

SUMMARY Analysis of FDA Compliance Check Data

FFY 2011-2021
through 01/31/2021

FDA Inspection Type	Year	Total Compliance Checks	Number of "NO Violations"	Number of Warning Letters	Number of Civil Money Penalties	Number of No-Tobacco-Sale Orders	Violation Rate
Where Minors were involved. (Example: Violations may be a sale to a minor, but may be other violations, such as observed banned self-service racks or other advertisement or merchandising violations.)	FFY2011	11,049	10,271	777	1		7.04%
	FFY2012	43,245	39,419	3,443	383		8.85%
	FFY2013	52,027	46,651	4,843	533		10.33%
	FFY2014	68,233	60,286	6,871	1,076		11.65%
	FFY2015	126,582	107,627	15,667	3,288		14.97%
	FFY2016	130,059	114,366	12,057	3,636	24	12.07%
	FFY2017	129,306	110,877	12,397	6,032	55	14.25%
	FFY2018	126,303	111,355	11,894	3,054	45	11.84%
	FFY2019	144,684	125,341	14,635	4,708	11	13.37%
	FFY2020	63,019	55,965	4,724	2,330	32	11.19%
FFY2021	736	726	2	8	1	1.36%	
		895,243	782,884	87,310	25,049	168	12.55%
Adult Inspectors Only (Example: Violations observed by an adult inspector may include banned self-service racks, vending machine, "loosies", banned advertising such as "light", etc.)	FFY2011	13,355	13,110	245			1.83%
	FFY2012	44,217	43,553	664			1.50%
	FFY2013	57,833	56,683	1,149	1		1.99%
	FFY2014	55,485	54,253	1,232			2.22%
	FFY2015	35,222	34,429	793			2.25%
	FFY2016	31,563	31,100	463			1.47%
	FFY2017	30,868	30,497	371			1.20%
	FFY2018	5,820	5,722	96	2		1.68%
	FFY2019	1,735	1,721	13	1		0.81%
	FFY2020	2,268	2,140	127	1	0	5.64%
FFY2021	1,211	1,211	0	0	0	0.00%	
		279,577	274,419	5,153	5	0	1.84%
TOTAL	FFY2011	24,404	23,381	1,022	1	0	4.19%
	FFY2012	87,462	82,972	4,107	383	0	5.13%
	FFY2013	109,860	103,334	5,992	534	0	5.94%
	FFY2014	123,718	114,539	8,103	1,076	0	7.42%
	FFY2015	161,804	142,056	16,460	3,288	0	12.20%
	FFY2016	161,622	145,466	12,520	3,636	24	10.00%
	FFY2017	160,174	141,374	12,768	6,032	55	11.74%
	FFY2018	132,123	117,077	11,990	3,056	45	11.39%
	FFY2019	146,419	127,062	14,648	4,709	11	13.22%
	FFY2020	65,287	58,105	4,851	2,331	32	11.00%
FFY2021	1,947	1,937	2	8	1	0.51%	
		1,174,820	1,057,303	92,463	25,054	168	10.00%

Information about FDA publicly available Enforcement Data

FDA raw data now enables the reporting of:

Federal Fiscal Year (FFY) statistics, which is Oct. 1-Sep. 30. -- based upon an FDA "Decision Date" of the reported results of an FDA inspection of a retail store

Identifying information on the type of enforcement check that was conducted and the results. For example, FDA conducts two types of inspections of retail stores:

- Inspections of retail stores where minors are involved. These inspections involve an attempted purchase by a minor of FDA regulated products.
- Inspections of retail stores where no minors are involved. These inspections involve adult inspectors who look for violations such as: banned self-service racks, banned vending machines, banned single cigarette sales also known as "loosies", banned advertising of product, such as "lights" or banned characterizing flavors.

