REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

TO NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR)
WASHINGTON, DC 20408

1 FROM (Agency or establishment)
Department of Health and Human Services

2 MAJOR SUBDIVISION
Food and Drug Administration (FDA)

3 MINOR SUBDIVISION
Center for Veterinary Medicine (CVM)

4 NAME OF PERSON WITH WHOM TO CONFER	5 TELEPHONE
Seung Ja Sinatra	(301) 827-4274

LEAVE BLANK (NARA use only)

JOB NUMBER N1-088-09-4

DATE RECEIVED 12/19/08

NOTIFICATION TO AGENCY

In accordance with the provisions of 44 U S C 3303a the disposition request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10

DATE	ARCHIVIST OF THE UNITED STATES
05 Jan 11	

6 AGENCY CERTIFICATION

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal on the attached 17 page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified, and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO Manual for Guidance of Federal Agencies,

☑ is not required, ☐ is attached, or ☐ has been requested

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
12/10/2008		HHS Records Officer

7 ITEM NO	8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10 ACTION TAKEN (NARA USE ONLY)
	Unless specifically stated otherwise in the description or the retention, all items are media-neutral and apply to paper, electronic, microform, or other media in which records may exist SEE attached sheet CVM Program Records Seung Ja Sinatra - FDA Records Officer — Date 11/9/07 Ann Wion - FDA Office of the Chief Counsel — Date 11/13/08		

Center for Veterinary Medicine (CVM) Records
File Code Prefix = CVM

Item No.	Records Description and Authorized Disposition	NARA Approved Citation
1	**Program Management Files**	
1.1	~~**Policy and Procedures Reference Materials.**~~ ~~Includes reference materials pertaining to rules, regulations and instructions important to responsibilities of all CVM program areas Includes such materials on the review of New Animal Drug Applications (NADA), postmarket surveillance and compliance activities, and instructional guides detailing content related to CVM's policy and procedures Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations~~ ~~Refer to agency-wide Web schedules for Internet versions of the policy and procedures manuals Internet versions are used as electronic access copies and as an index for quick reference to all parts of the manuals Internet versions also contain links to the manuals~~ ~~**Disposition: TEMPORARY.**~~ ~~Delete/destroy when superseded or obsolete, or when no longer needed for reference, whichever is latest~~	**WITHDRAWN 12/4/09** **Center will use agency-wide authority N1-088-07-2, item 2.1**
1.2	**CVM Subject Files.** Consists of research, precedent-setting materials, and correspondence that is not tracked by the Submission Tracking and Reporting System (STARS) or its successor system Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations	
1.2.1	~~**Program Development Files.**~~ ~~Includes files that may involve initial policy exploration Also includes records generated from one-time inquiries or directives, including requests from Congress and copies of CVM responses, that are not covered by another record series Representative topics include the Brown Amendment, food safety issues, biotech, cloning, Virginiamycin, and risk assessments~~ ~~Record copies of Congressional correspondence are maintained by the Office of Legislative Affairs, Office of the Commissioner (OC), record copies of correspondence processed by the Office of Executive Secretariat, OC, are maintained by that office~~	**WITHDRAWN 12/4/09 WITH ITEMS BELOW**

1.2.1.1	~~**Records maintained by CVM Program Offices.**~~ ~~**Disposition: TEMPORARY.**~~ ~~Cutoff at the end of the year after project is completed. Delete/destroy 50 years after cutoff.~~	**Supersedes NC1-88-78-1, items V-12a & V-12b** **WITHDRAWN 12/4/09 Center will use agency-wide authority, N1-088-07-2, item 3.1.1 & 3.1.2**
1.2.1.2	~~**Source documents used to produce recordkeeping copies.**~~ ~~**Disposition: TEMPORARY.**~~ ~~Cutoff after project is completed. Scan in paper and transfer paper copies to FRC upon completion of quality control of the imaged records. Delete/destroy 5 years after cutoff.~~	**WITHDRAWN 12/4/09 with related item above**
~~1.2.2~~	~~**Animal Feed Subject Files.**~~ ~~Includes correspondence and review of the safety and legal status of complete feeds, feed supplements, feed ingredients, ingredient standards, and contaminants, reports and evaluations relating to "Out of Specification" assays, compliance programs and field assignments for medicated feeds and Type A medicated articles, compliance programs and field assignments for feed contaminants, and scientific reviews of regulatory actions for animal feeds and medicated feeds.~~ ~~**Disposition: TEMPORARY.**~~ ~~Cutoff at end of the calendar year after completion of the final action. Delete/destroy 30 years after cutoff.~~	**New** **WITHDRAWN 6/8/10 Center will use agency-wide authority, N1-088-07-2, item 3.1.2**
1.2.3	**CVM Office Precedence Subject Files.** Includes files documenting CVM's position on issues, as well as files documenting CVM's deliberative process with regard to the drug review and approval processes. Subject files are used for reference to establish precedents and may be maintained at the Team, Division, or Office level **Disposition: TEMPORARY.** Cutoff at end of the calendar year in which completion of the project occurs. Delete/destroy 50 years after cutoff.	**New**
1.2.4	**CVM Regulatory Development Precedent Subject Files.** Includes files documenting CVM's deliberative process with regard to the development of regulations. Subject files are used for reference by CVM to establish precedents **Disposition: TEMPORARY.** Cutoff at the end of the calendar year in which completion of the	**New**

development process for each regulation occurs Delete/destroy 50 years after cutoff

