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FDA STAFF MANUAL GUIDES, VOLUME III – GENERAL ADMINISTRATION

INFORMATION RESOURCES MANAGEMENT

MANAGEMENT PROGRAMS - RECORDS MANAGEMENT

FIELD OFFICE FILING SYSTEM

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NOTE: This SMG is being revised

1. PURPOSE

This Guide details the recommended arrangement for filing documents in field offices. It is designed to provide guidance to Assistant Records Liaison Officers (ARLOs) in establishing and managing the files, and to assist records custodians in maintaining the files on a day-to-day basis.

2. REFERENCES

A. HHS Staff Manual – Records Management. Of particular importance are:

1. Files Management Handbook for PHS Regional Offices. (TN hr-76.1)

2. Handbook on Establishing and Maintaining Files in the Public Health Service (TN 76.1)

   These Handbooks are issued by PHS as appendices A and B to Chapter 4-00 of the Manual.

B. Files Operations (NSN 7610-00-985-6973) and related National Archives publications on records management.

3. POLICY

The Agency's records will be arranged in a filing system that is the most efficient and effective for inserting, retrieving, storing, and disposing of the filed documents.

4. RESPONSIBILITIES

District and/or Field Office Administrative Officers will implement a filing system that conforms to the Agency's policy and will insure that it is adhered to. This responsibility may be delegated to a staff member designated as the ARLO.

5. GENERAL SUBJECT FILE

Correspondence, memoranda for record, plans, reports, minutes of meetings, and other general subject file material may be placed in this file in the order given in Attachment A. This filing arrangement replaces the present decimal system. It is not necessary to establish a file folder for each subject listed. If no material on a particular subject is to be filed, do not make up a folder. Conversely, additional folders for a particular subject may be made if the volume of file material warrants. This may be done by breaking the subject down into specific categories or by time periods.

6. ESTABLISHMENT FILE

These files (also know as factory, EI, or EF jackets) consist of one or more jackets for each firm or producer over which FDA has jurisdiction, including those inspected by state and local officials. The firm's name, address, and central file number should be placed on each jacket. These files should be arranged in alphabetical order by name of firm. For economy and ease of access, rack or open face shelving is recommended over conventional file cabinets.

When the volume of documentation in a particular file warrants, separate color coded jackets may be used to divide the various categories of documents. This color coding is one of principal features of the system. It allows file searchers to go directly to the particular volume they need without searching through all the jackets on a particular firm. It also facilitates replacement of the volume in the file when no longer needed. Color coding may be done simply by attaching strips of self-sticking paper or tape in the desired color to the sides or ends of the jackets. A more expensive alternative is to purchase a supply of jackets in the desired colors.

Attach all documents related to the latest inspection to the white color coded jacket. When a later inspection is made, or when the volume of documents in the white folder makes it necessary to start a new folder, replace the white code strip on the previous jacket with a blue one. (If color coded jackets are used, transfer the older material from the white jacket to a blue one.) An index tab giving the date of each inspection should be attached to the first document related to that inspection. The white jacket should be filed first followed by the blue jackets in chronological order.

The EF jackets will contain:

1. Copies of licenses and registrations. (See paragraph 10 for antibiotic certifications) Another copy of each registration will be filed separately for public display.

   Attach licenses and registrations to the left side of white color coded jackets. Attach all other material to the right side of the jackets.

2. Establishment Inspection Reports (EIR) including:

   a. Establishment Inspection Report (original copies only) Forms FDA 481, 481a, or 481b.

   b. Notice of Inspection, Form FDA 482

   c. List of Observations, Form FDA 483

   d. Receipt for Samples, Form FDA 484

   e. Narrative Reports

   f. Exhibits including labeling, photographs, invoices, records, etc. (Exhibits of boxes, bottles, etc., may be photocopied.)

   g. Collection Reports and Analyst Worksheets for Factory Samples (samples collected during inspections and documented on the Form FDA 481).

   h. Interstate travel checklist reports

i. Negatives or positives of any pictures taken during the inspection.

3. Correspondence relating to the firm.

4. Original Consumer Complaint Forms FDA 2516 and 2516a and complaints in letter format.

5. Investigational reports

6. Surveillance reports

7. Copy of information letters.*

8. Copy of firm management's response to information letters.*

9. Copy of regulatory letters.*

   a. Copy of firm management's response to regulatory letters.

   b. Copy of written statement of FDA's final decision.