The raw data fields of the publicly available data are:

- Retailer Name**
- Street Address City, State, Zip**
- Decision Type** -- (No Violation, Warning Letter or Civil Money Penalty)
- Minor Involved** -- Yes or No
- Sale to Minor** -- Yes or No
- Decision Date** -- The date FDA determined a Decision Type from a previously completed FDA inspection.
- Link** -- a link to either a Warning Letter or a Civil Money Penalty
- Inspection Date** -- for data with violations
- Product & Brand** -- only available for Warning Letter and Civil Money Penalty data.



Data Analysis: This analysis was completed by The We Card Program, Inc. using publicly available raw data posted online at fda.gov. Calculations of Total Compliance Checks and Violation Rate were computed by The We Card Program. Inspections Data: FFY 2011-January 2021, accessed 02/02/21.

**Analysis of FDA Compliance Check Data
FFY 2021 By State through 01/31/2021**

State	FFY 2021 TOTAL ALL TYPES OF INSPECTIONS						FFY 2021 INSPECTIONS Involving a Minor						FFY 2021 INSPECTIONS NOT Involving a Minor					
	Total Compliance Checks	Number of "NO Violations"	Number of Warning Letters	Number of Civil Money Penalties	Number of No-Tobacco-Sale Orders	Violation Rate	Total Compliance Checks	Number of "NO Violations"	Number of Warning Letters	Number of Civil Money Penalties	Number of No-Tobacco-Sale Orders	Violation Rate	Total Compliance Checks	Number of "NO Violations"	Number of Warning Letters	Number of Civil Money Penalties	Number of No-Tobacco-Sale Orders	Violation Rate
1 AK	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0	
2 AL	55	55	0	0	0	0.00%	51	51	0	0	0	0.00%	4	4	0	0	0	0.00%
3 AR	4	4	0	0	0	0.00%	1	1	0	0	0	0.00%	3	3	0	0	0	0.00%
4 AZ	16	15	0	1	0	6.25%	16	15	0	1	0	6.25%	0	0	0	0	0	
5 CA	116	114	2	0	0	1.72%	33	31	2	0	0	6.06%	83	83	0	0	0	0.00%
6 CO	147	147	0	0	0	0.00%	4	4	0	0	0	0.00%	143	143	0	0	0	0.00%
7 CT	15	14	0	1	0	6.67%	1	0	0	1	0	100.00%	14	14	0	0	0	0.00%
8 DC	14	14	0	0	0	0.00%	12	12	0	0	0	0.00%	2	2	0	0	0	0.00%
9 DE	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0	
10 FL	195	195	0	0	0	0.00%	143	143	0	0	0	0.00%	52	52	0	0	0	0.00%
11 GA	53	53	0	0	0	0.00%	0	0	0	0	0		53	53	0	0	0	0.00%
12 HI	40	40	0	0	0	0.00%	5	5	0	0	0	0.00%	35	35	0	0	0	0.00%
13 IA	12	12	0	0	0	0.00%	0	0	0	0	0		12	12	0	0	0	0.00%
14 ID	14	14	0	0	0	0.00%	3	3	0	0	0	0.00%	11	11	0	0	0	0.00%
15 IL	42	42	0	0	0	0.00%	25	25	0	0	0	0.00%	17	17	0	0	0	0.00%
16 IN	3	3	0	0	0	0.00%	0	0	0	0	0		3	3	0	0	0	0.00%
17 KS	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0	
18 KY	17	17	0	0	0	0.00%	10	10	0	0	0	0.00%	7	7	0	0	0	0.00%