1.3 **CVM Pre-Market Activity General Correspondence (GC).**
General Correspondence files are used as a repository of general requests from industry or the public These files may include premarket related materials Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

1.3.1 ~~**Animal Drug User Fee Act (ADUFA) Waivers.**~~ **WITHDRAWN 12/4/09**

~~Includes waiver forms submitted annually by animal drug companies requesting exemption from fees, as well as related records Files are maintained in the General Correspondence file (GC 3126) ADUFA Waivers are vital records~~

Center will use agency-wide authority, N1-088-09-11, Item 1.2

~~**Disposition: TEMPORARY.**~~
~~Cutoff at end of each ADUFA cycle Delete/destroy 70 years after cutoff~~

1.3.2 **Premarket-related General Correspondence.**
Includes pre-Investigational New Animal Drug (INAD) correspondence, such as correspondence between CVM and sponsors concerning the New Animal Drug Application (NADA) and INAD processes prior to the submission of an application by a sponsor Records are tracked in the Submission Tracking and Reporting System (STARS) or its successor system and are maintained by the Document Control Unit

1.3.2.1 **Record Copies.** **Supersedes V-7 NC1-88-78-1**

Disposition: TEMPORARY.
Cutoff at end of calendar year after 10 years of no file activity and no INAD or NADA has been created from it Transfer paper record copies to FRC upon cutoff Delete/destroy 20 years after cutoff

1.3.2.2 **Review Copies.**
Includes duplicate, triplicate and other copies used for review

Disposition: TEMPORARY.
Cutoff immediately after completion of final action and file reconciliation Delete/destroy after cutoff

1.3.2.3 **Disaster Recovery or Reference Copies Created Before 2007**
Includes master records copied from original record copies onto microfiche or other media used for disaster recovery or reference

Disposition: TEMPORARY.
Delete/destroy when the related original record copy has been destroyed

according to other CVM retention schedules due to termination or withdrawal

1.4 **CVM Work Group Documentation.** — **New**

Includes meeting agendas, recommendations and work product created by CVM Work Groups Representative Work Groups include the Document Control Unit Facilities Work Group and the Corporate Database Portal (CDP) Configuration Control Board Work Groups Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after project is complete and no longer active Transfer paper records to FRC after cutoff
Delete/destroy 20 years after cutoff

2 **Premarketing and Marketing Applications: New Animal Drugs**

2.1 **Investigational New Animal Drugs (INAD).**

Submissions from a sponsor of safety and efficacy data supporting indications for a new animal drug on a proposed label prior to the submission of a New Animal Drug Application (NADA) Review status is tracked in the Submission Tracking and Reporting System (STARS) or its successor system INAD files are vital records Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

2.1.1 **INAD Submissions (Record Copies).** — **Supersedes NC1-88-78-1, item V-1 (in part)**

Includes Notices of Claimed Investigational Exemption (NCIE), Slaughter Authorization Requests, Protocol Review Requests, Meeting Requests, major and minor technical section data, and CVM reviews and responses, as well as other related materials

Disposition: TEMPORARY.
Review records at the end of the calendar year to determine those eligible for transfer to the FRC Retire paper records to the FRC after a 5 year period of no substantial file activity

Cut off at the end of the calendar year after all NADAs referring to the file have been withdrawn Delete/destroy 2 years after cutoff

2.1.2 **INAD Disaster Recovery and Reference Copies Created Before 2007.**

Includes master records copied from original record copies of INADs with regulatory or other interests onto microfiche or other media for disaster recovery or reference

Disposition: **TEMPORARY.**
Delete/destroy when record copy has been terminated

2.1.3 **Terminated INADs (Record Copies).** **Supersedes NC1-88-78-1, item V-1 (in part)**
Includes INADs for which the investigational exemption has been terminated by CVM or because the sponsor will no longer pursue the investigation of the drug

Disposition: **TEMPORARY.**
Cutoff at the end of the calendar year after completion of termination process. Delete/destroy 2 years after cutoff

2.1.4 **INAD Review Copies.** **Supersedes NC1-88-78-1, item V-1 (in part)**
Includes duplicate, triplicate and other copies used for review and not forwarded to the District Offices