10. Copies of seizure recommendation memoranda or TWX's to Headquarters.*

    a. Copies of Headquarters response memoranda or TWXs.

    b. Copy of Seizure Accomplishment Report, Form FDA 456

    c. Copy of Notice of Status of Decree, Form FDA 459

11. Copies of memoranda to Headquarters recommending citation.

    a. Copies of Headquarters response memoranda to citation recommendation.

    b. Copy of Notice of Hearing, Form FDA 466

    c. Copy of Record of Hearing.

12. Copies of cover memoranda for Prosecution Recommendation.*

    a. Copies of Headquarters response memoranda to Prosecution Recommendation.

    b. Copy of termination of Prosecution Report.

13. Copies of cover memoranda for Injunction Recommendation.*

Copies of Headquarters response memoranda to Injunction Recommendation.

15. Copy of Temporary Abeyance Letters.*

16. Copy of Recall Summary.

***NOTE**: Originals of all legal documents (forms and memoranda) are filed in the legal jackets.

7. CLOSED RECALLS

File in green colored jackets. Closed recalls may be filed immediately behind the last of the blue establishment jackets, or may be filed in a separate section of the central files by recall number or alphabetically by firm name.

8. CLOSED LEGAL FILES

(including Injunctions, Seizures, Citations, etc.). File in gray colored jackets. Closed legal files may be filed behind the green recall jackets, or may be filed in Compliance Branch where the open legal cases are filed.

9. NDAs, INDs, NADAs and VINDs

Leave in colored jacket in which they are received from Headquarters (red, orange, etc.). File behind gray legal jackets or in a separate section of central files by number or firm. (Note these records are no longer sent from Headquarters on a routine basis).

10. ANTIBIOTIC CERTIFICATES

(including exemptions). File in yellow jacket. Place behind NDA, etc., jackets. (Note these records are no longer sent from Headquarters.)

11. NAI (NO ACTION INDICATED) COLLECTION REPORTS AND ANALYSTS WORKSHEETS

Collection Reports (Official or INV) for non-actionable samples are filed in numerical order (by sample number) in the home district. Maintain in same location as the establishment files. A completed Collection Report includes the white copy of Collection Report; original copies of Analysts Worksheets, labeling, shipping documentation; and, if relevant, a copy of the related Consumer Complaint Form.

The exception to the above is field survey samples. Survey samples may consist of (a) more than one product from more than one manufacturer, or (b) one product from

many manufacturers. They should be marked "NAI" by the collecting district supervisor CSO and filed as follows:

1. When a survey sample is collected by one district and analyzed by another, the white copy of the Collection Report will be filed by the collecting district in the NAI file. The worksheet will be processed and filed by the analyzing district.

2. When a survey sample is examined by the Minneapolis Center for Microbiologic Investigations or by a Headquarters Center, the worksheets will not be returned to the district office. The collecting district should file the original (white) copy of the Collection Report in the NAI file.

12. FOREIGN DISTRICT FILE [WORK FOR OTHER DISTRICTS (WFOD)]

Arrange file alphabetically by firm name or by district. Maintain in same location as the establishment files. This file contains Recall Effectiveness Checks on foreign district firms, information of consignees in foreign districts, consumer complaint on products manufactured in foreign districts, assignments, or copies of worksheets for samples manufactured in another district.

13. POTENTIAL OBLIGATION FIRMS (MISCELLANEOUS FIRM FILE)

Arrange file alphabetically by firm name after the foreign district file. Maintain in same location as the establishment files. The file includes state inspections not having CF numbers, complaints, and general correspondence and information not in the district's inventory of firms. Do not keep Establishment Inspection Reports in this file. The purpose of this file is to preserve information on firms that may eventually become part of the district's Official Establishment Inventory and thus subject to inspection.

14. CONSUMER COMPLAINTS

Arrange file alphabetically by consumer name, by year or, as an alternative, by complaint number. Maintain in same location as establishment files. This file is a cross reference to the complaint form filed in the appropriate establishment file and is used to determine action taken. The file consists of yellow copies of Forms FDA 2516, 2516a, or copies letter format complaints (originals are placed in establishment files).

15. IMPORT FILE

Arrange Import Sample Reports in numerical order or by importer of record. Maintain in same location as establishment files. NAI Import Sample Reports will consist of the Import Collection Report (Form FDA 715), the Land Port Entry Notice (Form FDA 720), or the Mail Entry Collection Report (Form FDA 725); the Sample

Summary and Analyst Worksheet. If used, closed legal cases for Import Samples will, in addition, contain Detention Notices, Release Notices and/or Refusals of Admissions. Tea Import Chop lists are also included in this file.

