

SUMMARY Analysis of FDA Compliance Check Data

FFY 2011-2021
through 09/30/2021

FDA Inspection Type	Year	Total Compliance Checks	Number of "NO Violations"	Number of Warning Letters	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	20,472	18,599	1,863	10	1	9.15%
		914,979	800,757	89,171	25,051	168	12.48%
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	7,771	7,766	4	1	0	0.06%
		286,137	280,974	5,157	6	0	1.80%
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	28,243	26,365	1,867	11	1	6.65%
		1,201,116	1,081,731	94,328	25,057	168	9.94%

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 Pen)
- 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 D FFY 2011-September 2021, accessed 10/14/21.

**Analysis of FDA Compliance Check Data
FFY 2021 By State through 09/30/2021**

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	609	577	32	0	0	5.25%	591	559	32	0	0	5.41%	18	18	0	0	0	0.00%
3 AR	924	891	33	0	0	3.57%	702	669	33	0	0	4.70%	222	222	0	0	0	0.00%
4 AZ	385	360	24	1	0	6.49%	287	262	24	1	0	8.71%	98	98	0	0	0	0.00%
5 CA	1,338	1,238	100	0	0	7.47%	1,100	1,000	100	0	0	9.09%	238	238	0	0	0	0.00%
6 CO	1,027	964	63	0	0	6.13%	643	580	63	0	0	9.80%	384	384	0	0	0	0.00%
7 CT	237	202	34	1	0	14.77%	108	73	34	1	0	32.41%	129	129	0	0	0	0.00%
8 DC	33	24	9	0	0	27.27%	31	22	9	0	0	29.03%	2	2	0	0	0	0.00%
9 DE	291	276	15	0	0	5.15%	209	194	15	0	0	7.18%	82	82	0	0	0	0.00%
10 FL	1,758	1,457	301	0	0	17.12%	1,605	1,304	301	0	0	18.75%	153	153	0	0	0	0.00%
11 GA	1,117	1,107	10	0	0	0.90%	809	799	10	0	0	1.24%	308	308	0	0	0	0.00%
12 HI	411	399	12	0	0	2.92%	251	240	11	0	0	4.38%	160	159	1	0	0	0.63%
13 IA	1,171	1,101	70	0	0	5.98%	978	909	69	0	0	7.06%	193	192	1	0	0	0.52%
14 ID	479	461	18	0	0	3.76%	327	309	18	0	0	5.50%	152	152	0	0	0	0.00%
15 IL	1,750	1,550	200	0	0	11.43%	1,404	1,205	199	0	0	14.17%	346	345	1	0	0	0.29%
16 IN	126	118	8	0	0	6.35%	81	73	8	0	0	9.88%	45	45	0	0	0	0.00%
17 KS	622	601	21	0	0	3.38%	452	431	21	0	0	4.65%	170	170	0	0	0	0.00%
18 KY	1,010	953	57	0	0	5.64%	824	767	57	0	0	6.92%	186	186	0	0	0	0.00%
19 LA	358	331	27	0	0	7.54%	140	113	27	0	0	19.29%	218	218	0	0	0	0.00%