Disposition: **TEMPORARY.**
Cutoff immediately after completion of final action and file reconciliation Delete/Destroy after cutoff

2.1.5 **INAD Copies maintained in the District Offices.** **Supersedes NC1-88-78-1, item V-1 (in part)**
Includes copies forwarded from CVM to the District Offices

Disposition: **TEMPORARY.**
Delete/destroy when no longer needed for review or operational purposes, whichever is later

2.2 **Generic Investigational New Animal Drugs (JINAD).**
Submissions from a sponsor of safety and efficacy data supporting indications for a generic new animal drug on a proposed label prior to the submission of an Abbreviated New Animal Drug Application (ANADA) Review status is tracked in the Submission Tracking and Reporting System (STARS) or its successor system JINAD files are vital records Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

2.2.1 **JINADs with Regulatory or Other Interests (Record Copies).** **Supersedes NC1-88-78-1, item V-1 (in part)**
Includes Notices of Claimed Investigational Exemption (NCIE), Slaughter Authorization Requests, Protocol Review Requests, Meeting Requests, major and minor technical section data, and CVM reviews and responses, as well as other related materials

Disposition: **TEMPORARY.**
Review records at the end of the calendar year to determine those eligible for transfer to the FRC Retire paper records to the FRC after a 5 year period of no substantial file activity

Cut off at the end of the calendar year after all ANADAs referring to the file have been withdrawn Delete/destroy 2 years after cutoff

2.2.2 **JINAD Disaster Recovery and Reference Copies Created Before 2007.**
Includes master records copied from original record copies of JINADs with regulatory or other interests onto microfiche or other media for disaster recovery or reference

Disposition: TEMPORARY.
Delete/destroy when record copy has been terminated

2.2.3 **Terminated JINADs (Record Copies).** **Supersedes NC1-88-78-1, item V-1 (in part)**
Includes JINADs for which the investigational exemption has been terminated by CVM or because the sponsor will no longer pursue the investigation of the drug

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after completion of termination process. Delete/destroy 2 years after cutoff

2.2.4 **JINAD Review copies.** **Supersedes NC1-88-78-1, item V-1 (in part)**
Includes duplicate, triplicate and other copies used for review and not forwarded to the District Offices

Disposition: TEMPORARY.
Cutoff immediately after completion of final action and file reconciliation Delete/Destroy after cutoff

2.2.5 **JINAD Copies maintained in the District Offices.** **Supersedes NC1-88-78-1, item V-1 (in part)**
Includes copies forwarded from CVM to the District Offices

Disposition: TEMPORARY.
Delete/destroy when no longer needed for review or operational purposes, whichever is later

2.3 **New Animal Drug Applications (NADA).**
Applications submitted under section 512(b)(1) of the Federal Food, Drug and Cosmetic Act to request approval to market new animal drugs

Review status is tracked in the Submission Tracking and Reporting System (STARS) or its successor system NADA files are vital records Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

2.3.1 **Approved NADAs (Record Copies).** **Supersedes NC1-88-78-1 V-1 (in part), V-4**
Includes sponsor's application (Form 356V), Technical Section Complete Letters, Environmental Assessment, Freedom of Information

(FOI) Summary, labeling material, premarket related inspection and compliance files, and FDA reviews, as well as other supporting materials NADA jackets and associated Drug Experience Reports (DERs) are copied onto microfiche or other media to be used for disaster recovery or reference purposes

Disposition: TEMPORARY.
Review records at the end of the calendar year to determine those eligible for transfer to the FRC Retire paper records to the FRC after a 5 year period of no substantial file activity

Cut off at the end of the calendar year when notice of withdrawal has been published in the Federal Register Delete/destroy 2 years after cutoff

2.3.2 **Unapproved NADAs (Record Copies).** **Supersedes NC1-88-78-1 V-1 (in part), V-4**
Includes applications and supporting materials for new animal drugs which are pending review or have been issued an "incomplete" letter by FDA Records are copied onto microfiche or other media to be used for disaster recovery, reference, or research purposes

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after withdrawal of a pending application by a sponsor or upon completion of the CVM closure process Delete/destroy 2 years after cutoff

2.3.3 **NADA Disaster Recovery and Reference Copies Created Before 2007.**
Includes master records copied from original record copies of all NADAs onto microfiche or other media to be used for disaster recovery, reference, or research purposes

Disposition: TEMPORARY.
Delete/destroy when record copy has been withdrawn

2.3.4 **NADA Review Copies.** **Supersedes NC1-88-78-1 V-1 (in part), V-4**
Includes duplicate, triplicate and other copies used for review and not forwarded to the District Offices

Disposition: TEMPORARY.
Cutoff immediately after completion of final action and file reconciliation Delete/destroy after cutoff

