Request for Records Disposition Authority

Records Schedule Number	DAA-0088-2020-0001
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	Center for Tobacco Products
Schedule Subject	Center for Tobacco Products Record Schedule
Internal agency concurrences will be provided	No

Background Information

On June 22, 2009, the President signed into law the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Public Law 111-31). The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. To carry out this responsibility, FDA established the Center for Tobacco Products (CTP).

This Records Control Schedule covers CTP-specific programmatic records. This schedule has been reviewed and approved by the FDA/ Office of the Chief Counsel, FDA/Records Management Team and the HHS/Records Management Office.

Item Count

Number of Total Disposition Items	Number of Permanent Disposition Items	Number of Temporary Disposition Items	Number of Withdrawn Disposition Items
28	3	25	0

GAO Approval

Outline of Records Schedule Items for DAA-0088-2020-0001

Sequence Number	
1	Tobacco Industry Health and Research Documents Disposition Authority Number: DAA-0088-2020-0001-0001
2	Ingredient Listings (TI) Disposition Authority Number: DAA-0088-2020-0001-0002
3	Abbreviated Substantial Equivalent Reports (AS) Disposition Authority Number: DAA-0088-2020-0001-0003
4	Substantial Equivalence Exemption (EX) Disposition Authority Number: DAA-0088-2020-0001-0004
5	Substantial Equivalence (SE) Disposition Authority Number: DAA-0088-2020-0001-0005
6	Investigational Use of a Tobacco Product (ITP) Disposition Authority Number: DAA-0088-2020-0001-0006
7	Jurisdiction Committee Records Disposition Authority Number: DAA-0088-2020-0001-0007
8	Harmful and Potentially Harmful Constituents (HPHC) Disposition Authority Number: DAA-0088-2020-0001-0008
9	Modified Risk Tobacco Product Application (MRTPA)
9.1	Modified Risk Tobacco Product Application (MRTPA) Disposition Authority Number: DAA-0088-2020-0001-0009
9.2	MRTPA Technical Project Lead (TPL) Reviews for Authorized Products Disposition Authority Number: DAA-0088-2020-0001-0010
9.3	MRTPA Technical Project Lead (TPL) Reviews for Denied Products Disposition Authority Number: DAA-0088-2020-0001-0011
10	Premarket Tobacco Product Application (PMTA)
10.1	Premarket Tobacco Product Application (PMTA) Disposition Authority Number: DAA-0088-2020-0001-0012
10.2	PMTA Technical Project Lead (TPL) Reviews for Authorized Products Disposition Authority Number: DAA-0088-2020-0001-0013
10.3	PMTA Technical Project Lead (TPL) Reviews for Denied Products Disposition Authority Number: DAA-0088-2020-0001-0014
10.4	PMTAs Withdrawn for Safety Reasons Disposition Authority Number: DAA-0088-2020-0001-0015
11	Tobacco Inspections
11.1	Tobacco Retailer Inspection Case Files Disposition Authority Number: DAA-0088-2020-0001-0016

11.2	Tobacco Establishment Inspection and Investigation Review Memos
11.2.1	No Action Indicated (NAI) and Voluntary Action Indicated (VAI) Disposition Authority Number: DAA-0088-2020-0001-0017
11.2.2	Official Action Indicated (OAI) Disposition Authority Number: DAA-0088-2020-0001-0018
12	Tobacco Internet Surveillance or Inspection Activity Files
12.1	No Action Indicated (NAI) and Voluntary Action Indicated (VAI) Disposition Authority Number: DAA-0088-2020-0001-0019
12.2	Official Action Indicated (OAI) Disposition Authority Number: DAA-0088-2020-0001-0020
13	Pre-existing Tobacco Product (PX)
13.1	Withdrawn Disposition Authority Number: DAA-0088-2020-0001-0021
13.2	Unable to Grandfather Disposition Authority Number: DAA-0088-2020-0001-0022
13.3	Grandfathered Disposition Authority Number: DAA-0088-2020-0001-0023
14	Tobacco Warning Plans Disposition Authority Number: DAA-0088-2020-0001-0024
15	Other Media Submissions Disposition Authority Number: DAA-0088-2020-0001-0025
16	Tobacco Product Master Files (TPMF)
16.1	TPMF Reviewed to Support Regulatory Action Disposition Authority Number: DAA-0088-2020-0001-0026
16.2	TPMF With Right of Reference Granted With No Record of Review Disposition Authority Number: DAA-0088-2020-0001-0027
16.3	TPMF Not Referenced/Reviewed Disposition Authority Number: DAA-0088-2020-0001-0028