20 MA	550	536	13	1	0	2.55%	548	534	13	1	0	2.55%	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	227	225	2	0	0	0.88%	189	187	2	0	0	1.06%	38	38	0	0	0	0.00%
23 MI	451	348	103	0	0	22.84%	369	266	103	0	0	27.91%	82	82	0	0	0	0.00%
24 MN	980	958	22	0	0	2.24%	728	706	22	0	0	3.02%	252	252	0	0	0	0.00%
25 MO	1,043	970	73	0	0	7.00%	795	722	73	0	0	9.18%	248	248	0	0	0	0.00%
26 MS	1,020	988	32	0	0	3.14%	757	725	32	0	0	4.23%	263	263	0	0	0	0.00%
27 MT	1,382	1,368	14	0	0	1.01%	1,058	1,044	14	0	0	1.32%	324	324	0	0	0	0.00%
28 NC	262	242	19	1	0	7.63%	133	114	19	0	0	14.29%	129	128	0	1	0	0.78%
29 ND	175	171	4	0	0	2.29%	115	111	4	0	0	3.48%	60	60	0	0	0	0.00%
30 NE	363	345	18	0	0	4.96%	247	229	18	0	0	7.29%	116	116	0	0	0	0.00%
31 NH	167	151	16	0	0	9.58%	80	64	16	0	0	20.00%	87	87	0	0	0	0.00%
32 NJ	81	80	0	1	0	1.23%	73	72	0	1	0	1.37%	8	8	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	229	216	13	0	0	5.68%	162	149	13	0	0	8.02%	67	67	0	0	0	0.00%
35 NY	884	824	59	1	0	6.79%	619	559	59	1	0	9.69%	265	265	0	0	0	0.00%
36 OH	750	650	99	1	0	13.33%	591	491	99	1	0	16.92%	159	159	0	0	0	0.00%
37 OK	24	24	0	0	0	0.00%	9	9	0	0	0	0.00%	15	15	0	0	0	0.00%
38 OR	18	18	0	0	0	0.00%	6	6	0	0	0	0.00%	12	12	0	0	0	0.00%
39 PA	132	131	0	1	0	0.76%	60	59	0	1	0	1.67%	72	72	0	0	0	0.00%
40 RI	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0	
41 SC	363	332	31	0	0	8.54%	204	173	31	0	0	15.20%	159	159	0	0	0	0.00%
42 SD	268	262	6	0	0	2.24%	55	49	6	0	0	10.91%	213	213	0	0	0	0.00%
43 TN	447	411	35	1	0	8.05%	220	184	35	1	0	16.36%	227	227	0	0	0	0.00%
44 TX	1,228	1,158	70	0	1	5.70%	786	716	70	0	1	8.91%	442	442	0	0	0	0.00%
45 UT	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0	
46 VA	275	262	13	0	0	4.73%	58	46	12	0	0	20.69%	217	216	1	0	0	0.46%
47 VT	731	717	13	1	0	1.92%	276	262	13	1	0	5.07%	455	455	0	0	0	0.00%
48 WA	1,105	1,004	101	0	0	9.14%	698	597	101	0	0	14.47%	407	407	0	0	0	0.00%
49 WI	191	182	9	0	0	4.71%	184	175	9	0	0	4.89%	7	7	0	0	0	0.00%
50 WV	1,237	1,169	68	0	0	5.50%	906	838	68	0	0	7.51%	331	331	0	0	0	0.00%
51 WY	8	8	0	0	0	0.00%	3	3	0	0	0	0.00%	5	5	0	0	0	0.00%
TOTAL	28,243	26,365	1,867	11	1	6.65%	20,472	18,599	1,863	10	1	9.15%	7,771	7,766	4	1	0	0.06%

