

National Archives and Records Administration
REQUEST FOR DISPOSITION AUTHORITY

Records Schedule Number: DAA-0088-2024-0004

Status: APPROVED
Date Approved: 04/08/2024

General Information

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| Agency or Establishment | Food and Drug Administration |
| Record/Scheduling Group | 0088 - Records of the Food and Drug Administration |
| Records Schedule Applies To | Agency-wide |
| Schedule Subject | FDA Inspector Credential Records |
| Additional Schedule Information | <p>Sections 702 to 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372 to 374), authorizes officers or employees duly designated by FDA, upon presenting appropriate credentials, to enter regulated enterprises to conduct a variety of on-site inspections and reviews of regulated products and manufacturers, conduct sample analyses of regulated products, and review imported products offered for entry into the United States. These officers or employees are issued FDA inspector credentials as proof that the individual is a duly designated enforcement officer, and, in the case of State employees, an officer commissioned as an officer of the Department of Health.</p> <p>FDA inspector credential records include the following:</p> <ol style="list-style-type: none">1) Federal Credential request forms (FDA Form 2115 or equivalent), completed by the requester and signed by the supervisor and/or authorizing official in the requesting office,2) supporting documentation maintained by the FDA Security Office for tracking all holders of FDA inspectors' credentials for renewal and recovery purposes, and3) the physical credential issued to the inspector. <p>Exclusion: These records do not include personnel identification credentials issued for purpose of access to FDA information systems and facilities, i.e., Personal Identify Verification (PIV) cards or HSPD-12 credentials. These records are scheduled under GRS 5.6, item 120. See FDA-9655a.</p> |
| Is There a Classified Version of This Schedule? | No |
| Is consultation and coordination with Tribal Governments required? | No - the records covered by this schedule do not implicate Tribal interests |

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Item Count

Total number of disposition items: 4
Number of Temporary disposition items: 4
Number of Permanent disposition items: 0
Number of Items with Disposition Not Approved: 0
Number of Inactive disposition items: 0

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Outline of Records Schedule Items for DAA-0088-2024-0004

| Item # | Title | Disposition |
|---------------|--|--------------------|
| 0001 | Credential Request Forms for FDA Inspection and Compliance Personnel : Credential Request Forms for FDA Inspection and Compliance Personnel - Approved Requests. | Temporary |
| 0002 | Credential Request Forms for FDA Inspection and Compliance Personnel : Credential Request Forms for FDA Inspection and Compliance Personnel - Unapproved Requests. | Temporary |
| 0003 | Supporting Documentation for FDA Inspectors' Credentials | Temporary |
| 0004 | Inspector Credentials Issued to Inspection and Compliance Personnel | Temporary |

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Records Schedule Items

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| Group Title | Credential Request Forms for FDA Inspection and Compliance Personnel |
| Group Description | Applications for FDA inspectors and other compliance personnel. Records include completed request form (Federal Credential Record Form FDA 2115 or equivalent). FDA program office requesting the credential manages the recordkeeping copy. Legal citation: 21 U.S.C. 372 to 374. |
| DAA-0088-2024-0004-0001 | STATUS: Active |
| ITEM GENERAL INFORMATION | |
| Item Title | Credential Request Forms for FDA Inspection and Compliance Personnel - Approved Requests. |
| Item Description | Applications for FDA inspectors and other compliance personnel. Records include completed request form (Federal Credential Record Form FDA 2115 or equivalent). FDA program office requesting the credential manages the recordkeeping copy. Legal citation: 21 U.S.C. 372 to 374. |
| Is this item media neutral? | Yes |
| Is this item a Big Bucket? | No |
| MANUAL CITATION | |
| Agency Code | 0088 |
| SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS | |
| Does this item supersede existing disposition authorities? | No |
| Is this item a deviation from the GRS? | No |
| DISPOSITION INSTRUCTION | |
| Final Disposition | Temporary |
| Cutoff Instructions | Other: Cutoff files at end of fiscal year in which credential expires, is not renewed, retained or re-issued, or information is obsolete. |
| Retention Period | Other: Destroy 3 years after cutoff, but longer retention is authorized if required for business use. |
| ADDITIONAL INFORMATION | |
| Legal citation related to record retention (if applicable) | N/A |