2.3.5 **NADA Copies maintained in the District Offices.** **Supersedes NC1-88-78-1 V-1 (in part), V-4**
Includes copies forwarded from CVM to the District Offices

Disposition: TEMPORARY
Delete/destroy when no longer needed for review or operational purposes, whichever is later

2.4 **Abbreviated New Animal Drug Applications (ANADA).**
Applications submitted under section 512 (b)(2) of the Federal Food, Drug and Cosmetic Act to request approval to market generic new animal drugs Review status is tracked in the Submission Tracking and Reporting System (STARS) or its successor system ANADAs are vital records Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

2.4.1 **Approved ANADAs (Record Copies).** **Supersedes NC1-88-78-1 V-1 (in part)**
Includes sponsor's application, supporting data, and FDA reviews, as well as other related materials ANADA jackets and associated Drug Experience Reports (DERs) are copied onto microfiche or other media to be used for disaster recovery, reference, or research purposes

Disposition: TEMPORARY.
Review records at the end of the calendar year to determine those eligible for transfer to the FRC or eligible for destruction Retire paper records to the FRC after a 5 year period of no substantial file activity

Cut off at the end of the calendar year when notice of withdrawal has been published in the Federal Register Delete/destroy 2 years after cutoff

2.4.2 **Unapproved ANADAs (Record Copies).** **Supersedes NC1-88-78-1 V-1 (in part)**
Includes applications and supporting materials for generic new animal drugs which are pending review or have been issued an incomplete letter by FDA Records are copied onto microfiche or other media to be used for disaster recovery, reference, or research purposes

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after withdrawal of a pending application by a sponsor or upon completion of the CVM closure process Delete/destroy 2 years after cutoff

2.4.3 **ANADA Disaster Recovery and Reference Copies Created Before 2007.**
Includes master records copied from original record copies of all ANADAs onto microfiche or other media to be used for disaster recovery, reference, or research purposes

Disposition: TEMPORARY.
Delete/destroy when record copy has been withdrawn

2.4.4 **ANADA Review Copies.** **Supersedes NC1-88-78-1 V-1 (in part)**
Includes duplicate, triplicate and other copies used for review and not forwarded to the District Offices

Disposition: **TEMPORARY.**
Cutoff immediately after completion of final action and file reconciliation Delete/destroy after cutoff

2.4.5 **ANADA Copies maintained in the District Offices.** **Supersedes NC1-88-78-1 V-1 (in part)**
Includes copies forwarded from CVM to the District Offices

Disposition: **TEMPORARY.**
Delete/destroy when no longer needed for review or operational purposes, whichever is later

2.5 **Approved New Animal Drug Product Lists (Green Book).** **New**
Provides information submitted by sponsors regarding patents held for approved new animal drugs and/or their methods of use Includes a list and monthly updates of all new animal drug products approved by FDA for safety and effectiveness

Date span 1989-

Disposition: **PERMANENT.**
Cut off at the end of the calendar year in which published Transfer to NARA immediately after cutoff

Estimated date of first transfer January 2011

2.6 **Veterinary Master Files (VMF).**
Company proprietary manufacturing or process information, submitted by new animal drug producers and manufacturers

Includes information such as personnel involved, facilities, production methods and product formulations VMFs are vital records Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

2.6.1 **Type I VMFs.** **Supersedes NC1-88-78-1 V-1 (in part)**
Includes information regarding manufacturing sites, facilities, operating procedures and personnel

Disposition: **TEMPORARY.**
Cutoff when there has been no substantive activity in the VMF for 3 years and VMF is no longer needed for CVM business purposes Delete/destroy 1 year after cutoff

2.6.2 **Type II - V VMFs.**
Type II VMFs include information regarding manufacturing of finished dosage forms, medicated articles, and medicated feeds, as well as manufacturing information regarding bulk drug substances and substance intermediates used in the further manufacture of bulk drug substances

Type III VMFs include information regarding packaging materials.

Type IV VMFs include information regarding excipients, colorants, flavors, and essences, as well as materials used in the preparation of these.

Type V VMFs include FDA accepted reference information.

2.6.2.1 **VMFs referenced in New Animal Drug Applications (NADA).**
Includes records submitted by firms and used for review by CVM

2.6.2.1.1 **VMFs referencing NADAs that have not been withdrawn** — **Supersedes NC1-88-78-1 V-1 (in part)**

Disposition: TEMPORARY.
Cut off at the end of the calendar year after which the VMF has completed the CVM closure process. Transfer paper records to FRC 5 years after cutoff. Delete/destroy 25 years after cutoff.

2.6.2.1.2 **VMFs referencing NADAs that have been withdrawn** — **Supersedes NC1-88-78-1 V-1 (in part)**

Disposition: TEMPORARY.
Cut off at the end of the calendar year in which all NADAs referencing the VMF have been withdrawn Delete/destroy immediately after cutoff.

