

REQUEST FOR RECORDS DISPOSITION AUTHORITY
(See Instructions on reverse)

LEAVE BLANK

JOB NO.
N1-88-86-1

TO: **GENERAL SERVICES ADMINISTRATION
NATIONAL ARCHIVES AND RECORDS SERVICE, WASHINGTON, DC 20408**

DATE RECEIVED
6-2-86

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

NOTIFICATION TO AGENCY

2. MAJOR SUBDIVISION
Public Health Service

In accordance with the provisions of 44 U.S.C. 3303a the disposal request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10. If no records are proposed for disposal, the signature of the Archivist is not required.

3. MINOR SUBDIVISION
Food and Drug Administration

4. NAME OF PERSON WITH WHOM TO CONFER
Linda Querec

5. TELEPHONE EXT.
(301)443-2055

DATE
5-26-86

ARCHIVIST OF THE UNITED STATES
Frank A. Smith

6. CERTIFICATE OF AGENCY REPRESENTATIVE
Linda Querec

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposal of the agency's records; that the records proposed for disposal in this Request of 3 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, if required under the provisions of Title 8 of the GAO Manual for Guidance of Federal Agencies, is attached.

A. GAO concurrence: is attached; or is unnecessary.

B. DATE 5/23/86	C. SIGNATURE OF AGENCY REPRESENTATIVE <i>George Deal</i> Dr. George Deal	D. TITLE Department Records Management Officer
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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 GRS OR SUPERSEDED JOB CITATION	10.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)
	<p>This request is for a change to Item C-3 of the Food and Drug Administration Records Control Schedule approved by The Archivist on February 23, 1978 (NARS job No. NCI-88-78-1). This change is to categorize the several series of files presently lumped together and to assign a finite disposal time to each.</p> <p>(Note: The Hearing Clerk's Office has been renamed the Dockets Management Branch.)</p>	FDA Appendix B-331 Item C-3 (NARS Job No. NCI-88-78-1)	
	<p>Concur: <i>Linda K. Horton</i> 44-31345 4/25/86 Office of General Counsel (GCF-1) ext. Date</p> <p><i>Vicki J. Powers</i> 443-3290 4/29/86 FDA Assistant Records Liaison Officer (HFA-300) ext. Date</p> <p><i>Agnes L. Slawick</i> 443-4055 5/7/86 FDA Records Management Officer (HFA-250) ext. Date</p>		

MP 5/28/86
SVB 5/27/86
ASD 5/7/86

13 items

REQUEST FOR RECORDS DISPOSITION AUTHORITY – CONTINUATION

JOB NO.

N1-88-86-1

PAGE

2 OF 3

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	<p>C-3 <u>Dockets Management Branch (Formerly Hearing Clerk's Office) Records</u></p> <p>Records including <u>Federal Register</u> notices, comments, hearing materials concerning Agency policies, procedures, regulations, and decisions maintained by the Dockets Management Branch for review by participants in FDA proceedings, courts, and the general public as required by the Administrative Procedures Act, the Freedom of Information Act, the Federal Food, Drug and Cosmetic Act, and other laws. These files differ from those maintained by FDA program offices as they contain the documents making up the official administrative record required in the event of litigation. The material maintained may be purged or unpurged and contains documents received from persons inside and outside the FDA.</p> <p>1. <u>Electronic Product Variance and Exemption Requests</u> Cutoff after expiration date if approved or 1 year after final disapproval. Transfer to WNRC 1 year after expiration date or final disapproval. Destroy 6 years after expiration date or final disapproval.</p> <p>2. <u>Veterinary Medicine Guidelines for Submission of Applications</u> Cutoff after final action. Transfer to WNRC 3 years after final action. Destroy 6 years after final action.</p> <p>3. <u>Biologics Efficacy Reviews</u> Cutoff after completion of review including resolution of any litigation thereon. Transfer to WNRC 3 years after completion of review including resolution of any litigation thereon. Destroy 30 years after completion.</p> <p>4. <u>Drug Efficacy Study Implementation (DESI) Material</u> Cutoff after completion of review including resolution of any litigation thereon. Transfer to WNRC 3 years after completion of review including resolution of any litigation thereon. Destroy 30 years after completion.</p> <p>5. <u>Food Additive, Food Standard, Color Additive, and Generally Recognized as Safe (GRAS) Petitions</u> Cutoff after final action taken on petition including resolution of any objections and any litigation thereon. Transfer to WNRC 3 years after final action taken on petition including resolution of any objections and any litigations thereon. Destroy 30 years after final action.</p> <p>6. <u>Temporary Marketing and Temporary Test Permits</u> Destroy 1 year after expiration of permit.</p>	<p>FDA Appendix B-331 Item C-3 (NARA Job No. N1-88- 78-1)</p>	

REQUEST FOR RECORDS DISPOSITION AUTHORITY – CONTINUATION

JOB NO.
N1-88-86-1

PAGE
3 OF 3

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7.	<u>Generally Recognized as Safe (GRAS) Regulations (Scientific Literature)</u> Cutoff after completion of rulemaking including any litigation thereon. Transfer to WNRC 1 year after completion of rulemaking including any litigation thereon. Destroy 30 years after completion.	FDA Appendix B-331 (NARA Job No. NCl-88-78-1)	
8.	<u>Medical Device Classifications</u> Cutoff after final rule. Transfer to WNRC 3 years after final rule. Destroy 30 years after final rule.		
9.	<u>Medical Device Premarket Approval</u> Cutoff after approval and resolution of any requests for administrative or judicial review. Transfer to WNRC 3 years after approval and resolution of any requests for administrative or judicial review. Destroy 30 years after completion.		
10.	<u>Clinical Investigator Disqualification Records</u> Cutoff after final action. Destroy 3 years after final action. (Unlike other records listed in this request, these records do not constitute the official administrative records of clinical investigator disqualifications. The official administrative records of the proceedings are maintained by the initiating office.)		
11.	<u>Over-the Counter (OTC) and Related Dockets</u> Cutoff after completion of final monograph including litigation thereon and petitions to amend. Transfer to WNRC 3 years after completion of final monograph including litigation thereon and petitions to amend. Destroy 30 years after completion.		
12.	<u>Advisory Opinions, Petitions, and Proposed Rulemaking</u> Cutoff after final Action. Transfer to WNRC 3 years after final action. Destroy 30 years after final action.		
13.	<u>Hearing Materials for Parts 12-16 Hearings (Formal Evidentiary Hearings, Public Board of Inquiry Hearings, Advisory Committee Hearings, Public hearings before the Commissioner, Regulatory Hearings)</u> Cutoff on close of hearing. PERMANENT Transfer to WNRC when 3 years old. Offer to NARA when 25 years old in 5 year blocks.		

I concur with revisions made to this schedule.

Mark E. Pence
Agency Representative

3/6/87
Date

Ronald J. Hise
NARA Representative

9 Feb 87
Date

*Mark E. Pence
Ronald J. Hise*