RESPONSIBILITIES FOR CREATING AND KEEPING RECORDS

I. PURPOSE

The purpose of this guide is to explain what "records" are, what the Federal requirements for recordkeeping are, and what the responsibilities of Office of New Animal Drug Evaluation (ONADE) personnel[1] for creating and keeping these records are.

II. WHAT IS A RECORD?

The Federal Records Act governs the records management responsibilities of Federal agencies. Under the Federal Records Act,[2] "Federal records" are defined as:

> "all books, papers, maps, photographs, machine-readable materials, or other documentary material, regardless of physical form or characteristic, made or received by an agency of the United States government under Federal law or in connection with the transaction of public business and preserved, or appropriate for preservation, by that agency or its legitimate successor as evidence of the

[1] Personnel, or employees, includes contractors who have been hired to perform FDA functions. FDA should ensure that contracts require the return of FDA-owned materials and submission of program and administrative documentation needed by the agency, including background data and technical documentation.
[2] 44 U.S.C. §3301

organization, functions, policies, decisions, procedures, operations, or any other activities of the government or because of the informational value of data in them."

In other words, a Federal record is any recorded information created or received during the transaction of an agency's mission, regardless of physical format. Some common Federal record formats include:

- Paper,
- Electronic media (diskettes and CDs),
- Microfiche,
- E-mail and attachments,
- Faxes,
- Videotapes,
- Photographs, and
- Artifacts (feedbags, vials, promotional items, tissue samples, etc.).

Each agency is responsible for determining if the materials it creates or receives meet the definition of a record. Additional Agency records guidance is available at http://intranet.fda.gov/oirm/records/.

III. WHAT ARE CVM'S RECORDS?

Records made or received by CVM under Federal law or in connection with the transaction of business include:

A. Materials submitted by potential applicants, applicants, or sponsors to CVM. For example:

1. Submissions (original, duplicate, triplicate, desk, and review copies) to investigational new animal drug files (INADs), generic investigational new animal drug files (JINADs), investigational food additive petitions (IFAs), new animal drug applications (NADAs), abbreviated new animal

drug applications (ANADAs), master files (veterinary master files (VMFs) and drug master files (DMFs)), and food additive petitions (FAPs). These include, but are not limited to, notices of claimed investigational exemption, requests for meeting, protocols, technical sections, 356Vs, labeling,

2. Expedited review requests,

3. Suitability petitions, and

4. Samples, e.g.,

   - drug,

   - histopathology slides, and

   - product packing samples (e.g. containers, labels, syringes, blisterpacks, etc.).

B. Materials prepared by CVM personnel[3] to support final actions. For example:

1. Reviews (and references),

2. Environmental documents (Request for Categorical Exclusion, Finding of No Significant Impact (FONSI), Environmental Assessment (EA), Environmental Impact Statement (EIS)),

3. Memoranda of Telephone calls,

4. Memoranda of Meetings,[4]

5. Memoranda Recommending Approval,

[4] An agency may hold internal meetings or meetings with outside parties. At a minimum, documentation in a meeting file should include the names and organizational titles of participants, an agenda, a list of materials distributed to participants, a summary of discussion of significant policy or procedural matters, decisions reached and actions taken, actions to be taken following adjournment, and assignments of responsibility.

6. Preliminary drafts, if the information contained within is not incorporated into the final product,

7. Working papers. Working papers consist of documents such as rough notes, calculations, or drafts assembled or created, and used to prepare or analyze other documents. Working papers contain record material if they include supporting materials that are necessary to substantiate the final product, decision, or agency action, and are not documented anywhere else. Working papers that contain no record material can be destroyed by the reviewer when no longer needed, and

8. Communications relating to agency activities, e.g., e-mail between CVM personnel that support decision-making.

C. Materials documenting Agency decisions including, but not limited to:

1. Letters issued to a potential applicant, applicant, or a sponsor, and the internal copies, for example:

   Refuse to file, refuse to review, food use authorization, protocol concurrence, acknowledgement, incomplete application, incomplete technical section, technical section complete, application approval, or application withdrawal letters,

2. Records documenting decisions not communicated to an outside party who has submitted information regarding a new animal drug to CVM e.g., FNRs or FNRs with memo,

3. Letters documenting the granting or denial of suitability petitions or requests for expedited review status, and

4. Documents prepared for the public, such as the Freedom of Information (FOI) Summary, FONSI, EA, or EIS.

D. Other materials including, but not limited to:

Whether purchased by the government or not, diaries, journals, calendars, green "Record" books, data books, and electronic equipment (such as computers and personal digital assistants (PDAs)) can be record material if they document

activities that were performed while carrying out duties as a CVM employee or contractor.