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| Are any of the records covered by this item national security classified? | No |
| GAO Approval Required | No |
| DAA-0088-2024-0004-0002 STATUS: Active | |
| ITEM GENERAL INFORMATION | |
| Item Title | Credential Request Forms for FDA Inspection and Compliance Personnel - Unapproved Requests. |
| Item Description | Unapproved applications are retained by the requesting office. They are not sent to the FDA Security Office. |
| Is this item media neutral? | Yes |
| Is this item a Big Bucket? | No |
| MANUAL CITATION | |
| Agency Code | 0088 |
| SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS | |
| Does this item supersede existing disposition authorities? | No |
| Is this item a deviation from the GRS? | No |
| DISPOSITION INSTRUCTION | |
| Final Disposition | Temporary |
| Cutoff Instructions | Other: Cutoff files at end of fiscal year in which application is not approved or otherwise rejected. |
| Retention Period | Destroy when no longer needed |
| ADDITIONAL INFORMATION | |
| Legal citation related to record retention (if applicable) | N/A |
| Are any of the records covered by this item national security classified? | No |
| GAO Approval Required | No |

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| DAA-0088-2024-0004-0003 STATUS: Active | |
| ITEM GENERAL INFORMATION | |
| Item Title | Supporting Documentation for FDA Inspectors' Credentials |
| Item Description | Documentation on holders of FDA inspectors' credentials maintained by the FDA Security Office for tracking and auditing purposes. |
| Is this item media neutral? | Yes |
| Is this item a Big Bucket? | No |

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| MANUAL CITATION | |
| Agency Code | 0088 |
| SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS | |
| Does this item supersede existing disposition authorities? | No |
| Is this item a deviation from the GRS? | No |
| DISPOSITION INSTRUCTION | |
| Final Disposition | Temporary |
| Cutoff Instructions | Cut off at end of Fiscal year. |
| Retention Period | Other: Destroy 3 years after cutoff or when no longer needed for audit purposes, whichever is later, but longer retention is authorized if required for business use. |
| ADDITIONAL INFORMATION | |
| Legal citation related to record retention (if applicable) | N/A |
| Are any of the records covered by this item national security classified? | No |
| GAO Approval Required | No |

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| DAA-0088-2024-0004-0004 | STATUS: Active |
| ITEM GENERAL INFORMATION | |
| Item Title | Inspector Credentials Issued to Inspection and Compliance Personnel |
| Item Description | Official FDA Inspectors' credentials issued by FDA to individuals conducting inspections and compliance operations under 21 U.S.C. 372 to 374. |
| Is this item media neutral? | Yes |
| Is this item a Big Bucket? | No |
| MANUAL CITATION | |
| Agency Code | 0088 |
| SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS | |
| Does this item supersede existing disposition authorities? | No |
| Is this item a deviation from the GRS? | No |
| DISPOSITION INSTRUCTION | |
| Final Disposition | Temporary |

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| Cutoff Instructions | Other: Credential holder must surrender their credential upon 1) termination of employment, including resignation, retirement, or expiration of appointment; 2) expiration of the credential; 3) reassignment to a position which does not require the credential; 4) FDA request, or 5) when no longer needed for business use. |
| Retention Period | Other: Surrendered credentials shall be sent to the security office. Destroy upon receipt by security office. |
| ADDITIONAL INFORMATION | |
| Are any of the records covered by this item national security classified? | No |
| GAO Approval Required | No |

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Signatory Information

| Action | User | Date |
|---------------|-----------------|-------------|
| Accept | Bethany Reiswig | 12/08/2023 |
| Approve | Colleen Shogan | 04/08/2024 |