2.6.2.2 **VMFs Not Referenced in NADAs.** — **Supersedes NC1-88-78-1 V-1 (in part)**
Includes records submitted by firms but not used for review by CVM.

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after which the VMF has completed the CVM closure process Transfer paper records to FRC 5 years after cutoff. Delete/destroy 25 years after cutoff.

2.6.3 **VMF Disaster Recovery and Reference Copies Created Before 2007.**
Master records copied from original record copies onto microfiche or other media to be used for disaster recovery, reference, or research purposes.

Disposition: TEMPORARY.
Delete/destroy when record copy has been closed.

2.6.4 **VMF Review Copies.** — **Supersedes NC1-88-78-1 V-1 (in part)**
Includes duplicate, triplicate and other copies used for review.

Disposition: TEMPORARY.
Cutoff immediately after completion of final action and file reconciliation. Delete/destroy after cutoff.

2.7 **Public Master Files (PMFs).**
Information containing safety and efficacy data which has been

generated with public funds Included information can be disclosed to the public without violating trade secret/confidentiality requirements. Manufacturing information is typically not included. Notice of availability is announced in the Federal Register. PMFs are vital records. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

2.7.1 **PMFs Referenced in New Animal Drug Applications (NADA).** **Supersedes NC1-88-78-1 V-1 (in part)**
Includes records submitted by firms and used for review by CVM

Disposition: TEMPORARY.
If a NADA referencing the PMF has been withdrawn and the PMF has had no references from other NADAs, cutoff at the end of the calendar year after withdrawal of the NADA. Delete/destroy after cutoff.

2.7.2 **PMFs Not Referenced in NADAs.** **Supersedes NC1-88-78-1 V-1 (in part)**
Includes records submitted by firms but not used for review by CVM.

Disposition: TEMPORARY.
Cutoff at the end of the calendar year when there has been no substantive activity in the PMF for 10 years. Transfer paper records to FRC 5 years after cutoff Delete/destroy 50 years after cutoff.

2.7.3 **PMF Disaster Recovery and Reference Copies Created Before 2007.**
Includes master records copied from original record copies onto microfiche or other media to be used for disaster recovery, reference, or research purposes.

Disposition: TEMPORARY.
Delete/destroy when parent record has been deleted/destroyed.

2.7.4 **PMF Review Copies.** **Supersedes NC1-88-78-1 V-1 (in part)**
Includes duplicate, triplicate and other copies used for review.

Disposition: TEMPORARY.
Cutoff immediately after upon completion of final action and file reconciliation Delete/destroy after cutoff.

2.8 **Drug Master File (DMF) Tracking Records.** **New**
Tracks FDA's Center for Drug Evaluation and Research's (CDER) Drug Master Files that have been either requested by CVM reviewers or assigned to CVM reviewers by CDER. The DMF files routed to CVM from CDER are recorded into a Document Receipt Log maintained by the CVM Document Control Unit and then forwarded to CVM reviewers. DMF files loaned to CVM are used for reference with read-only access. Includes file number, volume number, CVM reviewer, dates of dispatch and return, issue date for CVM-generated letters (if applicable), and package description Certain records contain trade

secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

Disposition: TEMPORARY.
Cutoff tracking records at the end of the calendar year in which DMF was requested Delete/destroy 5 years after cutoff.

3 Premarketing and Marketing Applications: Animal Feeds

3.1 Investigational Food Additive (IFA) Files. **New**
Submissions from a sponsor to CVM in order to facilitate the animal Food Additive Petition (FAP) process. IFA files ensure confidential exchanges between CVM and a sponsor while the sponsor investigates the safety and utility of a food additive for its intended use. Review status is tracked in the Submission Tracking and Reporting System (STARS) or its successor system. IFA files are vital records. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

3.1.1 IFA Record Copies.
Includes Notices of Claimed Investigational Exemption (NCIE), Slaughter or Marketing Authorization Requests, Protocol Review Requests, Meeting Requests, and major and minor technical section data, CVM reviews and responses, as well as other related materials.

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after completion of final action. Delete/destroy when no longer needed for business and regulatory purposes, or 20 years after cutoff, whichever is later.

3.1.2 IFA Review Copies.
Includes duplicate, triplicate and other copies used for review.

Disposition: TEMPORARY.
Cutoff immediately after completion of final action and file reconciliation. Delete/destroy after cutoff.

