

National Archives and Records Administration
REQUEST FOR DISPOSITION AUTHORITY

Records Schedule Number: DAA-0088-2024-0005

Status: APPROVED
Date Approved: 10/31/2024

General Information

Agency or Establishment	Food and Drug Administration
Record/Scheduling Group	0088 - Records of the Food and Drug Administration
Records Schedule Applies To	Agency Subdivision
Major Subdivision	Office of Regulatory Affairs (ORA)
Minor Subdivision	Office of Criminal Investigations
Schedule Subject	Criminal Investigation Records of the Office of Criminal Investigations and the Office of Internal Affairs
Additional Schedule Information	<p>As a component of the Food and Drug Administration (FDA), the Office of Criminal Investigations (OCI) protects the public's health by investigating suspected criminal violations of the Federal Food, Drug, and Cosmetic Act (FDCA) and other related laws. Additionally, as a sub-component of OCI, the Office of Internal Affairs (OIA) investigates allegations of wrongdoing or misconduct by FDA employees, contractors, Commissioned Corps personnel, local or foreign exchange program participants, guest researchers, visiting scientists, fellows, interns, volunteers, any other non-government employees, or authorized personnel who have access to FDA supported facilities or FDA information, all collectively referred to in this records schedule as "FDA personnel."</p> <p>Criminal and Administrative Investigative Records are related to suspected violations of the FDCA and other related laws or suspected wrongdoing by non-FDA entities, including businesses, corporations, establishments, individuals, and other entities outside of FDA, or by FDA personnel, as defined above.</p> <p>These records contain trade secret, confidential, and/or law enforcement sensitive information; access and disclosure are subject to the Trade Secrets Act, the Privacy Act, Freedom of Information Act (FOIA) exemptions such as b(7) for law enforcement and restrictions in other statutes and FDA's implementation regulations.</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

National Archives and Records Administration
REQUEST FOR DISPOSITION AUTHORITY

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Item Count

Total number of disposition items: 8

Number of Temporary disposition items: 7

Number of Permanent disposition items: 1

Number of Items with Disposition Not Approved: 0

Number of Inactive disposition items: 0

National Archives and Records Administration
REQUEST FOR DISPOSITION AUTHORITY

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Outline of Records Schedule Items for DAA-0088-2024-0005

Item #	Title	Disposition
0001	Criminal investigative records of suspected violations of the FDCA and other related laws by non-FDA entities, or criminal investigative records related to FDA personnel wrongdoing or misconduct, resulting in judicial actions.	Temporary
0002	Criminal investigative records of suspected violations of the FDCA and other related laws by non-FDA entities, or criminal investigative records related to FDA personnel wrongdoing or misconduct NOT resulting in judicial actions.	Temporary
0003	Criminal investigative records of suspected violations of the FDCA and other related laws by non-FDA entities or criminal investigative records related to FDA personnel wrongdoing, or misconduct resulting in judicial actions and designated as a significant case requiring permanent retention.	Permanent
0004	Administrative investigations related to suspected wrongdoing and/or misconduct by FDA personnel resulting in administrative actions	Temporary
0005	Allegations related to suspected violations of the FDCA and other related laws not resulting in a formal criminal investigation case files or administrative investigations related to suspected wrongdoing and/or misconduct by FDA personnel not resulting in criminal or civil investigations nor disciplinary actions	Temporary
0006	Giglio request and records held by Office of Internal Affairs (OIA)	Temporary
0007	Criminal and counter-intel scope polygraph records	Temporary
0008	Confidential informant records	Temporary

National Archives and Records Administration
REQUEST FOR DISPOSITION AUTHORITY

Records Schedule Number: DAA-0088-2024-0005

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Records Schedule Items

DAA-0088-2024-0005-0001		STATUS: Active
ITEM GENERAL INFORMATION		
Item Title	Criminal investigative records of suspected violations of the FDCA and other related laws by non-FDA entities, or criminal investigative records related to FDA personnel wrongdoing or misconduct, resulting in judicial actions.	
Item Description	Criminal investigative records developed during investigations of known or alleged violations of the FDCA and other related laws by non-FDA entities, or criminal investigative records related to FDA personnel wrongdoing or misconduct (e.g., attempted bribery, injuries, or fatalities, use of force incidents, loss/theft of critical or sensitive equipment, espionage, theft of trade secrets), which resulted in formal judicial action (i.e., indictment/information, plea agreement, trial, and sentencing). Records include, but are not limited to, electronic database for criminal records management, trial documents, lab reports, chain of custody documents, asset forfeiture documents, interview notes, grand jury materials, undercover operations, surveillance records, Search/Seizure Warrant documents, body-worn camera data, open-source records, and external agency criminal intelligence documents. They include, but are not limited to, case files that were created because of independent findings, referrals from various agencies outside of and programs within FDA, FDA hotline complaints, and other miscellaneous complaint files via mail, email, telephone, or fax to OCI or OIA.	
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: Cut off at end of calendar year in which case is closed.	
Retention Period	Destroy 12 year(s) after cutoff	