19 LA	32	32	0	0	0	0.00%	25	25	0	0	0	0.00%	7	7	0	0	0	0.00%
20 MA	3	2	0	1	0	33.33%	1	0	0	1	0	100.00%	2	2	0	0	0	0.00%
21 MD	5	5	0	0	0	0.00%	0	0	0	0	0		5	5	0	0	0	0.00%
22 ME	8	8	0	0	0	0.00%	0	0	0	0	0		8	8	0	0	0	0.00%
23 MI	66	66	0	0	0	0.00%	38	38	0	0	0	0.00%	28	28	0	0	0	0.00%
24 MN	37	37	0	0	0	0.00%	11	11	0	0	0	0.00%	26	26	0	0	0	0.00%
25 MO	5	5	0	0	0	0.00%	0	0	0	0	0		5	5	0	0	0	0.00%
26 MS	31	31	0	0	0	0.00%	16	16	0	0	0	0.00%	15	15	0	0	0	0.00%
27 MT	64	64	0	0	0	0.00%	0	0	0	0	0		64	64	0	0	0	0.00%
28 NC	56	56	0	0	0	0.00%	56	56	0	0	0	0.00%	0	0	0	0	0	
29 ND	53	53	0	0	0	0.00%	14	14	0	0	0	0.00%	39	39	0	0	0	0.00%
30 NE	32	32	0	0	0	0.00%	7	7	0	0	0	0.00%	25	25	0	0	0	0.00%
31 NH	22	22	0	0	0	0.00%	0	0	0	0	0		22	22	0	0	0	0.00%
32 NJ	10	9	0	1	0	10.00%	7	6	0	1	0	14.29%	3	3	0	0	0	0.00%
33 NM	1	0	0	1	0	100.00%	1	0	0	1	0	100.00%	0	0	0	0	0	
34 NV	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0	
35 NY	104	103	0	1	0	0.96%	72	71	0	1	0	1.39%	32	32	0	0	0	0.00%
36 OH	66	66	0	0	0	0.00%	39	39	0	0	0	0.00%	27	27	0	0	0	0.00%
37 OK	17	17	0	0	0	0.00%	5	5	0	0	0	0.00%	12	12	0	0	0	0.00%
38 OR	12	12	0	0	0	0.00%	4	4	0	0	0	0.00%	8	8	0	0	0	0.00%
39 PA	35	34	0	1	0	2.86%	12	11	0	1	0	8.33%	23	23	0	0	0	0.00%
40 RI	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0	
41 SC	55	55	0	0	0	0.00%	55	55	0	0	0	0.00%	0	0	0	0	0	
42 SD	42	42	0	0	0	0.00%	7	7	0	0	0	0.00%	35	35	0	0	0	0.00%
43 TN	20	19	0	1	0	5.00%	19	18	0	1	0	5.26%	1	1	0	0	0	0.00%
44 TX	121	121	0	0	1	0.00%	5	5	0	0	1	0.00%	116	116	0	0	0	0.00%
45 UT	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0	
46 VA	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0	
47 VT	140	140	0	0	0	0.00%	0	0	0	0	0		140	140	0	0	0	0.00%
48 WA	89	89	0	0	0	0.00%	25	25	0	0	0	0.00%	64	64	0	0	0	0.00%
49 WI	14	14	0	0	0	0.00%	10	10	0	0	0	0.00%	4	4	0	0	0	0.00%
50 WV	57	57	0	0	0	0.00%	0	0	0	0	0		57	57	0	0	0	0.00%
51 WY	7	7	0	0	0	0.00%	3	3	0	0	0	0.00%	4	4	0	0	0	0.00%
TOTAL	1,947	1,937	2	8	1	0.51%	736	726	2	8	1	1.36%	1,211	1,211	0	0	0	0.00%

We Card's Analysis of FDA Compliance Check Data FFY 2021 - October 2020 to September 2021

through 1-31-21

SUMMARY

By PRODUCT TYPE

Product Type	Warning Letter	%	Civil Money Penalty		Grand Total	%	% of Overall Violation Rate	
			Penalty	%				
Cigar(s)	0		5	62.50%	5	62.50%	0.26%	
Cigarette tobacco	0		0	0.00%	0	0.00%	0.00%	
Cigarettes in a package	0		1	12.50%	1	12.50%	0.05%	
ENDS / E-liquid	0		2	25.00%	2	25.00%	0.10%	
N/A	0		0	0.00%	0	0.00%	0.00%	
Single cigarette	0		0	0.00%	0	0.00%	0.00%	
Smokeless tobacco	0		0	0.00%	0	0.00%	0.00%	
Grand Total	0		8	100.00%	8	100.00%	0.41%	

