complete, conduct a final review.

C. Reviewing and Redacting Documents (Copy Set A) and Updating Index With Document Dispositions

The Director of DIDP will:

- Discuss any applicable protective order with OCC. With the Team Leader for Litigation, determine the redaction rules for the document production. For example, certain b(4) information may be released in documents produced under a subpoena if a protective order is in place for the underlying litigation. Discuss the redaction rules with the Team Leader for Litigation and CSO or Regulatory Counsel.

- Resolve issues that arise during the redaction of documents.

- Conduct a review of the b(5) determinations and redactions; make changes as necessary.

The Team Leader for Litigation will:

- With the Director, DIDP, determine the redaction rules for the document production. Discuss the redaction rules with the CSO or Regulatory Counsel.

- Provide input on issues needing resolution and answer any questions about the application of redaction rules.

- Determine whether the documents should undergo a second review for quality control.

The Consumer Safety Officer or Regulatory Counsel will:

- Discuss the redaction rules with the Director, DIDP, and Team Leader for Litigation.

- Review the documents and apply the redaction rules in determining what can be released, partially released, or withheld.

- Make redactions as necessary.

- Following the rules for indexing, note in the blank fields of the model index the disposition of each document redacted.

The Litigation Paralegal will:

- Remove any documents from Set A that are to be withheld in full, and place them in a separate box identified as “Documents Withheld in Full.”

- Update the index to include the withholding and redacting decisions made by the CSOs, Regulatory Counsels, Team Leader for Litigation, and Director, DIDP. The Litigation Paralegal will include the following information in the disposition designation:

– whether the document will be released, partially released, or withheld; and
– the reason and authority for partially releasing or withholding documents.

- Review the index for quality control.

D. Preparation for Production

The Litigation Paralegal will:

- Make a copy of Set A once it has been completely reviewed and redacted and once any additional withheld documents have been removed. This copy is designated "Set B."

- Copy Set B.

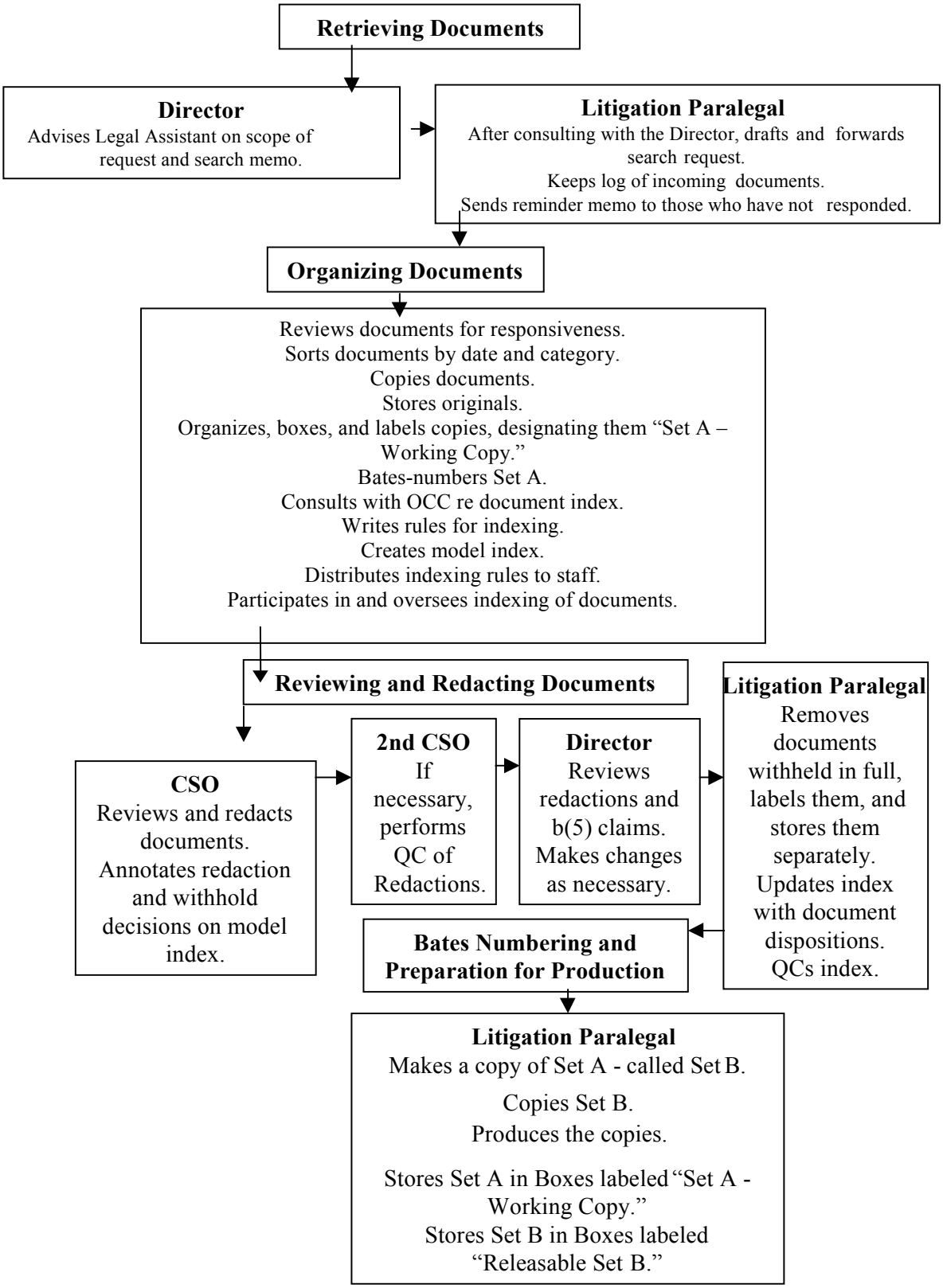
- Produce to OCC (if responsive to FOI litigation or a subpoena) the requisite number of copies of the Bates-numbered Set B documents.