Records Schedule Items

Sequence Number

1 Tobacco Industry Health and Research Documents

Disposition Authority Number DAA-0088-2020-0001-0001

Collection of health and research documents submitted by tobacco product manufacturers, importers or agents that relate to health, toxicological, behavioral, or physiologic effect of current or future tobacco products, their constituents, ingredients, components, and additives as required under Section 904(a)(4) and 904(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387d(a)(4)]. Records are stored in documentum and viewed through Image and records tracked in the iTRAC system or its successor system and are maintained by the Document Control Center. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations. Note: Record copies are maintained in the electronic records repository.

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?	Yes

Disposition Instruction

Cutoff Instruction	Cut off at the end of the calendar year after the final determination has been taken or product has been taken off the market, whichever is later.
Retention Period	Destroy 30 year(s) after cutoff.

Additional Information

GAO Approval	Not Required

2 Ingredient Listings (TI)

Disposition Authority Number DAA-0088-2020-0001-0002

Listing of all ingredients including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of

each tobacco product that's submitted to the FDA as required under Section 904(a)(1) and 904(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387d(a)(4)]. Records are stored in documentum and viewed through Image and records tracked in the iTRAC system or its successor system and are maintained by the Document Control Center. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations. Note: Record copies are maintained in the electronic records repository. Section 904(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387d(a)(4)] also requires submission of information whenever any additive, or the quantity of any additive, is changed.

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?	Yes

Disposition Instruction

Cutoff Instruction	Cut off at end of the calendar year after final determination has been taken or product has been taken off the market, whichever is later.
Retention Period	Destroy 30 year(s) after cutoff.

Additional Information

GAO Approval	Not Required

3 Abbreviated Substantial Equivalent Reports (AS)

Disposition Authority Number	DAA-0088-2020-0001-0003

Contains the abbreviated SE reports submitted to the FDA after receiving an exemption order under Section 905(j)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387d(a)(4)]. Records are stored in Documentum and viewed through Image and records tracked in the iTRAC system or its successor system and are maintained by the Document Control Center. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations. Note: Record copies are maintained in the electronic records repository.

	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?	Yes
	Disposition Instruction	
	Cutoff Instruction	Cut off at end of the calendar year after final determination has been taken or product has been taken off the market, whichever is later.
	Retention Period	Destroy 30 year(s) after cutoff.
	Additional Information	
	GAO Approval	Not Required
4	Substantial Equivalence Exemption (EX)	
	Disposition Authority Number	DAA-0088-2020-0001-0004
	Contains requests for exemptions to submitting a Substantial Equivalence report as required under Section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387d(a)(4)]. Records are stored in documentum and viewed through Image and records tracked in the iTRAC system or its successor system and are maintained by the Document Control Center. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations. Note: Record copies are maintained in the electronic records repository.	
	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?	Yes
	Disposition Instruction	

	Cutoff Instruction	Cut off at end of the calendar year after final determination has been taken or product has been taken off the market, whichever is later.
	Retention Period	Destroy 30 year(s) after cutoff.
	Additional Information	
	GAO Approval	Not Required
5	Substantial Equivalence (SE)	
	Disposition Authority Number	DAA-0088-2020-0001-0005
	Substantial Equivalence reports submitted to FDA to demonstrate that a tobacco product is substantially equivalent to a legally marketed tobacco product that is not subject to Pre-Market Tobacco Approval (PMTA) or Modified Risk Tobacco Product Approval (MRTPA) as required under Section 905(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387d(a)(4)]. May include correspondence and other documents received from persons and manufacturers seeking to introduce a tobacco product on the market, FDA evaluations and approval decisions made under Section 910(a)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387d(a)(4)]. Records are stored in Documentum and viewed through Image and records tracked in the iTRAC system or its successor system and are maintained by the Document Control Center. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations. Note: Record copies are maintained in the electronic records repository.	
	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?	Yes
	Disposition Instruction	
	Cutoff Instruction	Cut off at end of the calendar year after final determination has been taken or product has been taken off the market, whichever is later.
	Retention Period	Destroy 30 year(s) after cutoff.
	Additional Information	

