

Rec'd NCO 11/24/80

REQUEST FOR RECORDS DISPOSITION AUTHORITY  
(See Instructions on reverse)

LEAVE BLANK	
JOB NO	
NCI-88-80-2	
DATE RECEIVED	
August 14, 1980	
NOTIFICATION TO AGENCY	
In accordance with the provisions of 44 U.S.C. 3303a the disposal request, including amendments, is approved except for items that may be stamped "disposal not approved" or "withdrawn" in column 10	
Date	Archivist of the United States
12-2-80	<i>[Signature]</i>

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

1 FROM (AGENCY OR ESTABLISHMENT)  
Department of Health and Human Services

2 MAJOR SUBDIVISION  
Public Health Service, Food and Drug Administration

3 MINOR SUBDIVISION  
Executive Director of Regional Operations

4 NAME OF PERSON WITH WHOM TO CONFER  
Joseph Reiff

5 TEL EXT  
443-4055

6 CERTIFICATE OF AGENCY REPRESENTATIVE

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 5 page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified.

A Request for immediate disposal.

B Request for disposal after a specified period of time or request for permanent retention.

C DATE <u>2/28/80</u>	D SIGNATURE OF AGENCY REPRESENTATIVE <i>Jacquelyn L. Tolson</i> <i>Norman E. Shepp</i>	E TITLE <u>PHS Records Officer</u> Chief, Management Methods Branch, DMS, OMO
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7 ITEM NO	8 DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9 SAMPLE OR JOB NO	10 ACTION TAKEN
	<p>This request is for an addition to the Food and Drug Administration Records Control Schedule approved on February 23, 1978, job No. 1-88-78-1. The following records pertain to the Government Wide Quality Assurance Program. This is a new program under which FDA certifies as to the safety and efficacy of drug products procured by all government agencies. This proposal covers 5 different files maintained by the Medical Products Quality Assurance Staff (MPQAS) Associate Director for Field Support, EDRO and the districts, namely:</p> <p>Contract Files Quality Assurance Profiles Product Specifications Preacceptance Sample Files Complaint Files</p> <p><i>Agnes Slavitch of FDA has concurred in all changes. (JA) 1/26/80</i></p>	<del>Previously Appendix B-600, now superseded by Appendix B-331</del>	

Closed Out: 12-5-80: K.T.J.  
Copy sent to AA FRCS, Agency & NNF

13 items

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8 DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
0-23	<p><u>CONTRACT FILE</u></p> <p>Each file bears an identification number, e.g. D9001.            A file may include:</p> <p>contract            solicitation            modifications; amendments; waivers            reports of post-award examinations (PAE)            Material Inspection and Receiving Reports (form DD-250)            Certificates of Conformance (COC)            documentation concerning evaluations of the firms(s)              and/or products involved            correspondence with firm(s) involved            related material.</p> <p>Transfer to FRC 2 years after expiration of contract.            Destroy <del>7 years</del> <sup>6 yrs. 3 mos.</sup> after expiration of contract.</p>		
0-24	<p><u>QUALITY ASSURANCE PROFILE</u></p> <p>Each profile is identified with the name and address            of the firm involved. A file may include:</p> <p>Quality Assurance Profile (form FD 2860)            six hour update TWXs            "FAI" (future action indicated) status TWXs            related material.</p> <p>a. <u>Firms still requiring profiling:</u> <i>transmittals</i>            Destroy TWXs and profiles 2 years after date of            receipt. <del>Retain other material.</del> <i>Destroy profiles when            no longer needed for reference.</i></p> <p>b. <u>Firms no longer requiring profiling:</u> e.g. OOB (out            of business) or not in OEI (official establishment            inventory):</p> <p>Destroy 2 years after profiling is no longer required.</p>		