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

**SUMMARY
By PRODUCT TYPE**

Product Type	Warning		Civil Money		Grand Total	%	% of Overall	
	Letter	%	Penalty	%			Violation Rate	
Cigar(s)	393	21.05%	6	54.55%	399	21.25%		1.41%
Cigarette tobacco	1		0	0.00%	1	0.05%		0.00%
Cigarettes in a package	427		1	9.09%	428	22.79%		1.52%
ENDS / E-liquid	1,006		2	18.18%	1,008	53.67%		3.57%
N/A	4		1	9.09%	5	0.27%		0.02%
Single cigarette	4		0	0.00%	4	0.21%		0.01%
<u>Smokeless tobacco</u>	<u>32</u>		<u>1</u>	<u>9.09%</u>	<u>33</u>	<u>1.76%</u>		<u>0.12%</u>
Grand Total	1,867		11	100.00%	1,878	100.00%		6.65%



By PRODUCT TYPE & BRAND

Product Type	Brand	Warning		Civil Money		Grand Total	%	% Of All
		Letter	%	Penalty	%			
Cigar(s)	Swisher	234	59.54%	2	33.33%	236	59.15%	
Cigar(s)	Other	61	15.52%	1	16.67%	62	15.54%	
Cigar(s)	Black & Mild	58	14.76%	1	16.67%	59	14.79%	
Cigar(s)	White Owl	25	6.36%		0.00%	25	6.27%	
Cigar(s)	Game	15	3.82%	2	33.33%	17	4.26%	
Cigar(s)			0.00%		0.00%	0	0.00%	
Cigar(s)			0.00%		0.00%	0	0.00%	
Cigar(s) Total		393	100.00%	6	100.00%	399	100.00%	21.25%
Cigarette tobacco	TOP			1		1		0.05%
Cigarettes in a package	Marlboro	250	58.55%		0.00%	250	58.41%	
Cigarettes in a package	Camel	78	18.27%		0.00%	78	18.22%	
Cigarettes in a package	Newport	72	16.86%	1	100.00%	73	17.06%	
Cigarettes in a package	Other	14	3.28%		0.00%	14	3.27%	
Cigarettes in a package	Kool	5	1.17%		0.00%	5	1.17%	
Cigarettes in a package	Pall Mall	5	1.17%		0.00%	5	1.17%	
Cigarettes in a package	Decade	2	0.47%		0.00%	2	0.47%	
Cigarettes in a package	Winston	1	0.23%		0.00%	1	0.23%	
Cigarettes in a package Total		427	100.00%	1	100.00%	428	100.00%	22.79%
ENDS / E-liquid	Other	522	51.89%	1	50.00%	523	51.88%	
ENDS / E-liquid	JUUL	318	31.61%	1	50.00%	319	31.65%	
ENDS / E-liquid	Vuse	120	11.93%		0.00%	120	11.90%	
ENDS / E-liquid	blu	38	3.78%		0.00%	38	3.77%	
ENDS / E-liquid	NJOY	7	0.70%		0.00%	7	0.69%	
ENDS / E-liquid	Logic	1	0.10%		0.00%	1	0.10%	
ENDS / E-liquid			0.00%		0.00%	0	0.00%	
ENDS / E-liquid Total		1,006	100.00%	2	100.00%	1,008	100.00%	53.67%
N/A		4		1		5		0.27%
Single cigarette		4				4		0.21%
Smokeless tobacco	Grizzly	12	1.19%	1	100.00%	13	1.29%	
Smokeless tobacco	Copenhagen	10	0.99%		0.00%	10	0.99%	
Smokeless tobacco	Longhorn	4	0.40%		0.00%	4	0.40%	
Smokeless tobacco	Other	2	0.20%		0.00%	2	0.20%	
Smokeless tobacco	Kodiak	1	0.10%		0.00%	1	0.10%	
Smokeless tobacco	Skool	1	0.10%		0.00%	1	0.10%	
Smokeless tobacco	Stokers	1	0.10%		0.00%	1	0.10%	
Smokeless tobacco	Timber Wolf	1	0.10%		0.00%	1	0.10%	
Smokeless tobacco			0.00%		0.00%	0	0.00%	
Smokeless tobacco Total		32	3.18%	1	100.00%	33	3.27%	1.76%
Grand Total		1,867		11		1,878		100.00%

Highlights of Oct 2020-September 2021 - FFY2021

28,243 Total Compliance Checks
 26,365 # of Compliance Checks with NO VIOLATIONS

1,867 # of Warning Letters (WL)
11 # of Civil Money Penalties (CMP)

1,878 Total of WL and CMP

6.65% Calculated Violation Rate

- Violations of CIGAR products sold to minors represent 21% of all violations.
- Violations of CIGARETTES IN A PACKAGE products sold to minors represent more than 23% of all violations.
- Violations of ENDS / E-liquid products sold to minors represent less than 54% of all violations
- Violations of SMOKELESS TOBACCO products sold to minors represent less than 2% of all violations
- Violations of SINGLE CIGARETTE products (LOOSIES) represent 0.21% of all violations

Important Unknowns about the publicly available FDA enforcement Data

- An Important 'unknown' are the Products and Brands associated with the 26,365 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.