	GAO Approval	Not Required
6	Investigational Use of a Tobacco Product (ITP)	
	Disposition Authority Number	DAA-0088-2020-0001-0006
	Study information submitted to FDA as required under Section 910(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387d(a)(4)] for an investigational use of a tobacco product. This may include correspondence and other documents received from persons seeking to study the use of a tobacco product. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations. Note: Record copies are maintained in the electronic records repository.	
	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?	Yes
	Disposition Instruction	
	Cutoff Instruction	Cut off at end of the calendar year after final determination has been taken or product has been taken off the market, whichever is later.
	Retention Period	Destroy 30 year(s) after cutoff.
	Additional Information	
	GAO Approval	Not Required
7	Jurisdiction Committee Records	
	Disposition Authority Number	DAA-0088-2020-0001-0007
	Records produced by the Jurisdiction Committee between 2011 to 2015 evaluating products submitted to CTP for marketing authorization that were not clearly tobacco products under the original 2009 TCA which was limited to cigarettes, smokeless, and roll your own tobacco products. The Jurisdiction Committee determined whether or not the product was a tobacco product under the 2009 TCA. The submissions considered were for tobacco products that were not specified under the 2009 TCA but were incorporated into the product categories of the	

2016 Deeming rule. The 2016 rule eliminated need for the committee, and it was disbanded prior to final rule publication.

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?	Yes

Disposition Instruction

Cutoff Instruction	Cut off at end of the calendar year after final determination has been taken or product has been taken off the market, whichever is later.
Retention Period	Destroy 30 year(s) after cutoff.

Additional Information

GAO Approval	Not Required

8 Harmful and Potentially Harmful Constituents (HPHC)

Disposition Authority Number	DAA-0088-2020-0001-0008

Records submitted to FDA as required under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387d(a)(4)] concerning the testing and reporting of tobacco product constituents, including smoke constituents, additives, and ingredients by brand and sub-brand. Records may include product information, HPHC quantities and testing information, spreadsheets, FDA reviews and related records. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations. Note: Record copies are maintained in the electronic records repository.

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?	Yes
	Disposition Instruction	
	Cutoff Instruction	Cut off at end of the calendar year after final determination has been taken or product has been taken off the market, whichever is later.
	Retention Period	Destroy 30 year(s) after cutoff.
	Additional Information	
	GAO Approval	Not Required
9	Modified Risk Tobacco Product Application (MRTPA) Applications submitted to the FDA as required under Section 911(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387d(a)(4)] to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products and resulting review file documentation.	
9.1	Modified Risk Tobacco Product Application (MRTPA)	
	Disposition Authority Number	DAA-0088-2020-0001-0009
	Applications submitted to the FDA as required under Section 911(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387d(a)(4)] to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. The records may include product information, test data, manufacturers' information, investigations of health risks, samples of the product and its components, and specimens of proposed advertising and labeling, FDA responses and related records. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations. Note: Record copies are maintained in the electronic records repository.	
	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?	Yes
	Disposition Instruction	

Cutoff Instruction	Cut off at end of the calendar year after final determination has been taken or product has been taken off the market, whichever is later.
Retention Period	Destroy 30 year(s) after cutoff.

Additional Information

GAO Approval	Not Required

9.2

MRTPA Technical Project Lead (TPL) Reviews for Authorized Products

Disposition Authority Number	DAA-0088-2020-0001-0010

A summary for the CTP review process and determination decision for authorized MRTPA applications. Includes information such as the review process, product ingredients, and decision to authorize. Access is restricted under FOIA exemptions.

Final Disposition	Permanent
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	Cut off at the end of the calendar year after the final FDA determination has been made.
Transfer to the National Archives for Accessioning	Transfer to the National Archives 15 year(s) after cutoff.

Additional Information

What will be the date span of the initial transfer of records to the National Archives?	From 2017 To 2017
How frequently will your agency transfer these records to the National Archives?	Every 1 Years

	Estimated Current Volume	Annual Accumulation
Electronic/Digital	60 MB	15 MB

Paper		
Microform		
Hardcopy or Analog Special Media		

9.3 MRTPA Technical Project Lead (TPL) Reviews for Denied Products

Disposition Authority Number DAA-0088-2020-0001-0011

A summary for the CTP review process and determination decision for denied MRTPA applications. Includes information such as the review process, product ingredients, and decision to deny. Access is restricted under FOIA exemptions.

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 Cut off at the end of the calendar year after the final FDA determination has been made.