- Store Set A in boxes labeled "Set A – Working Copy" with a brief description of the contents. Store Set B in boxes labeled "Released Set B" with a brief description of the contents.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

Attachment 1: Document Control Process



Attachment 2
SAMPLE LITIGATION SEARCH REQUEST

The FDA has been sued under the Freedom of Information Act [or has received a subpoena] for records related to **Sampledrug (hypothetical hydrochloride) NDA 12-123.**

The Agency is required to do a search. We are required to conduct a thorough search for the following documents:

1. **The NDA**, including reviews of the NDA
2. **Memoranda or minutes recording communications between FDA and the sponsor** or any written communication between the Agency and the sponsor related to the Agency's assessment of safety and efficacy data for these drugs
3. **Written correspondence or memoranda recording communications between FDA and regulatory agencies of foreign countries** relating to the safety and efficacy of the drug
4. **Any other records** of Agency commentary, discussions, or decisions pertaining to the NDA

Your part in this search: If you have received this e-mail, you must review all files in your possession, custody, or control and locate any documents that refer or relate to any of these items. (These documents are ***responsive documents***.)

Instruct your staff to conduct a search. If you are in charge of an organizational unit that might have responsive documents, you must direct your staff to review all files in the possession, custody, or control of the office and locate any documents that refer or relate to any of these items. Please forward this e-mail to any members of your unit who might have responsive documents, and work with those individuals to coordinate your search.

Send copies of responsive documents. Please send **COPIES** (not the originals) of all responsive documents to the address below.

Project managers — forward the NDA. If you are the project manager for the NDA, please arrange to have the document room send the original application to me at the address below.

Include a cover page or note with the following information:

- The sender
- The organizational unit
- The time you spent searching

Use this address: Please send all documents to:

Director, DIDP
HFD-13
5600 Fishers Lane
Rockville, MD 20857

Send ALL responsive documents. You should send copies of all documents you have identified as responsive, regardless of whether or not you believe the documents are releasable. The Division of Information Disclosure Policy will review all the documents to determine whether they should be released.

Respond to this e-mail. Please send me an e-mail indicating whether or not you have identified any responsive documents. HEARING THAT YOU HAVE SEARCHED AND FOUND NO RESPONSIVE DOCUMENTS IS AS IMPORTANT AS HEARING THAT YOU HAVE IDENTIFIED AND SENT RESPONSIVE DOCUMENTS.

Send documents by this date: We need the responsive documents by [date].

Forward this e-mail to others. If you know of any office in CDER that might have responsive documents and that is not included on the addressee list, please forward this e-mail to the office and copy me on the e-mail. If you have any questions, please call me at 7-4565.

Thank you,

Director, DIDP

Attachment 3

Sample Indexing Rules

1. Use all small case letters in the index.

2. The “Document Type” field will be identified as one of the following categories of documents:

    - letter
    - e-mail
    - memo
    - telecon
    - preclincial study (insert study number)
    - clinical study (insert study number)
    - review
    - meeting minutes
    - handwritten notes

3. The “Subject" field should contain a brief description of the document you are indexing.

4. Dates should be entered in the month/day/yr format (e.g., 04/08/65).

5. Names are to be entered last name first (e.g., smith, mary). If there is more than one recipient or sender, enter the first name on the list and then "et al." For example, “smith, mary et al.”

6. The "Attachment(s)" field is for documents noted as attachments in the source document. If there are several attachments to a single document, list them all in the same attachment field (for example, a single source document may list: Att 1 — copy of letter; Att 2 — agenda; Att 3 — notes from meeting. They should all be in one cell on the same line as the source document).

7. For the “Reason for Withholding” field, choose the appropriate reasons from the following list:

    - Confidential commercial information
    - Trade secret
    - Deliberative process
    - Attorney-client privilege
    - Personal privacy
    - Law enforcement records or information

8. For the “Authority for Withholding” field, choose the appropriate exemption from the following list:

    - b(4)
    - b(5)

- b(6)
- b(7)

9. For the "Disposition" field, choose the appropriate disposition from the following list:

    - Release
    - Partial release
    - Withhold

10. If the indexing staff has questions on how to index a particular document, they should consult with the Litigation Paralegal, resolve the issue, and then notify the rest of the indexing staff on how to index that particular type of document. The indexing rules should then be amended by the Litigation Paralegal to document this decision.

Attachment 4

Sample Model Index Entries –

BegBates	EndBates	Date	Document Type	To	From	Subject	Attachment(s)	Disposition	Reason for Withholding	Auth for W/H	# of Pages W/H	Bates Range of Pages W/H
doc0001	doc0009	01/09/1999	letter	smith, joe	jones, judy	re: labeling review	draft labeling review	partial release	deliberative process	b(5)	3	doc007-009
doc0010	doc0011	01/09/2002	email	smith, joe	jones, judy	re: labeling review		withhold	deliberative process	b(5)	2	doc0010-011