IV. WHAT ARE FEDERAL RECORDKEEPING REQUIREMENTS AND WHY ARE THEY IMPORTANT?

The Federal Records Act[5] requires each Federal agency "to make and preserve records containing adequate and proper documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the agency and designed to furnish the information necessary to protect the legal and financial rights of the Government and of persons directly affected by the agency's activities."

The practice of ensuring "adequate and proper documentation" contributes to efficient and economical agency operations by guaranteeing that information is documented in organized official files, including paper and electronic recordkeeping systems,[6] where it will be accessible to all authorized staff who may need it. Recordkeeping by federal agencies, such as FDA, is the systematic control of the creation, maintenance, use, and disposition of records.

Without recordkeeping requirements, agencies cannot ensure that they are creating and maintaining accurate and complete documentation essential to a responsive and responsible government. Among other things, good recordkeeping contributes to the smooth operation of an agency's programs; creates a complete record of official actions that will provide information useful to successor officials and staff; ensures accountability to the Administration, Congress, and the American people; and protects records from inappropriate and unauthorized access.

Records must stand the test of time. Not only must records be adequate and understandable at the current time, they must also be sufficiently detailed and clear so that they will be understood in the future. Division Directors have primary responsibility for ensuring that complete and accurate records are created. Division Directors best understand the functions and operations of their office and have the authority needed to direct staff members to follow good documentation procedures.

[5] 44 U.S.C. § 3101

[6] Electronic recordkeeping systems should be designed to ensure the security and integrity of records, preserve records for the time they are needed, and ensure the records are readable as agency electronic systems and software change.

V. WHAT ARE YOUR RESPONSIBILITIES TO KEEP RECORDS?

The record management responsibilities of CVM employees are to:

A. Create records needed to do the business of the agency, record decisions made and actions taken, and document activities for which you are responsible.

Every significant FDA decision on any matter under the laws administered by FDA, e.g., relating to a decision whether or not to approve a new animal drug, must be documented.[7] That is, FDA employees responsible for handling a matter are responsible for making sure the administrative record relating to it is complete.

In CVM, this involves documenting the review of submissions, internal meetings, and meetings and phone calls with outside parties. Until an official electronic recordkeeping system has been developed and implemented, relevant e-mails should be printed out and placed in the file. Products such as reviews, document summaries, meeting minutes, and final action letters to submissions help to record decisions and actions taken on behalf of the Center.

B. Maintain administrative files so that administrative records can be found when needed.

FDA employees responsible for handling an agency matter are responsible for ensuring the completeness of the administrative file relating to the matter[8]. Under FDA's regulations,[9] "administrative file" means "the file or files containing the documents pertaining to a particular administrative action, including internal working memoranda, and recommendations." "Administrative records" are the documents in the administrative file of a particular administrative action on which the Commissioner relies to support the action.[10]

For example, CVM's administrative file for the approval of a particular drug includes the collection of administrative records of the sponsor's submissions in the original jackets or manila folders, other associated materials (regardless of

[7] 21 CFR §10.70
[8] 21 CFR §10.70(b)
[9] 21 CFR §10.3(a)
[10] 21 CFR §10.3 (a)

format or type), and CVM's response to the submission. The Document Control Unit (DCU) is the custodian of the administrative file.

The administrative file must contain:[11]

1. Appropriate documentation of the basis for the decision, including relevant evaluations, reviews, memoranda, letters, opinions of consultants, minutes of meeting, and other pertinent written documents,

2. Recommendations and decisions of individual employees, including supervisory personnel, and

3. Documentation of any significant controversies or differences of opinion and their resolution.

Written documents placed in the administrative file must:[12]

1. Relate to the factual, scientific, legal or related issues under consideration,

2. Be dated and signed by the author,

3. Be directed to the file, to appropriate supervisory personnel, and to other appropriate employees, and show all persons to whom copies were sent,

4. Avoid defamatory language,

5. If it records the views, analyses, recommendations, or decisions of an agency employee in addition to the author, be given to the other employees, and

6. Once completed, not be altered or removed. Later additions to or revisions of the document must be made in a new document.

Documents prepared by agency personnel that are not in the administrative file have no status or effect.

[11] 21 CFR §10.70(b)
[12] 21 CFR §10.70(c)

The electronic file copy on the CVM Records Drive (R: Drive) is **not** an administrative record of CVM-related documents. The original paper copy is the official record. Because current electronic storage methods cannot ensure the authenticity of R: Drive documents, (i.e., the completeness of documents, timeliness of uploading of documents, electronic signatures or version control), the R: Drive is only a convenience (or reference) copy. ONADE personnel should not use R: Drive documents as templates. Templates that have been established by the Office would be found in P&P manual guides or guidances or in a designated electronic repository.