Retention Period Destroy 30 year(s) after cutoff.

Additional Information

GAO Approval Not Required

10 Premarket Tobacco Product Application (PMTA)
Applications submitted to the FDA for new tobacco products as required under Section 910(a)(2) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387d(a)(4)] and resulting review file documentation.

10.1 Premarket Tobacco Product Application (PMTA)

Disposition Authority Number DAA-0088-2020-0001-0012

Applications submitted to the FDA for new tobacco products as required under Section 910(a)(2) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387d(a)

(4)]. The records may include product information, test data, manufacturers' information, investigations of health risks, samples of the product and its components, and specimens of proposed advertising and labeling, FDA responses and related records. Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations. Note: Record copies are maintained in the electronic records repository.

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?	Yes

Disposition Instruction

Cutoff Instruction	Cut off at end of the calendar year after final determination has been taken or product has been taken off the market, whichever is later.
Retention Period	Destroy 30 year(s) after cutoff.

Additional Information

GAO Approval	Not Required

10.2

PMTA Technical Project Lead (TPL) Reviews for Authorized Products

Disposition Authority Number	DAA-0088-2020-0001-0013

A summary for the CTP review process and determination decision for authorized PMTA applications. Includes information such as the review process, product ingredients, and decision to authorize. Access is restricted under FOIA exemptions.

Final Disposition	Permanent
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: Cut off at the end of the calendar year after the final FDA determination has been made.

Transfer to the National Archives for Accessioning: Transfer to the National Archives 15 year(s) after cutoff.

Additional Information

What will be the date span of the initial transfer of records to the National Archives? From 2017 To 2017

How frequently will your agency transfer these records to the National Archives? Every 1 Years

	Estimated Current Volume	Annual Accumulation
Electronic/Digital	94 MB	24 MB
Paper		
Microform		
Hardcopy or Analog Special Media		

10.3

PMTA Technical Project Lead (TPL) Reviews for Denied Products

Disposition Authority Number: DAA-0088-2020-0001-0014

A summary for the CTP review process and determination decision for denied PMTA applications. Includes information such as the review process, product ingredients, and decision to deny. Access is restricted under FOIA exemptions.

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	Cut off at the end of the calendar year after the final FDA determination has been made.
	Retention Period	Destroy 30 year(s) after cutoff.
	Additional Information	
	GAO Approval	Not Required
10.4	PMTAs Withdrawn for Safety Reasons	
	Disposition Authority Number	DAA-0088-2020-0001-0015
	Files consist of PMTAs and the accompanying review materials and decisional documents regarding the withdrawal of a previously approved PMTA for safety reasons discovered and identified after the initial determination.	
	Final Disposition	Permanent
	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	Cut off at the end of the calendar year after the withdrawal decision is made.
	Transfer to the National Archives for Accessioning	Transfer to the National Archives 30 year(s) after cutoff.
	Additional Information	
	What will be the date span of the initial transfer of records to the National Archives?	From 2017 To 2017
	How frequently will your agency transfer these records to the National Archives?	Every 1 Years

	Estimated Current Volume	Annual Accumulation
Electronic/Digital		10 MB
Paper		
Microform		
Hardcopy or Analog Special Media		

11 Tobacco Inspections
Contains retailer and other establishment inspection case files, investigation review memos, and supporting documentation.

11.1 Tobacco Retailer Inspection Case Files

Disposition Authority Number DAA-0088-2020-0001-0016

CTP retailer compliance check inspections which includes routine surveillance. Includes inspection reports and case files, including any attachments or exhibits related to the inspection and other inspection related records originated by the field inspectors.

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? Yes

Disposition Instruction

Cutoff Instruction Cut off after establishment goes out of business, or product is withdrawn or no longer marketed.

Retention Period Destroy 10 year(s) after cutoff.

Additional Information

GAO Approval Not Required

11.2 Tobacco Establishment Inspection and Investigation Review Memos

Review memoranda drafted by Office of Compliance and Enforcement (OCE) staff during review of establishment inspection reports and investigation memoranda. No Action Indicated (NAI), Voluntary Action Indicated (VAI), or Official Action Indicated (OAI) files will result.

11.2.1 No Action Indicated (NAI) and Voluntary Action Indicated (VAI)

Disposition Authority Number	DAA-0088-2020-0001-0017
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?	Yes

Disposition Instruction

Cutoff Instruction	Cut off at the end of the fiscal year when the final classification of inspection occurs.
Retention Period	Destroy 10 year(s) after cutoff.