By PRODUCT TYPE & BRAND

Product Type	Brand	Warning Letter	%	Civil Money Penalty		Grand Total	%	% Of ALL
				Penalty	%			
Cigar(s)	Black & Mild			1	20.00%	1	20.00%	
Cigar(s)	Other			1	20.00%	1	20.00%	
Cigar(s)	Game			2	40.00%	2	40.00%	
Cigar(s)	Swisher			1	20.00%	1	20.00%	
Cigar(s)					0.00%	0	0.00%	
Cigar(s)					0.00%	0	0.00%	
Cigar(s)					0.00%	0	0.00%	
Cigar(s) Total		0		5	100.00%	5	100.00%	62.50%
Cigarette tobacco	Other					0		0.00%
Cigarettes in a package	Newport			1	100.00%	1	100.00%	
Cigarettes in a package					0.00%	0	0.00%	
Cigarettes in a package					0.00%	0	0.00%	
Cigarettes in a package					0.00%	0	0.00%	
Cigarettes in a package					0.00%	0	0.00%	
Cigarettes in a package					0.00%	0	0.00%	
Cigarettes in a package					0.00%	0	0.00%	
Cigarettes in a package Total		0		1	100.00%	1	100.00%	12.50%
ENDS / E-liquid	Other			1	50.00%	1	50.00%	
ENDS / E-liquid	JUUL			1	50.00%	1	50.00%	
ENDS / E-liquid					0.00%	0	0.00%	
ENDS / E-liquid					0.00%	0	0.00%	
ENDS / E-liquid					0.00%	0	0.00%	
ENDS / E-liquid					0.00%	0	0.00%	
ENDS / E-liquid Total		0		2	100.00%	2	100.00%	25.00%
N/A						0		0.00%
Single cigarette						0		0.00%
Smokeless tobacco						0		0.00%
Smokeless tobacco						0		0.00%
Smokeless tobacco						0		0.00%
Smokeless tobacco						0		0.00%
Smokeless tobacco						0		0.00%
Smokeless tobacco						0		0.00%
Smokeless tobacco						0		0.00%
Smokeless tobacco Total		0		0	0.00%	0	0.00%	0.00%
Grand Total		0		8	100.00%	8	100.00%	



Highlights of Oct 2020-September 2021 - FFY2021

1,947 Total Compliance Checks
1,937 # of Compliance Checks with NO VIOLATIONS

2 # of Warning Letters (WL)
8 # of Civil Money Penalties (CMP)

10 Total of WL and CMP

0.51% Calculated Violation Rate

- Violations of CIGAR products sold to minors represent 63% of all violations.
- Violations of CIGARETTES IN A PACKAGE products sold to minors represent more than 13% of all violations.
- Violations of ENDS / E-liquid products sold to minors represent less than 25% of all violations
- Violations of SMOKELESS TOBACCO products sold to minors represent less than 0% of all violations
- Violations of SINGLE CIGARETTE products (LOOSIES) represent 0.00% of all violations

Important Unknowns about the publicly available FDA enforcement Data

- An Important 'unknown' are the Products and Brands associated with the 1,937 compliance checks with NO VIOLATIONS. In other words, the data is not available, and therefore, we don't know if one product type or another (or brand) is associated with higher or lower NO VIOLATIONS.
- FDA has indicated (in We Card's Sept 20, 2018 meeting with FDA CTP Director and CTP staff), that it is left up to the States (who sub-contract with FDA to perform the compliance checks) to decide what Products and which Brands are requested by the minors involved in the compliance checks. Therefore, the Products and Brands requested by minors may vary widely amongst the states. We Card is aware that some states specify to the minors what products and brands to attempt to purchase and others do not.