16. TRANSITORY CHRONOLOGICAL FILES

Arrange chronologically or in order that best meets the needs of the district. These files should be kept in the same location as the general subject files. These files contain material evaluated by the Assistant Records Liaison Officer as valuable only for a short time. Examples are requests for information, advance notices to changes in directives, and correspondence of temporary value. In order to prevent the needless accumulation of these documents, papers of temporary value should be kept separately and destroyed at appropriate intervals such as 30 days, six months, or one year.

17. WORKING FILES

Working files answer operational needs and are kept at the work site. These files consist primarily of documents relating to work in progress. Examples include legal jackets for ongoing actions (filed in Compliance Branch) and recalls in process.

18. CONVENIENCE REFERENCE FILES

These files are collections of material kept for reference in work sites rather than central files. They do not document FDA actions, expenditures, or decisions and are not official records. They are an information resource to the user. Examples would include copies of unusual pleadings in the Compliance Branch, copies of analytical procedures kept in the Laboratory Branch, and district reading files. Convenience reference files should be disposed of when the user finds them no longer essential. Every effort should be made to minimize the volume of these files.

19. RECORDS DISPOSAL

Time frames and disposal methods for most of the files described above are given in the HHS Staff Manual - Records Management, Appendix B-331. In some cases, the files described individually in the Appendix have been consolidated into the establishment or other file. For example, the drug registration documents covered in item 11 of the Appendix are now included in the establishment file. In these instances the entire consolidated file may be kept for as long as the longest retention period for any of its components. For example, drug registration documents would be held for 10 years (eight years at a Federal Records Center) after the firm has gone out of business or is of no further regulatory interest rather than a flat five years. This will negate the need to pull the jackets apart to dispose of different categories of records at different times.

However, when retaining the documents beyond their presently authorized disposal time causes space or other problems, they may be disposed of as authorized in Appendix B-331. This can easily be done with NDAs and other material kept in separate jackets.

ATTACHMENT A

GENERAL SUBJECT FILING ARRANGEMENT

ADMINISTRATION - MANAGEMENT

BUDGET AND FINANCE

BUD-l	General
BUD-2	Budget formulation and planning (including estimates)
BUD-3	Budget execution (including appropriations, allotment of funds, authorizations for use, notices of allowances, and ceiling allowances)
BUD-4	Collection of funds (from collection of fees, tax refunds, and property sales)
BUD-5	Disbursements (including payroll, travel and transportation documents, invoices, claims, vouchers, collection reports, imprest funds, and transfer of funds)
BUD-6	Contracts (including leases)
BUD-7	Financial reports and statements
BUD-8	Audits
BUD-9	Other

PERSONNEL

PER-1	General
PER-2	Personnel management (including personnel allotments, staffing, position classifications, job descriptions, and performance requirements)
PER-3	Recruitment
PER-4	Employment (including assignments, promotions, transfers, performance ratings, and adverse actions)
PER-5	Employee relations and affirmative actions (including Equal Employment Opportunity and Federal Women's Programs as well as grievances, counseling, labor relations, awards, and insurance and other fringe benefits)
PER-6	Working conditions (including employee safety and time and leave)
PER-7	Training
PER-8	Separations (including retirement and out-of-agency transfers)
PER-9	Other personnel (including employee credentials, fund drives, and lists of employees)

FACILITIES

FAC- 1	General
FAC-2	Property management (including purchases, inventory, and disposal of supplies, equipment, and furniture)
FAC-3	Building space (including space arrangements, parking, and security)
FAC-4	Utilities and communications (including heating, lighting, plumbing, telephones, teletype, facsimile, and ADP terminals [but not ADP management])
FAC-5	Transportation (private, Government, and commercial vehicles)
FAC-6	Services (including printing and reproduction and mail distribution)
FAC-9	Other facilities

MANAGEMENT AND ORGANIZATION

MGT- 1	General (including missions and function statements, policies, procedures, rules, and regulations)
MGT-2	Management program (including planning and evaluation, studies and surveys, and Management Information Systems such as LMS and PODS)
MGT-3	Report on management activities
MGT-4	Organization (including delegations of authority and organization charts)
MGT-5	Records management (including forms, directives, correspondence, and filing management as well as Freedom of Information and Privacy Act requirements)
MGT-9	Other management (including geographical boundaries and areas of responsibility)

REGULATED PRODUCTS

BIOLOGICS

BIO-1	General (includes product definitions and standards, analysis, research, industry records and reports, and industry requests for approval [INDs, licenses, etc.])
BIO-2	Production (includes production methods, adulteration and contamination, dangerous ingredients, and injuries and ailments caused by product)
BIO-3	Marketing (includes advertising, labeling, containers, importing, shipping, storage, and distribution)
BIO-4	Specific biological products
BIO-5	Blood, blood banks, and blood derivatives
BIO-9	Other