Additional Information

GAO Approval	Not Required

11.2.2 Official Action Indicated (OAI)

Disposition Authority Number	DAA-0088-2020-0001-0018
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?	Yes

Disposition Instruction

Cutoff Instruction	Cut off after CTP confirms that the firm is out of business.

	Retention Period	Destroy 30 year(s) after cutoff.
	Additional Information	
	GAO Approval	Not Required
12	Tobacco Internet Surveillance or Inspection Activity Files Regulatory and Enforcement Action Cases initiated by Office of Compliance and Enforcement (OCE) which result in internet surveillance or inspection activity. No Action Indicated (NAI), Voluntary Action Indicated (VAI), or Official Action Indicated (OAI) files will result.	
12.1	No Action Indicated (NAI) and Voluntary Action Indicated (VAI)	
	Disposition Authority Number	DAA-0088-2020-0001-0019
	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?	Yes
	Disposition Instruction	
	Cutoff Instruction	Cut off at the end of the fiscal year when the final classification of inspection occurs.
	Retention Period	Destroy 10 year(s) after cutoff.
	Additional Information	
	GAO Approval	Not Required
12.2	Official Action Indicated (OAI)	
	Disposition Authority Number	DAA-0088-2020-0001-0020
	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?	Yes
	Disposition Instruction	
	Cutoff Instruction	Cut off at the end of the fiscal year after the case is closed.
	Retention Period	Destroy 30 year(s) after cutoff.
	Additional Information	
	GAO Approval	Not Required
13	Pre-existing Tobacco Product (PX) Pre-Existing Tobacco Products, also known as Grandfathered Tobacco Products (GF), are products regulated under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387j(a)(2)]. Files contain review memoranda and reference documents used in determining whether a product was commercially marketed (not in test market) as of February 15, 2007. Reference documents can include documentation of commercial marketing, Requests for Information and the associated response from the submitter, and determination letters.	
13.1	Withdrawn	
	Disposition Authority Number	DAA-0088-2020-0001-0021
	PX submissions/applications that are withdrawn from OCE consideration by the submitter.	
	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?	Yes
	Disposition Instruction	
	Cutoff Instruction	Cut off after completion of determination and any resulting litigation, or when no longer needed for review in the continued regulation of these products, whichever is later.
	Retention Period	Destroy 15 year(s) after cutoff.

Additional Information

GAO Approval: Not Required

13.2

Unable to Grandfather

Disposition Authority Number: DAA-0088-2020-0001-0022

PX submissions where a determination is made by OCE that PX or Grandfather status cannot be granted to the product.

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? Yes

Disposition Instruction

Cutoff Instruction: Cut off after completion of determination and any resulting litigation, or when no longer needed for review in the continued regulation of these products, whichever is later.

Retention Period: Destroy 30 year(s) after cutoff.

Additional Information

GAO Approval: Not Required

13.3

Grandfathered

Disposition Authority Number: DAA-0088-2020-0001-0023

Submissions where OCE has determined that PX or Grandfathered status is appropriate for the product.

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?	Yes
	Disposition Instruction	
	Cutoff Instruction	Cut off after completion of determination and any resulting litigation, or when no longer needed for review in the continued regulation of these products, whichever is later.
	Retention Period	Destroy 60 year(s) after cutoff.
	Additional Information	
	GAO Approval	Not Required
14	Tobacco Warning Plans	
	Disposition Authority Number	DAA-0088-2020-0001-0024
	Plans submitted by industry which are then reviewed by CTP for the display and rotation of required warnings on packaging and advertising for smokeless tobacco and cigarette products.	
	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?	Yes
	Disposition Instruction	
	Cutoff Instruction	Cut off after establishment goes out of business, or product is withdrawn and no longer marketed, whichever is later.
	Retention Period	Destroy 10 year(s) after cutoff.
	Additional Information	
	GAO Approval	Not Required
15	Other Media Submissions	
	Disposition Authority Number	DAA-0088-2020-0001-0025

Submissions from firms notifying CTP that they will advertise in media not listed in 21 CFR 1140.30, and CTP memoranda evaluating submission. Media listed in 21 CFR 1140.30 include newspapers; magazines; periodicals or other publications (whether periodic or limited distribution); billboards, posters, and placards; in nonpoint-of-sale promotional material (including direct mail); in point-of-sale promotional material; and in audio or video formats delivered at a point-of-sale.

