REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

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

LEAVE BLANK (NARA use only)	
JOB NUMBER	N1-88-92-1
DATE RECEIVED	2-3-92

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

2. MAJOR SUBDIVISION
Public Health Service

3. MINOR SUBDIVISION
Food and Drug Administration

4. NAME OF PERSON WITH WHOM TO CONFER	5. TELEPHONE
Johanna Bonnelycke 1/17/92	(301) 443-2055

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.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
3-12-96	WITHDRAWN

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 8 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,

[X] is not required; [ ] is attached; or [ ] has been requested.

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
1/23/92	Thomas Lamm, Jr.	DHHS Records Management Officer

7. ITEM NO.	8. DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARA USE ONLY)
	This request is for a revision to the Center for Veterinary Medicine's records disposal instructions approved by the Archivist on 2/23/78 and 4/30/82. This revision establishes more definite and/or shorter retention periods for certain files, deletes those files no longer needed, and combines others. Some item numbers have been changed. A list comparing the present and the proposed numbers is attached. No new file series have been added. Mark L. Pincus FDA Records Officer 1/6/92 (Date) (301)443-4055 (Extension)	NC1-88-78-1 and NC1-88-82-5	WITHDRAWN

7. ITEM NO.	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARS USE ONLY)
V-1	New Animal Drug Applications (NADAs) (Includes Antibiotics, Dosage Forms, and Type A Medicated Articles.) Applications, in triplicate, to market new animal drugs, including antibiotics, in dosage form or in medicated feeds, filed under 21 CFR 514. File includes application (form FDA 356V), clinical and other data/information, labeling and promotional material, reports, adverse reactions, amendments and supplements, evaluations and recommendations, notices of approval or withdrawal, with related correspondence and material. a. Approved NADAs. (1). Original Transfer to Washington National Records Center (WNRC) when inactive for 3 years (if no supplements or reports are received)*. The Center for Veterinary Medicine (CVM) will re-evaluate the need to retain the NADA every 5 years. Destroy when CVM determines the NADA is no longer needed. Exception: If the NADA is inactive due to safety concerns, contains a new chemical entity, is the basis for a related application, or is of historical/scientific interest, CVM will determine which parts are essential and retain those parts. Transfer these retained parts to WNRC when no longer needed. Transfer unessential parts to WNRC when the NADA becomes inactive. CVM will reevaluate need to retain every 5 years. Destroy when CVM determines the NADA is no longer needed. *Note: An NADA is considered active if an associated Drug Experience Report (see item V-16) is active and these reports are submitted for more than three consecutive years.		

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	(2). Duplicate. Forward essential manufacturing material to the appropriate FDA field unit at time of approval (see item R-24, NC1-88-78-1) to aid in plant inspections. Destroy unessential parts at time of approval. (3). Triplicate. If requested, forward essential parts (for example bio-research, environmental, and manufacturing material) to requesting unit. Destroy requested parts when no longer needed. Destroy unessential parts or, if not requested, all parts at time of approval. b. NADAs withdrawn or otherwise not approved. If inactive for 1 year, transfer original to WNRC and destroy duplicate and triplicate copies. CVM will reevaluate need to retain original every 5 years. Exception: If the NADA is inactive due to safety concerns, contains a new chemical entity, is the basis for a related application, or is of historical/scientific interest, CVM will determine which parts are essential and retain only these original parts. Transfer unessential parts to WNRC when NADA becomes inactive. Transfer retained parts to WNRC when no longer needed. CVM will re-evaluate need to retain every 5 years. Destroy when no longer needed.		
V-2	(Veterinary) Drug Master Files. Privileged information, in triplicate, provided by drug producers concerning animal drugs. Contains production procedures, methods, site information (personnel and facilities), formulations, evaluations, and recommendations, clinical data, correspondence, etc. Files used as a reference for review of INADS, NADAs, etc.		

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a. Original.
Transfer to WNRC when inactive for 3 years (no information has been received or use made of the file during that time).
Destroy 8 years after file becomes inactive.
Also, destroy the older version upon receipt of a new Drug Master File that is specifically stated to be a complete replacement of the existing file.

b. Duplicate.
(1). Domestic site operations.
Forward duplicate copy to appropriate FDA field unit (see item R-24, NC1-88-79-1) when CVM review is completed.

(2). Foreign site operations.
Destroy when CVM review is completed.

c. Triplicate.
Destroy when review is completed.

V-3 INVESTIGATIONAL NEW ANIMAL DRUG APPLICATIONS (INADs)

Applications, in triplicate, to ship and test unapproved new animal drug products (both dosage forms and medicated feeds) prior to submission of an NADA. INAD files include evaluations, related correspondence, recommendations, and materials.

a. Original.
Transfer to WNRC 3 years after investigation is discontinued, terminated, or after no communication has been received. CVM will reevaluate need to retain every 5 years.
Destroy when no longer needed.
Exception: If INAD is discontinued, terminated, or otherwise inactive due to safety concerns, contains a new chemical entity, is the basis for a related application, or is of historical /scientific interest, CVM will determine which parts are essential and retain those parts.
Transfer these retained parts to WNRC when no longer needed.
Transfer unessential parts to WNRC when INAD becomes inactive. CVM will reevaluate need to retain every 5 years.
Destroy all parts of application when no longer needed.