COLORS AND DYES

COL-1	General (includes product definitions and standards, analysis, research, industry records and reports, and industry petitions for approval)

COL-2 Production (includes production methods, adulteration and contamination, dangerous ingredients, and injuries and ailments caused by product)
COL-3 Marketing (includes advertising, labeling, containers, importing, shipping, storage, and distribution)
COL-4 Specific color and dye products (includes red #2, charcoal black, etc.)
COL-9 Other

COSMETICS

CSM-1 General (includes product definitions and standards, analysis, research, industry records and reports, and industry requests for approval licenses.)
CSM-2 Production (includes production methods, adulteration and contamination, dangerous ingredients, and injuries and ailments caused by product)
CSM-3 Marketing (includes advertising, labeling, containers, importing, shipping, storage, and distribution)
CSM-4 Specific cosmetic products
CSM-9 Other

DEVICES, MEDICAL AND DIAGNOSTIC PRODUCTS

DEV-1 General (includes product definitions, standards, analysis, research, industry records and reports, and industry requests for approval [PMAs. etc.])
DEV-2 Production (includes production methods, adulteration and contamination, dangerous ingredients, and injuries and ailments caused by product)
DEV-3 Marketing (includes advertising, labeling, containers, importing, shipping, storage, and distribution)
DEV-4 Specific medical devices and diagnostic products
DEV-9 Other

DRUGS

DRG- 1 General (includes product definitions, standards, analysis, research, industry records and reports, and industry requests for approval [INDs, NDAs, etc.])
DRG-2 Production (includes production methods, adulteration and contamination, dangerous ingredients, and injuries and ailments caused by product)
DRG-3 Marketing (includes advertising, labeling, containers, importing, shipping, storage, and distribution)
DRG-4 Specific drug products
DRG-5 Special drug programs (includes methadone monitoring, etc.)
DRG-9 Other (includes eye and other body organ banks)

FOODS, ADDITIVES, AND SUPPLEMENTS

FOD-1	General (including product definitions and standards, reports, analysis, research, industry records and reports, and industry requests for approval [food additive petitions])
FOD-2	Production (includes production methods, adulteration and contamination, dangerous ingredients, and injuries, poisoning, and ailments caused by product)
FOD-3	Marketing (includes advertising, labeling, containers, importing, shipping, storage, distribution, and branded foods)
FOD-4	Meat, poultry, fish, eggs, and dairy products
FOD-5	Fruits, grains, and vegetables
FOD-6	Beverages
FOD-7	Food additives and supplements
FOD-8	Special food programs (includes milk and food sanitation, interstate travel sanitation, shellfish sanitation, meat imports, etc.)
FOD-9	Other (includes oils, fats, waxes, spice condiments, prepared foods, etc.)

RADIOLOGICAL HEALTH

RAD-1	General (includes product definitions and standards, analysis, research, industry records and reports, and requests for approval [licenses, etc.])
RAD-2	Production (includes production methods, contamination, dangerous ingredients, and injuries and ailments caused by product)
RAD-3	Marketing (includes advertising, labeling, containers, importing, shipping, storage, and distribution)
RAD-4	Specific radiological products
RAD-9	Other

VETERINARY MEDICINE

VET- 1	General (includes product definitions and standards, analysis, research, industry records and reports, and industry requests for approvals [VINDs, NADAs, etc.])
VET-2	Production (includes production methods, adulteration and contamination, dangerous ingredients, and injuries and ailments caused by product
VET-3	Marketing (includes advertising, labeling, containers, importing, shipping, storage, and distribution)
VET-4	Specific veterinary medical products (includes antibiotics and medical devices)
VET-5	Specific medicated feed products (includes vitamins)
VET-9	Other

SPECIALIZED PROGRAMS

ENFORCEMENT ACTIVITIES

ENF-1	General (includes correspondence on regulations, jurisdiction, and court precedents)
ENF-2	Other

FEDERAL - STATE RELATIONS

FSR- 1	FDA-state contracts
FSR-2	Memoranda of agreement/understanding
FSR-3	FDA commissions for state officials
FSR-4	Directory listing of state officials
FSR-5	State legislation/regulations
FSR-6	State resource data
FSR-7	NRSTEN/communications
FSR-8	State training
FSR-9	IPA details
FSR-10	Miscellaneous

QUALITY ASSURANCE

QLT- 1	General
QLT-2	Cooperative Quality Assurance Program
QLT-3	ORA (EDRO) Quality Assurance Program
QLT-4	Government-wide Quality Assurance Program
QLT-5	Quality Assurance for Selected Marketed Drugs
QLT-9	Other

(Other specialized programs are to be added in alphabetical order as they come into being.)