3.2 Food Additive Petitions (FAP). **New**
Petitions received from producers under section 409(b) of the Federal Food, Drug and Cosmetic Act and 21 CFR 571 proposing the issuance of regulations prescribing the conditions under which a food additive may safely be included in food products intended for use in animals. Petition includes name, chemical identity and composition of additive, statement of proposed use, labeling, data on additive's effects, additive detection analytical methodology, and additive safety investigation reports Review status is tracked in the Submission Tracking and Reporting System (STARS) or its successor system. FAPs are vital

records

Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

3.2.1 **FAP Record Copies.**
Includes Protocol Review Requests, Meeting Requests, and major and minor technical section data. May also include internal documentation supporting the issuance of a regulation, rejection or denial of petition, and correspondence, as well as other related materials.

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after completion of final action. Delete/destroy when no longer needed for business and regulatory purposes, or 30 years after cutoff, whichever is later.

3.2.2 **FAP Review Copies.**
Includes duplicate, triplicate and other copies used for review

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after completion of final action and file reconciliation Delete/destroy after cutoff.

3.3 **GRAS Notifications/Petitions (GRN).**
A GRAS Notification informs FDA that a firm has made a determination that a particular use of a substance in animal food is eligible for classification as generally recognized as safe (GRAS) as described in 21 CFR 570.30. Formal requests for FDA affirmation that a use is GRAS may be made under 21 CFR 570.35. Submissions may include Meeting Requests, Notifications, and documentation in support of the action taken. Review status is tracked in the Submission Tracking and Reporting System (STARS) or its successor system. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after regulatory decision has been made Delete/destroy when no longer needed for business and regulatory purposes, or 30 years after cutoff, whichever is later

4 **Postmarket Records: New Animal Drugs**

4.1 **Drug Experience Reports (DER).** **Supersedes NC1-88-78-1 V-4, V-14, V-16**
Reports submitted by sponsors of approved New Animal Drug Applications (NADAs) and Abbreviated New Animal Drug Applications (ANADAs). Annual and Semi-Annual DERs include

clinical data, promotional material, current labeling, Adverse Drug Experiences (ADE), ADE follow-ups, ADE summary reporting, product defects, and distribution data for the reporting period. Related data are maintained in the DER System, one of the modules supported by the Corporate Database Portal. DERs are vital records. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

Disposition: TEMPORARY.
For approvals older than 5 years, maintain paper volumes with the 5 most recent annual reports in the Document Control Unit Transfer volumes with other annual reports to FRC.

Cut off at the end of the calendar year when related NADA is withdrawn because of profitability/marketing purposes and published in the Federal Register. Delete/destroy immediately after cutoff, or when no longer needed for research or legal purposes.

Note: Maintain DERS in FRC for NADAs withdrawn because of safety concerns until no longer needed for research or legal purposes

5 Compliance Records: Animal Feeds

5.1 Medicated Feed Mill Licensing Files.
Concerns licensing of feed mills to manufacture animal feeds containing Category II, Type A medicated articles (21 CFR 515) Files may include record (original) copies of Form FDA 3448 (Medicated Feed Mill License Application).

Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

May also include copies of applicable Establishment Inspection Reports (EIR), as well as other supplementary material including copies of Form FDA 483 (Inspectional Observations) and correspondence generated from, or addressed to, feed mills, FDA District Offices, and State Feed Control Officials.

5.1.1 Approved Licenses. **Supersedes NC1-88-82-5, item V-23a**
Files are organized by license number and maintained by CVM's Division of Animal Feeds.

Disposition: TEMPORARY.
Cutoff at the end of the calendar year in which the feed mill license has been voluntarily revoked. Delete/destroy 10 years after cutoff or when no longer needed for business or regulatory purposes, whichever is later

5.1.2 **Revoked Applications.**
Files are maintained by CVM's Division of Animal Feeds.

Supersedes NC1-88-82-5, item V-23a

Disposition: TEMPORARY.
Cutoff at the end of the calendar year in which the feed mill license decision has been revoked. Delete/destroy when no longer needed for business or regulatory purposes, or 50 years, whichever is later.

5.1.3 **Medicated Feed Mill License Status Tracking System.**
Tracks the status of medicated feed mill license applicants and licensees. Includes information on manufacturing site, such as name, address, and responsible party, as well as other related data. Records are tracked by reference number before approval, and by license number after approval.

Disposition: TEMPORARY.
Cut off at the end of the calendar year in which the feed mill license decision has been rejected/withdrawn. Delete/destroy 50 years after cutoff, or when no longer needed for administrative and reference purposes, whichever is later.

~~6~~ ~~**CVM Data Systems**~~

~~6.1~~ ~~**Corporate Database Portal (CDP).**~~

WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.