In CVM, the review of submissions requires the coordination of review activity by individual reviewers, teams, divisions, and offices. This makes it critical to keep track of the custody of the submission's manila folders and document volumes (jackets). It is essential that these folders and jackets be routed through the DCU to record information in STARS (see section VI) to track their location. Then, using STARS, the files can easily be located. In order to ensure that records can readily be located, the DCU will track, among other things:

1. The reassignment of submissions between divisions,

2. The processing of library loan requests,

3. The issuance and completion of consulting reviews, including those going to other CVM offices or to outside consulting contractors, and

4. The transfer of custody of any whole or partial submission from the CVM to any other person, including District Offices.

The DCU inventories submission materials, i.e., the submission copies (originals, duplicates, and triplicates) and components (including diskettes, CDs) submitted by outside parties to CVM and logs them into STARS. STARS refers to these submission materials as the "AA package." The contents of the AA package are printed on the submission routing slip to assist reviewers in keeping track of the submission materials.

In addition to ensuring that the complete set of submission materials are returned to the DCU, reviewers must ensure that reviews and materials prepared on behalf of CVM are returned to the DCU before or at the time of final action. If the submission is multi-volume, all volumes must be returned before DCU will final the submission. Once DCU completes the review of a submission by

processing the final action package, that submission may be checked out as a library loan.

C. Dispose of records under their control in accordance only with agency records schedules and Federal regulations.

It is the responsibility of the reviewer to ensure all submission copies are returned to the DCU so the DCU can complete the reconciliation of the records and comply with the storage and disposition requirements of the records. In CVM, the DCU is assigned the responsibility to ensure the security and completeness of the documents and can only be successful in carrying out this responsibility with the cooperation of reviewers. The DCU tracks all movements of the submission materials and carries out the instructions for document storage and disposition as indicated in the FDA Records Schedules. Original documents are stored and preserved for some period, while duplicates and triplicates are generally shredded. Only DCU is authorized to shred the duplicates and triplicates.

D. Treat CVM documents with the appropriate level of security.

CVM employees are responsible for both the physical and informational security of CVM documents.

1. Section 301(j) of the Federal Food, Drug and Cosmetic Act (FFDCA).

   Under this section, every person is prohibited from using "to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department of Health and Human Services, or to the courts when relevant in any judicial proceedings under [the FFDCA], any information acquired under the authority of sections … 512 [and other sections]… concerning any method or process which as a trade secret is entitled to protection."

   For example, CVM employees are prohibited from revealing any information received relating to a NADA or its investigational use that is trade secret information or confidential commercial information.

2. The Privacy Act of 1974.[13]

   The Privacy Act[14] prohibits an agency from disclosing information, that is contained in a system of records, concerning an individual to any person or another agency except with the prior written consent of the individual to whom the record pertains. Information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, that is not part of the Privacy Act system of records cannot be disclosed under the FOIA.[15]

3. The Freedom of Information Act (FOIA).

   FOIA also protects certain types of information from disclosure. FOIA generally provides that any person has a right, enforceable in court, of access to federal agency records, except to the extent such records (or portions thereof) are protected from mandatory disclosure by one of nine exceptions.[16] CVM employees are responsible for making sure that such information is <u>not</u> disclosed. FOI exceptions from disclosure include:

   a. Personal Information,[17]

   b. Confidential Commercial Information,

      Confidential commercial information means 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,[18] and

   c. Trade Secrets

      A trade secret may consist of "any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be

[13] 5 USC §552a
[14] With exceptions permitted by §552a(b)
[15] 5 USC §552(b)(6)
[16] 5 USC 552(b)(1)-(9)
[17] 5 USC 552(b)
[18] 21 CFR §20.61(b)

said to be the end-product of either innovation or substantial effort." [19] There must be a direct relationship between the trade secret and the productive process. Examples of trade secrets include materials used in manufacture that are not immediately identifiable, manufacturing processes, quality control procedures, sterilization techniques, formulas, schematics or circuit diagrams, and related data not contained in the product labeling. Trade secrets are frequently found in:

i) Establishment Inspection Reports (EIRs),

ii) Applications (NADAs and ANADAs),

iii) Investigational files (INADs and JINADs), and

iv) Certain technical proposals or bids from contractors.