National Archives and Records Administration
REQUEST FOR DISPOSITION AUTHORITY

Records Schedule Number: DAA-0088-2024-0005

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ADDITIONAL INFORMATION	
Are any of the records covered by this item national security classified?	No
GAO Approval Required	No

DAA-0088-2024-0005-0002	STATUS: Active
ITEM GENERAL INFORMATION	
Item Title	Criminal investigative records of suspected violations of the FDCA and other related laws by non-FDA entities, or criminal investigative records related to FDA personnel wrongdoing or misconduct NOT resulting in judicial actions.
Item Description	Criminal investigative records developed during investigations of known or alleged violations of the FDCA and other related laws by non-FDA entities, or criminal investigative records related to FDA personnel wrongdoing or misconduct (e.g., attempted bribery, injuries, or fatalities, use of force incidents, loss/theft of critical or sensitive equipment, espionage, theft of trade secrets), which DID NOT result in formal judicial action (i.e., indictment/information, plea agreement, trial, and sentencing). Records include, but are not limited to, electronic database for criminal records management, trial documents, lab reports, chain of custody documents, asset forfeiture documents, interview notes, grand jury materials, undercover operations, surveillance records, Search/Seizure Warrant documents, body-worn camera data, open-source records, and external agency criminal intelligence documents. They include, but are not limited to, case files that were created because of independent findings, referrals from various agencies outside of and programs within FDA, FDA hotline complaints, and other miscellaneous complaint files via mail, email, telephone, or fax to OCI or OIA.
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	

National Archives and Records Administration
REQUEST FOR DISPOSITION AUTHORITY

Records Schedule Number: DAA-0088-2024-0005

Status: APPROVED
Date Approved: 10/31/2024

Final Disposition	Temporary
Cutoff Instructions	Other: Cut off at end of calendar year in which case is closed.
Retention Period	Destroy 5 year(s) after cutoff
ADDITIONAL INFORMATION	
Are any of the records covered by this item national security classified?	No
GAO Approval Required	No

DAA-0088-2024-0005-0003		STATUS: Active
ITEM GENERAL INFORMATION		
Item Title	Criminal investigative records of suspected violations of the FDCA and other related laws by non-FDA entities or criminal investigative records related to FDA personnel wrongdoing, or misconduct resulting in judicial actions and designated as a significant case requiring permanent retention.	
Item Description	<p>Criminal investigative records developed during investigations of known or alleged violations of the FDCA and other related laws by non-FDA entities, or criminal investigative records related to FDA personnel wrongdoing or misconduct (e.g., attempted bribery, injuries, or fatalities, use of force incidents, loss/theft of critical or sensitive equipment, espionage, theft of trade secrets) which resulted in formal judicial action (i.e., indictment/information, plea agreement, trial, and sentencing). Records include, but are not limited to, electronic database for criminal records management, trial documents, lab reports, chain of custody documents, asset forfeiture documents, interview notes, grand jury materials, undercover operations, surveillance records, Search/Seizure Warrant documents, body-worn camera data, open-source records, and external agency criminal intelligence documents. They include, but are not limited to, case files that were created because of independent findings, referrals from various agencies outside of and programs within FDA, FDA hotline complaints, and other miscellaneous complaint files via mail, email, telephone, or fax to OCI or OIA. Cases designated as significant with permanent retention will be determined at the discretion of the Assistant Commissioner for Criminal Investigations, and may include, but are not limited to, cases that:</p> <ul style="list-style-type: none"> - Involve congressional investigation; 	

National Archives and Records Administration
REQUEST FOR DISPOSITION AUTHORITY

Records Schedule Number: DAA-0088-2024-0005

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	- Received widespread national and/or international attention in the media; or - Result in substantive changes in agency policies or procedures.
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	Permanent
Cutoff Instructions	Other: Cut off in calendar year in which case is closed.
Are there multiple instructions for this item?	No
Transfer Instruction	Transfer to the National Archives 15 year(s) after cutoff
ADDITIONAL INFORMATION	
Current Records Format	Textual data:100 MB ; Paper-based textual records:25 cubic feet
Approximate first year of records covered by this authority	1992
End year of records covered by this authority	Still being created
Date span of the initial transfer	From: 01/01/1992 To: 12/31/2009
Frequency of transfer	1
Are any of the records covered by this item subject to a FOIA exemption?	Yes
FOIA Exemption(s)	FOIA (b)(7) Law Enforcement, FOIA (b)(7f) Law Enforcement, FOIA (b)(7e) Law Enforcement, FOIA (b)(7d) Law Enforcement, FOIA (b)(7c) Law Enforcement, FOIA (b)(7b) Law Enforcement, FOIA (b)(7a) Law Enforcement, FOIA (b)(4) Trade Secrets and Commercial or Financial Information, FOIA (b)(6) Personal Information

DAA-0088-2024-0005-0004	STATUS: Active
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National Archives and Records Administration
REQUEST FOR DISPOSITION AUTHORITY