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	b. Duplicate and triplicate. Destroy after original INAD review is completed unless needed for further reference.		
V-4	(This item has been combined with item V-1.)		
V-5	Recalls. Documents relating to a closed recall. Includes requests for recall action, extent of recall (wholesale or retail), recommendations to approve, approvals or denials, and effectiveness of the approved actions. Transfer to WNRC 3 years after action is completed. Destroy 6 years after recall action is completed.		
V-6	(This item has been deleted.)		
V-7	General Correspondence (Specific Drug & Industry File) Copies of correspondence replying to inquiries on drugs and feeds, regulations, studies, and other CVM areas of responsibility. CVM will review need to retain at 4 year intervals. Destroy when no longer needed.		
V-8	Guidelines. Procedures developed by CVM explaining and clarifying its regulations. Destroy when guideline is superseded or outdated and is no longer needed.		
V-9, V-10, and V-11	(These items have been deleted.)		
V-12	Special Projects. Correspondence, working papers, committee minutes, reports, and other data for each special project such as Salmonella food poisoning. a. Final reports. Permanent. Transfer to WNRC 2 years after completion of project. Offer to National Archives 5 years after completion.		

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	b. Other material. Destroy 1 year after completion of project.		
V-13	(Veterinary Medicine) Food Additive Petitions (FAPs) Petitions for specific food additives for use in feed and drinking water of animals filed under 21 CFR 571 for additive listings under 21 CFR 573. Dispose of as prescribed by Item V-1, New Animal Drug Applications.		
V-14	(Veterinary Medicine) Substances Generally Recognized as Safe (GRAS) Petitions for substances to be officially classified as GRAS or affirmed as GRAS substances. Dispose of as prescribed by Item V-1, New Animal Drug Applications.		
V-15	(This item has been deleted.)		
V-16	(Veterinary) Drug Experience Reports. (NADA/DER) Reports updating active NADAs regarding producers, current labeling, promotional material, production, manufacturing, distribution, adverse drug reactions (form FDA 1932), and clinical studies. Transfer DER material more than 5 years old to WNRC. CVM will reevaluate need to retain every 5 years. Destroy when associated NADA is destroyed or when no longer needed.		
V-17	Intramural Projects. Protocols, lab notebooks, raw data (including instrument readouts), quarterly and semi-annual reports, project correspondence, and final manuscripts on research and evaluations done by the Agency. a. All original material. Transfer to WNRC 1 year after completion of project. Destroy 5 years after completion.		

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	b. Copies. Destroy after completion of project unless needed for further reference.		
V-18	Contract (Extramural) Projects. Contract copies, invoices, reports, correspondence, research papers, and final manuscripts on research and evaluation done under contract. a. All original material. Transfer to WNRC 1 year after completion of project. Destroy 5 years after completion. b. Copies. Destroy after completion of project unless needed for further reference.		
V-19	Colony Files. Data on the effects of various substances on test animals. a. Data pertaining to a significant test or that is of historical/scientific interest. Transfer to WNRC 2 years after completion of test or when it is of no further interest. Destroy 10 years after completion of test unless needed for further reference. b. Data from all other tests. Transfer to WNRC 2 years after completion of test. Destroy 5 years after completion of test.		
V-20	Drug Experience Report. (ADP file) (NC 1-88-79-2) This system, which is the Drug Experience Report (DER), monitors approved new animal drug applications. This information is in regard to marketed quantities and adverse reactions encountered in the use of approved drugs. Destroy, by erasure, 2 years after data has been collected and analyzed.		

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V-21	New Animal Drug Applications Index. (ADP file) (NC 1-88-79-2) This system is the new animal drug applications index which provides data regarding applications for approval to market new animal drugs, which are distributed periodically throughout CVM. Destroy, by erasure, 2 years after data has been collected and analyzed.		
V-22	Investigational New Animal Drug Index. (ADP file) (NC 1-88-79-2) This system provides information related to activities associated with the investigation of new animal drugs. Quarterly distribution of index is forwarded to all divisions in CVM. Destroy, by erasure, 2 years after data has been collected and analyzed.		
V-23	Medicated Feed Applications. Applications from producers of medicated animal feeds to market their products. Applications include three copies of form FDA 1900, Medicated Feed Application; labels and promotional material; supplements; Agency evaluations with supporting material; notices of approval; correspondence; and other documentation. a. Original. Destroy when application is superseded or withdrawn. b. Duplicate. Return to applicant with notice of approval. c. Triplicate. Forward to appropriate FDA field unit (see item R-24, NC 1-88-78-1).		