~~CDP is a CVM-wide Oracle-based relational database system consisting of several subsystems. CDP supports common data tables and provides a link to CVM's Corporate Document Management System (CDMS).~~

~~CDP is a vital system. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.~~

~~Representative CDP systems include, but are not limited to.~~

~~Submission Tracking and Reporting System (STARS). Monitors the review status of new animal drug applications during the development and investigational phases, as well as during any resulting application for marketing of the product. Also tracks review status of Animal Food Additive Petitions (FAP), Generally Recognized as Safe Petitions (GRP) and other CVM premarket related activities.~~

~~Drug Experience Reports System (DER). Tracks and monitors postmarket submissions including both original and follow-up new animal drug Adverse Drug Experience (ADE) reports.~~

~~Drug Product Listing (DPL). Monitors marketed new animal drugs, food~~

additives and veterinary devices to assure their safety and effectiveness and to enforce compliance with the new animal drug regulations.

Bio-research Monitoring System (BIMO) Tracks and reports on key BIMO related activities in the following three compliance programs: Good Laboratory Practices (GLP); Sponsors, Contract Research Organizations, and Monitors (Sponsor/Monitor); and Clinical Investigators (CI).

Activity Time Reporting (ATR) Provides information on hours spent on
activities and tracks assigned workloads under the Animal Drug User Fee Act (ADUFA).

6.1.1	**CDP Inputs:** — Includes data manually and/or electronically input at each application level by authorized users. ADUFA-related billing information is electronically updated via a link to the Office of Financial Management's financial management database. Employee timekeeping, salary and location information is electronically downloaded via a link from the Office of the Commissioner's (OC) production timekeeping database.	**WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**
	Disposition: TEMPORARY. If records are used for input only, delete/destroy after the verification of successful data entry. If records are input as part of another record series, apply authorized disposition for that series.	
6.1.2	**CDP Data Files:** STARS Includes status information on pending, approved and withdrawn or terminated new animal drug applications. Includes data on active ingredient, applicant name and address, species, indication, label, feed withdrawal periods, manufacturing information, postmarketing annual/semi-annual reports, premarket related adverse event reports, and supplemental changes. Also includes tracking data on ADUFA information DERS Includes data on original and follow-up ADE reports on Form FDA 1932, as well as other reports, including quantity marketed reports. Data may include animal drug product labels, bibliographies and promotional/advertisement pieces. DPL Includes data on marketed new animal drugs, food additives and veterinary devices. Also includes data on the tracking and reporting of Drug Listing Information, including new animal drug manufacturer's establishments, distributors, labeling data, ingredients and trade names. Information is compiled for all approved and unapproved new animal drugs that are in commercial distribution or have been discontinued. ATR Includes real-time data for use in strategic and operational	**WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**

	planning; management information reports, budget requests, justifications, and evaluation; cost and trend analyses; user fee negotiations, and management activities. Data is used to determine the ADUFA percentages for process and non-process activities and to calculate the cost of the review process of new animal drug applications as identified in ADUFA. **Disposition: TEMPORARY.** Delete when no longer needed for operational, trend analysis, research or reference purposes, whichever is the latest. If data is migrated into a new system, delete after the verification of successful migration. For monitoring and tracking data from requesting the inspection assignments to final Establishment Inspection Reports (EIR) classifications and close outs under the BIMO Program, apply authorized disposition for BIMO Program records.	
6.1.3	**CDP Outputs: Routine Reports.** Includes pre-programmed and ad hoc reports generated by end users. **Disposition: TEMPORARY.** Delete/destroy when superseded, obsolete, or when no longer needed for administrative and reference purposes, whichever is latest.	**WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**
6.1.4	**CDP Outputs: STARS Routing Forms.** Includes routing slips generated when a new submission is entered into STARS. Used to track applications both physically and electronically in STARS. **Disposition: TEMPORARY.** Cutoff after final action. Destroy 1 year after cutoff.	**WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**
6.1.5	**CDP Outputs: Final Action Form.** Includes cover sheets indicating final action code and routing of final action packages through the signatory process. **Disposition: TEMPORARY.** Cutoff after final action. Destroy 1 year after cutoff.	**WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**
6.1.6	**CDP System Documentation.** Includes systems operations manuals, user manuals, data dictionaries, and requirements documents, as well as other systems related materials. **Disposition: TEMPORARY.** Delete/destroy when superseded or obsolete, upon authorized deletion of the related master file or database, or upon the destruction of the output if the output is needed to protect legal rights, whichever is latest.	**WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**