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8 DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
0-25	<p><u>PRODUCT SPECIFICATIONS</u></p> <p>Each specification is identified with product name and document number. The file includes:</p> <ul style="list-style-type: none"><li>military standards</li><li>military specifications</li><li>federal standards</li><li>federal specifications</li><li>Defense Medical Purchase Description</li><li>specification data sheets</li><li>procurement item descriptions</li></ul> <p>Destroy 5 years after specification is suspended or deleted.</p>		
0-26	<p><u>PREACCEPTANCE SAMPLES</u></p> <p>Each file bears an identification number e.g., V90001. A file may include:</p> <ul style="list-style-type: none"><li>contract/purchase order</li><li>documentation concerning the need for a sample</li><li>teletypes/memos concerning sample results and evaluation</li><li>related materials</li></ul> <p>Transfer to FRC 2 years after evaluation is completed. Destroy 7 years after completion.</p>		
0-27	<p><u>COMPLAINT FILES</u></p> <p>Each file bears an identification number such as: 80001 (Drug Complaint); TC9001 (Device Complaint); 9A001 (Depot Quality Audit Report-(DQAR); TA9001 (DQAR - Device). A file may include:</p> <ul style="list-style-type: none"><li>complaint/DQAR</li><li>teletypes/memos concerning samples and/or investigations</li><li>documents concerning the evaluation of the complaint</li><li>related material</li></ul> <p>Transfer to FRC 2 years after complaint is resolved. Destroy 5 years after complaint is resolved.</p>		

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8 DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
R-33	<p><u>CONTRACT FILE</u></p> <p>Each file bears an identification number, e.g. D9001.                      A file may include:</p> <p>contract  <del>solicitations</del> <i>solicitations</i>                      modifications; amendments; waivers                      reports of post-award examinations (PAE)                      Material Inspection and Receiving Reports (form DD-250)                      Certificates of Conformance (COC)                      documentation concerning evaluations of the firms(s)                      and/or products involved                      correspondence with firm(s) involved                      related material.</p> <p>a. <u>PAE reports, Certificates of Conformance and Correspondence with firm:</u>                      Transfer to FRC 2 years after contract expires.                      Destroy <del>7 years</del> <i>2 years</i> after contract expires.  <i>by N. S. memo.</i></p> <p>b. <u>All other material</u>                      Destroy 2 years after contract expires</p>		
R-34	<p><u>QUALITY ASSURANCE PROFILE</u></p> <p>Each profile is identified with the name and address of the firm involved. A file may include:</p> <p>Quality Assurance Profile (form FD 2860)                      six hour update TWXs                      "FAI" (future action indicated) Status TWXs                      related material.</p> <p>a. <u>Firms still requiring profiling:</u> <i>transmittals</i>                      Destroy TWXs and profiles <del>2 years</del> <i>2 years</i> after date of <i>issue</i> receipt. <del>Retain other material</del> <i>Retain other material</i>  <del>no longer needed for reference</del> <i>change made by request by</i></p> <p>b. <u>Firms no longer requiring profiling:</u> e.g. OOB (out of business) or not in OEI (official establishment inventory); <i>entire profile</i>                      Destroy <del>2 years</del> <i>2 years</i> after profiling is no longer required.</p>	<p><i>retain other material</i>  <i>of the</i>  <i>above</i>  <i>blaw</i>  <i>4/8/81</i></p>	

REQUEST FOR AUTHORITY TO DISPOSE OF RECORDS—Continuation Sheet

7. ITEM NO.	8 DESCRIPTION OF ITEM (WITH INCLUSIVE DATES OR RETENTION PERIODS)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
<p>R 8-35</p>	<p><u>PRODUCT SPECIFICATIONS</u></p> <p>Each specification is identified with product name and document number. The file includes:</p> <p>military standards            military specifications            federal specifications            Defense Medical Purchase Description            specification Data Sheets            procurement Item Descriptions</p> <p>Destroy when specification is <del>suspended</del><sup>superseded</sup> or deleted.</p>		
<p>R 8-36</p>	<p><u>PREACCEPTANCE SAMPLES</u></p> <p>Each file bears an identification number e.g., V90001. A file may include:</p> <p>contract/purchase order            documentation concerning the need for a sample            teletypes/memos concerning sample results and evaluation            related materials</p> <p>Transfer to FRC 2 years after evaluation is completed.            Destroy 7 years after completion.</p>		
<p>R 8-37</p>	<p><u>COMPLAINT FILES</u></p> <p>Each file bears an identification number such as: 80001 (Drug Complaint); TC9001 (Device Complaint); 9A001 (Depot Quality Audit Report-DQAR); TA9001 (DQAR - Device). A file may include:</p> <p>complaint/DQAR            teletypes/memos concerning samples and/or investigations            documents concerning the evaluation of the complaint            related material</p> <p>Transfer to FRC 2 years after complaint is resolved.            Destroy 5 years after complaint is resolved.</p>		
<p>NOTE:</p>	<p>Some files may contain privileged information (examples: NDA information; trade secrets). Therefore, any destruction should be in accordance with applicable policy/procedures.</p>		