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ITEM GENERAL INFORMATION	
Item Title	Administrative investigations related to suspected wrongdoing and/or misconduct by FDA personnel resulting in administrative actions
Item Description	Administrative investigative records developed during investigations of allegations related to FDA personnel wrongdoing and/or misconduct (e.g., attempted bribery, injuries, or fatalities, use of force incidents, loss/theft of critical or sensitive equipment, contract fraud, misuse of FDA assets, theft, trade secret violations) which resulted in formal administrative actions (e.g., termination or suspension from employment, reprimand, or counseling, etc.). Records include, but are not limited to, personnel research records, surveillance records, open-source records, and motor vehicle accident records. They include, but are not limited to, case files that were created because of independent findings, referrals from various agencies outside of and programs within FDA, FDA hotline complaints, and other miscellaneous complaint files such as those coming in via mail, email, telephone, or fax to the Office of Internal Affairs. These records may contain interview notes, evidence, forensic analysis records, contracts, travel information, and investigative reports.
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: Cut off at end of calendar year in which case is closed
Retention Period	Destroy 5 year(s) after cutoff
ADDITIONAL INFORMATION	
Are any of the records covered by this item national security classified?	No
GAO Approval Required	No

DAA-0088-2024-0005-0005	STATUS: Active
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National Archives and Records Administration
REQUEST FOR DISPOSITION AUTHORITY

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ITEM GENERAL INFORMATION	
Item Title	Allegations related to suspected violations of the FDCA and other related laws not resulting in a formal criminal investigation case files or administrative investigations related to suspected wrongdoing and/or misconduct by FDA personnel not resulting in criminal or civil investigations nor disciplinary actions
Item Description	Complaints, referrals, leads, and investigative records, alleging violations of FDCA and other related laws or allegations related to FDA employee, contractor, or other authorized personnel wrongdoing or misconduct (e.g., attempted bribery, injuries or fatalities, use of force incidents, loss/theft of critical or sensitive equipment) which did NOT result in a formal criminal investigation and did NOT result in judicial action (e.g., indictment/information, plea agreement, trial, sentencing), and did NOT result in formal administrative disciplinary actions (e.g., termination or suspension from employment; reprimand, etc.). They include, but are not limited to, case files that were created because of independent findings, referrals from various agencies outside of and programs within FDA, FDA hotline complaints, and other miscellaneous complaint files such as those coming in via mail, email, telephone, or fax to OCI or OIA. These records include matters referred to other agencies for handling, and other general information.
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: Cut off at end of calendar year in which case is closed
Retention Period	Other: Destroy no sooner than 3 years and no later than 5 years after cutoff
ADDITIONAL INFORMATION	
Are any of the records covered by this item national security classified?	No

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REQUEST FOR DISPOSITION AUTHORITY

Records Schedule Number: DAA-0088-2024-0005

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GAO Approval Required	No
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DAA-0088-2024-0005-0006	STATUS: Active
ITEM GENERAL INFORMATION	
Item Title	Giglio request and records held by Office of Internal Affairs (OIA)
Item Description	Giglio records contain information requests and documents obtained during a review conducted pursuant to the Amended U. S. Attorney General’s Policy Regarding the Disclosure to Prosecutors of Potential Impeachment Information Concerning Law Enforcement Agency Witnesses. They include, but are not limited to, the request and the inquiry response, as well as records created because of independent findings of various databases, i.e., NCIC checks, OIA investigative files, and FDA personnel records. These records include matters referred to the Department of Justice for judicial proceedings.
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: Cut off at end of calendar year in which case is closed
Retention Period	Destroy 10 year(s) after cutoff
ADDITIONAL INFORMATION	
Are any of the records covered by this item national security classified?	No
GAO Approval Required	No

DAA-0088-2024-0005-0007	STATUS: Active
ITEM GENERAL INFORMATION	
Item Title	Criminal and counter-intel scope polygraph records

National Archives and Records Administration
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Item Description	Polygraph Examination Files are created upon agency approval to conduct a polygraph examination and completed upon Quality Control evaluation of the conducted polygraph examination. The files consist of all originals of the following documents: the Polygraph Approval, the Quality Control Review Worksheet, and all polygraph operational documents which include, but are not limited to, any Rights Warning, Polygraph Consent Form(s), Biographical Data Sheet(s), Question Lists, the Polygraph Report and all Polygrams (Polygraph Charts) conducted during the examination.
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: Cut off at end of calendar year in which case is closed
Retention Period	Destroy 3 year(s) after cutoff
ADDITIONAL INFORMATION	
Are any of the records covered by this item national security classified?	No
GAO Approval Required	No

DAA-0088-2024-0005-0008	STATUS: Active
ITEM GENERAL INFORMATION	
Item Title	Confidential informant records

National Archives and Records Administration
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Item Description	Confidential Informant records are created upon the introduction of a confidential source of an investigation. The documents and information provided are based on useful and credible information regarding criminal activities provided by a confidential source or a source of information. They include but are not limited to records consisting of initial and continued suitability determinations, approvals and registrations of the source, agreements of assistance, records of financial compensation to the source including requests and disbursements, records of contacts for investigative activities, instructions, surveillance records, certifications and de-certifications, informant files, and special notifications.
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: Cut off at end of calendar year in which case is closed
Retention Period	Destroy 10 year(s) after cutoff
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
Approve	Colleen Shogan	10/31/2024