7	**Special Subjects**	
~~7.1~~	~~**National Antimicrobial Resistance Monitoring System (NARMS) Retail Meat Database.**~~ ~~NARMS is a collaborative effort between FDA/CVM, the United States Department of Agriculture (USDA) and the Centers for Disease Control and Prevention (CDC). CVM operates the retail meat component of NARMS in collaboration with states participating in the FoodNet program. Retail meat testing began in 2002. CVM's Office of Research tests for *Salmonella, Campylobacter, E. coli,* and *Enterococcus* isolates in retail meats.~~ ~~NARMS provides descriptive data on the temporal trends and extent of antimicrobial drug susceptibilities of selected enteric bacterial organisms in humans, animals, and retail meats to a panel of antimicrobial drugs important in human and animal medicine. It provides timely information to veterinarians and physicians on antimicrobial drug resistance patterns. Data produced by NARMS is a vital resource for CVM's drug approval process. Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.~~	**WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**
~~7.1.1~~	~~**NARMS Input Records.**~~ ~~Includes retail meat data on log sheets that are filled out by FoodNet sites and electronically submitted to CVM, electronically entered data on biological isolates, and research data that is manually input into the database.~~ ~~**Disposition: TEMPORARY.**~~ ~~Delete/destroy when no longer needed for research or reference purposes, whichever is later.~~	**WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**
~~7.1.2~~	~~**NARMS Database Records.**~~ ~~Includes data from results of retail meat sampling and analysis of fresh meat for *Salmonella, Campylobacter, E. coli,* and *Enterococcus*. Includes data fields such as bacterial genus and species, as well as antibiotic resistance.~~ ~~**Disposition: TEMPORARY.**~~ ~~Delete/destroy when no longer needed for research or reference purposes, whichever is later.~~	**WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**
~~7.1.3~~	~~**NARMS Annual Reports: Outputs.**~~ ~~Includes results generated to establish a reference point for analyzing trends of antimicrobial resistance among the foodborne bacteria in retail meats. Annual reports summarizing data starting in 2002 are located on the CVM Internet home page.~~	**WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**

	Disposition: PERMANENT. Cutoff in 5-year blocks at the end of the calendar year. Transfer to NARA in NARA approved format 20 years after cutoff. At the time of transfer, NARA and FDA will determine the media and format in which the records will be transferred. FDA will ensure record format integrity during the retention period according to NARA regulations. For extracted data which is input into another database, apply the disposition authorized for that database.	
7.1.4	**NARMS System Documentation.** Includes systems operations manuals, data dictionaries, and user manuals. **Disposition: TEMPORARY.** Delete/destroy when superseded or obsolete, upon authorized deletion of the related master file or database, or upon the destruction of the output if the output is needed to protect legal rights, whichever is latest.	**WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**
7.2	**Pulsenet (CVM).** Provides information on DNA fingerprints of food-borne disease-causing bacteria. Developed by standardized DNA fingerprinting, pulsed-field gel electrophoresis (PFGE). DNA fingerprints and isolate data are entered into the Bionumerics databases maintained by CVM's Office of Research. Fingerprints are exported to PulseNet, established in 1996, which is a collaborative effort of the Centers for Disease Control and Prevention (CDC), FDA, the United States Department of Agriculture (USDA), and state/local health departments. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.	**WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**
7.2.1	**Pulsenet (CVM) Input Records.** Includes DNA fingerprints and isolate data collected and entered manually or automatically loaded from Microsoft Excel. **Disposition: TEMPORARY.** Delete/destroy after data is entered into the database and verification of successful data entry.	**WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**
7.2.2	**Pulsenet (CVM) Database Records.** Includes data on DNA fingerprints and isolate data, dates when isolates are added and removed, and dates when changes are made to the analysis of the fingerprints. Databases include, but are not limited to, databases on the following organisms: *Salmonella*, *E. coli* and *Campylobacter*.	**WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**

~~**Disposition:** TEMPORARY.~~
~~Delete/destroy when no longer needed for business, research or reference purposes, whichever is the latest.~~

~~7.2.3~~ ~~**Pulsenet (CVM) Output Records.**~~ **WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**
~~Includes data exported to PulseNet, built in log files for tracking purposes, and routine reports produced as needed.~~

~~**Disposition:** TEMPORARY.~~
~~Delete/destroy when no longer needed for administrative or operational purposes, whichever is later.~~

~~7.2.4~~ ~~**Pulsenet (CVM) System Documentation.**~~ **WITHDRAWN 12/4/09 Items resubmitted under N1-088-09-12.**
~~Includes systems operations manuals, user manuals, data dictionaries, requirements documents, and other systems related materials.~~

~~**Disposition:** TEMPORARY.~~
~~Delete/destroy when superseded or obsolete, upon authorized deletion of the related master file, or upon the destruction of the output if the output is needed to protect legal rights, whichever is latest.~~

7.3 **Aquaculture Information Tracking Records.** **New**
Serves as an internal repository of aquaculture information extracted from Investigational New Animal Drugs (INAD), as well as from related aquaculture Public Master Files (PMF), about specific drugs under review by FDA on fish. Information collected includes INAD/PMF number, drug, sponsor, authorization status and number, number of animals used, species authorized, withdrawal period, comments, other related information and reports. Records are updated daily. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

Disposition: TEMPORARY.
Cutoff at the end of the calendar year when related INADs are terminated or when related PMFs are not referenced or become inactive. Delete/destroy 30 years after cutoff or when data is migrated to a new system, whichever is sooner