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?	Yes

Disposition Instruction

Cutoff Instruction	Cut off after establishment goes out of business, or product is withdrawn and no longer marketed.
Retention Period	Destroy 10 year(s) after cutoff.

Additional Information

GAO Approval	Not Required

16

Tobacco Product Master Files (TPMF)
Files consist of case files used to provide trade secret and/or confidential commercial information about a tobacco product or component that an owner does not want to share with other persons. These may be referenced by another manufacturer (customer) as part of a Premarket Tobacco Product application, other product applications, other product submissions, or another TPMF (Referencing Submission). A complete file includes the original records submitted by the TPMF holder containing information regarding trade secret and/ or confidential commercial information for tobacco products and components as well as additional administrative information regarding tobacco products and components, additional submissions from the TPMF holder, FDA reviews, and correspondence. TPMFs are reviewed when: 1. The TPMF is “open”; 2. A submission or application references the TPMF; and 3. There is a valid Letter of Authorization to allow for referencing of the TPMF for the referencing application/ submission. Each TPMF is assigned a submission tracking number when received. Access is restricted under FOIA exemptions. TPMF is considered “closed” if: 1) the TPMF owner notifies FDA that they wish the TPMF to be closed; or 2) the TPMF has not been updated nor referenced within a three-year period, and the TPMF

owner does not respond to the notification letter noting intent to close or concurs with closure.

16.1 TPMF Reviewed to Support Regulatory Action

Disposition Authority Number: DAA-0088-2020-0001-0026

Includes TPMFs reviewed to support an action on tobacco products or components under an application (e.g., PMTA) or other submission.

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	Cut off when the TPMF is “closed.”
Retention Period	Destroy 30 year(s) after cutoff, but longer retention is authorized if needed for business use.

Additional Information

GAO Approval	Not Required

16.2 TPMF With Right of Reference Granted With No Record of Review

Disposition Authority Number: DAA-0088-2020-0001-0027

Includes TPMFs with a Letter of Authorization (LOA) submitted by the holder and there is no record of a review. These are more than three years old, and the TPMFs were not used to support a regulatory action.

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	Cut off when the TPMF is “closed.”
Retention Period	Destroy 5 year(s) after cutoff.

Additional Information

GAO Approval	Not Required

16.3

TPMF Not Referenced/Reviewed

Disposition Authority Number	DAA-0088-2020-0001-0028

TPMFs that do not have a LOA by the holder, or TPMFs with no record of a review.

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	Cut off when the TPMF is “closed.”
Retention Period	Destroy 3 year(s) after cutoff.

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
11/05/2019	Certify	Garland Hodges	Management Analyst	Food and Drug Administration - OC
01/21/2020	Return for Revision	Richard Green	Archivist Specialist	National Archives and Records Administration - ACR3, Appraisal Team 3
12/02/2020	Submit For Certification	Christina Dannunzio	Management Analyst	Center for Tobacco Products - Office of Management
12/07/2020	Certify	Garland Hodges	Management Analyst	Food and Drug Administration - OC
01/08/2021	Return for Revision	Richard Green	Archivist Specialist	National Archives and Records Administration - ACR3, Appraisal Team 3
04/20/2021	Submit For Certification	Christina Dannunzio	Management Analyst	Center for Tobacco Products - Office of Management
04/29/2021	Certify	Garland Hodges	Management Analyst	Food and Drug Administration - OC
07/01/2021	Return for Revision	Richard Green	Archivist Specialist	National Archives and Records Administration - ACR3, Appraisal Team 3
12/23/2021	Submit For Certification	Christina Dannunzio	Management Analyst	Center for Tobacco Products - Office of Management
01/11/2022	Certify	Garland Hodges	Management Analyst	Food and Drug Administration - OC
07/14/2022	Submit for Concurrence	Richard Green	Archivist Specialist	National Archives and Records Administration - ACR3, Appraisal Team 3

07/21/2022	Concur	Margaret Hawkins	Director of Records Management Services	National Records Management Program - ACNR Records Management Services
07/22/2022	Concur	Laurence Brewer	Chief Records Officer	National Records and Archives Administration - National Records and Archives Administration
07/27/2022	Approve	Debra Wall	Deputy Archivist	National Archives and Records Administration - ND Archives I Office