Questions about what constitutes confidential commercial information or trade secrets can be directed to the Center's FOI Officer. Further guidance on the Confidentiality of Center files can be found in CVM P&P Guide 1240.2520 and in FDA Staff Manual Guide 2280.10.

VI. WHAT FUNCTION DOES STARS SERVE IN CVM RECORDKEEPING?

STARS (Submission Tracking and Reporting System) is CVM's principal pre-approval submission tracking database. STARS is able to:

- Track the processing and physical movement of submissions by CVM. STARS tracks, for records management purposes, who has custody of, and thus, responsibility for, any part of a submission under active review. It also provides a record of the location of parts of the administrative file that have been requested from the DCU for use as reference material.

- Provide a Reviewer Desktop Management module to reflect the Center's target processing times and priorities,

- Serve as a repository of document approval review status,

[19] 21 CFR §20.61(a)

- Provide a link to electronic submissions, and
- Provide useful information on the type and quantity of work received by the Center to assist in resource, budget, and management planning.

These objectives can only be accomplished by physically moving the submissions through the DCU and documenting when control of a submission (or part of a submission), is transferred from one individual or location to another. Movement that is tracked includes:

- Receipt of incoming submissions,
- Routing to the primary reviewer,
- Corrections and changes in routing or division assignment,
- Distribution and collection of consulting reviews,
- Quality assurance routing,
- Approval package routing,
- Final action package routing,
- Date and publication of approvals,
- Library loans, and
- Document destruction.

VII. WHAT IS NOT A RECORD?

Non-records are Government-owned documentary materials that do not meet the definition of a record[20] or that are specifically excluded by statute.[21] Non-record materials should not be interfiled with record materials and should be destroyed when no longer needed for reference. Non-records include:

[20] 36 CFR §1222.34(b)
[21] 44 U.S.C. §3301

A. Extra copies of documents that function only as convenience or reference copies and serve no other purpose as a record.

Extra copies of submission materials should be routed to the DCU for determination of their status and disposition. Copies of submission materials are the property of CVM.

B. Personal papers.

Personal papers are excluded from the definition of Federal records and are not owned by the Government. Personal papers are documents or materials, or any reasonably segregated portion thereof, that are not used in the transaction of agency business but that may be maintained in a Government office. Personal papers and files may refer to or comment on the subject matter of agency business, provided they are not actually used to conduct business. If maintained in a Government office, personal papers should be clearly labeled and maintained separately from the office's records. See FDA Staff Manual Guide 3291.3 for additional information.

Examples of personal papers include:

1. Materials accumulated by an official before joining Government service that are not used subsequently in the transaction of Government business,

2. Materials relating solely to an individual's private affairs, such as outside business pursuits, professional affiliations, or private political associations that do not relate to agency business, and

3. Diaries, journals, personal correspondence, or other personal notes that are not prepared or used for, or circulated or communicated in the course of, transacting Government business.

C. Technical Reference

Technical reference materials are documents that are otherwise excluded from the definition of records, such as:

1. Professional journals,

2. CFR and Federal Register collections,
3. Training and conference material,
4. Standard operating procedure, policy, or guidance manuals, and
5. Stocks of publications for distribution.

VIII. SUMMARY

ONADE employees should:

- Adequately document the work they do and make sure it becomes part of the administrative file.
- Treat information contained within paper and electronic documents (as well as the physical manifestation of such documents), i.e., jackets, manila folders, diskettes, CDs, e-mails, with the appropriate level of security.
- Use the DCU and STARS to track movements of all submissions and their parts so that CVM can know at any time who has custody of a particular administrative record.
- Return all copies of documents to the DCU upon completion of work to provide for adequate security tracking and appropriate disposition.

IX. REFERENCES

The Federal Food, Drug and Cosmetic Act, 21 U.S.C. §331(j)

The Federal Records Act, 44 U.S.C. §3101

The Freedom of Information Act, 5 U.S.C. §552(b)(1)-(9)

The Privacy Act of 1974, 5 U.S.C. §552a

Code of Federal Regulations

21 CFR §10.3(a), Definitions

21 CFR §10.70(a)-(c), Documentation of significant decisions in administrative file

21 CFR §20.61(a) and (b), Trade secrets and commercial or financial information which is privileged or confidential

36 CFR §1222.34(b), Identifying federal records

FDA Staff Manual Guides

2280.10, Non-Public Information

3291.3, Disposition of Records and Personal Papers by Separating Individuals

CVM Program Policy and Procedure Manual Guides

1240.2520, Confidentiality of Center Files

FDA Records Management Home Page: http://intranet.fda.gov/oirm/records/