Request for Records Disposition Authority

Records Schedule Number	DAA-0088-2018-0009
Schedule Status	Approved
Agency or Establishment	Food and Drug Administration
Record Group / Scheduling Group	Records of the Food and Drug Administration
Records Schedule applies to	Major Subdivsion
Major Subdivision	Office of Regulatory Affairs
Minor Subdivision	Import Operations
Schedule Subject	Entry Documents
Internal agency concurrences will be provided	Yes
Background Information	Import documents for import reviews and actions. Entry review consist of the examination of any electronic data and/or hard copy entry documentation received by FDA for an FDA regulated entry line. The information received is reviewed to determine if entry admissibility criteria for the commodity are met, and if additional actions, such as examination sampling or detention request are applicable and/or necessary.

Item Count

Number of Total Disposition Items	Number of Permanent Disposition Items	Number of Temporary Disposition Items	Number of Withdrawn Disposition Items
2	0	2	0

GAO Approval

Outline of Records Schedule Items for DAA-0088-2018-0009

Sequence Number	
1	Entry Documents of Entries May Proceeded Disposition Authority Number: DAA-0088-2018-0009-0001
2	Entry Documents for Entries Released by Investigations Branch Disposition Authority Number: DAA-0088-2018-0009-0002

Records Schedule Items

Sequence Number	
1	**Entry Documents of Entries May Proceeded**
	Disposition Authority Number: DAA-0088-2018-0009-0001
	The office responsible for maintaining the records are Office of Regulatory Affairs (Field Offices) who conduct Import Operations. Entry Documents of Entries May Proceeded - Documents include materials related to FDA regulated products imported into the country. Types of Entry Documents might include copies of Customs Forms (CF3461, CF7501), Certificates of Analysis, commercial invoices, packing lists, manifests, bill of ladings, airway bills, tracking screens, Personal Importation documents, letters or forms. The records are submitted to FDA Import electronically or in hard copy to initiate the review of FDA regulated products offered for importation into the United States. These records are used to determine the admissibility of the declared imported product on a daily basis.
	Final Disposition: Temporary
	Item Status: Active
	Is this item media neutral?: Yes
	Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing?: Yes
	Do any of the records covered by this item exist as structured electronic data?: No
	Disposition Instruction
	Cutoff Instruction: For May Proceed, Cutoff on the final day of the fiscal year upon the issuance of the May Proceed.
	Retention Period: Destroy hardcopy when data has been entered into the electronic master file or databased and verified. Destroy 3 year (s) after electronic record cutoff if no longer needed for administrative, legal, audit or operational purposes.
	Additional Information
	GAO Approval: Not Required
2	**Entry Documents for Entries Released by Investigations Branch**
	Disposition Authority Number: DAA-0088-2018-0009-0002

Entry Documents for Entries Released by Investigations Branch (IB) AKA "IB Release" – Documents include materials related to FDA regulated products imported into the country. Entry Documents describe the articles offered for importation (copies of Customs Forms (CF3461, CF7501), Certificates of Analysis, commercial invoices, packing lists, manifests, bill of ladings, airway bills, tracking screens, Personal Importation documents, letters, forms), copies of FDA Notices of Action, labeling, documentation related to field examinations. The entry documents are submitted to FDA Import Operations electronically and in hard copy to initiate the review of FDA regulated products offered for importation into the United States. After review of these records the entry is set up for FDA examination, whereby a field examination is conducted. After completing the field examination the investigator proceeds with the admissibility decision. If it appears to be in compliance, an IB Release would be issued.

Final Disposition	Temporary
Item Status	Active
Is this item media neutral?	Yes
Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing?	Yes
Do any of the records covered by this item exist as structured electronic data?	No

Disposition Instruction

Cutoff Instruction	Cutoff on the final day of the fiscal year within the issuance of the IB Release.
Retention Period	Hardcopy maybe destroyed when data has been entered into the electronic master file or database and verified. Destroy electronic records 3 years after cutoff if no longer needed for administrative, legal, audit or operational purposes.

Additional Information

GAO Approval	Not Required

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 in this schedule are not now needed for the business of the agency or will not be needed after the retention periods specified.

Signatory Information

Date	Action	By	Title	Organization
10/01/2018	Certify	Garland Hodges	Management Analyst	Food and Drug Administration - OC
11/07/2018	Return for Revision	Carly Docca	Archives Specialist	National Archives and Records Administration - ACRA
12/14/2018	Submit For Certification	Garland Hodges	Management Analyst	Food and Drug Administration - OC
12/14/2018	Certify	Garland Hodges	Management Analyst	Food and Drug Administration - OC
10/07/2019	Submit for Concurrence	Carly Docca	Archives Specialist	National Archives and Records Administration - ACRA
10/10/2019	Concur	Margaret Hawkins	Director of Records Management Services	National Records Management Program - ACNR Records Management Services
10/15/2019	Concur	Laurence Brewer	Chief Records Officer	National Records and Archives Administration - National Records and Archives Administration
10/17/2019	Approve	David Ferriero	Archivist of the United States	Office of the Archivist - Office of the Archivist