

**SUMMARY Analysis of FDA Compliance Check Data**

**FFY 2011-2022**  
through 03/31/2022

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
<b>Where Minors were involved.</b> (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	22,785	18,728	4,047	10	1	17.81%
	FFY2022	40,031	33,878	6,009	144	0	15.37%
		<b>957,323</b>	<b>834,764</b>	<b>97,364</b>	<b>25,195</b>	<b>168</b>	<b>12.80%</b>
<b>Adult Inspectors Only</b> (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		0	5.64%
	FFY2021	7,780	7,767	12		0	0.17%
	FFY2022	73	73	0		0	0.00%
		<b>286,219</b>	<b>281,048</b>	<b>5,165</b>	<b>6</b>	<b>0</b>	<b>1.81%</b>
<b>TOTAL</b>	FFY2011	24,404	23,381	1,022		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	30,565	26,495	4,059	11	1	13.32%
	FFY2022	40,104	33,951	6,009	144	0	15.34%
		<b>1,243,542</b>	<b>1,115,812</b>	<b>102,529</b>	<b>25,201</b>	<b>168</b>	<b>10.27%</b>

**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-March 2022, accessed 04/13/22.

**Analysis of FDA Compliance Check Data  
FFY 2022 By State through 03/31/2022**

State	FFY 2022 TOTAL ALL TYPES OF INSPECTIONS						FFY 2022 INSPECTIONS Involving a Minor						FFY 2022 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	0	0
2 AL	357	347	10	0	0	2.80%	355	345	10	0	0	2.82%	2	2	0	0	0	0.00%
3 AR	907	867	38	2	0	4.41%	907	867	38	2	0	4.41%	0	0	0	0	0	0
4 AZ	594	501	93	0	0	15.66%	593	500	93	0	0	15.68%	1	1	0	0	0	0.00%
5 CA	1,323	1,182	131	10	0	10.66%	1,320	1,179	131	10	0	10.68%	3	3	0	0	0	0.00%
6 CO	1,040	917	118	5	0	11.83%	1,039	916	118	5	0	11.84%	1	1	0	0	0	0.00%
7 CT	938	664	261	13	0	29.21%	937	663	261	13	0	29.24%	1	1	0	0	0	0.00%
8 DC	6	6	0	0	0	0.00%	6	6	0	0	0	0.00%	0	0	0	0	0	0
9 DE	316	277	37	2	0	12.34%	316	277	37	2	0	12.34%	0	0	0	0	0	0
10 FL	2,440	1,729	696	15	0	29.14%	2,435	1,724	696	15	0	29.20%	5	5	0	0	0	0.00%
11 GA	1,286	1,284	2	0	0	0.16%	1,282	1,280	2	0	0	0.16%	4	4	0	0	0	0.00%
12 HI	213	205	8	0	0	3.76%	213	205	8	0	0	3.76%	0	0	0	0	0	0
13 IA	1,048	957	86	5	0	8.68%	1,048	957	86	5	0	8.68%	0	0	0	0	0	0
14 ID	439	423	16	0	0	3.64%	432	416	16	0	0	3.70%	7	7	0	0	0	0.00%
15 IL	2,370	1,923	445	2	0	18.86%	2,364	1,917	445	2	0	18.91%	6	6	0	0	0	0.00%
16 IN	675	579	93	3	0	14.22%	675	579	93	3	0	14.22%	0	0	0	0	0	0
17 KS	710	668	42	0	0	5.92%	707	665	42	0	0	5.94%	3	3	0	0	0	0.00%
18 KY	1,567	1,415	151	1	0	9.70%	1,567	1,415	151	1	0	9.70%	0	0	0	0	0	0
19 LA	389	249	140	0	0	35.99%	382	242	140	0	0	36.65%	7	7	0	0	0	0.00%
20 MA	1,788	1,546	242	0	0	13.53%	1,788	1,546	242	0	0	13.53%	0	0	0	0	0	0
21 MD	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22 ME	514	500	14	0	0	2.72%	514	500	14	0	0	2.72%	0	0	0	0	0	0
23 MI	993	756	232	5	0	23.87%	992	755	232	5	0	23.89%	1	1	0	0	0	0.00%
24 MN	2,275	1,997	272	6	0	12.22%	2,274	1,996	272	6	0	12.23%	1	1	0	0	0	0.00%
25 MO	1,421	1,247	163	11	0	12.24%	1,418	1,244	163	11	0	12.27%	3	3	0	0	0	0.00%
26 MS	1,598	1,464	131	3	0	8.39%	1,596	1,462	131	3	0	8.40%	2	2	0	0	0	0.00%
27 MT	227	220	7	0	0	3.08%	227	220	7	0	0	3.08%	0	0	0	0	0	0
28 NC	1,429	1,143	276	10	0	20.01%	1,428	1,142	276	10	0	20.03%	1	1	0	0	0	0.00%
29 ND	49	44	5	0	0	10.20%	47	42	5	0	0	10.64%	2	2	0	0	0	0.00%
30 NE	270	250	18	2	0	7.41%	270	250	18	2	0	7.41%	0	0	0	0	0	0
31 NH	193	154	37	2	0	20.21%	192	153	37	2	0	20.31%	1	1	0	0	0	0.00%
32 NJ	1,270	941	326	3	0	25.91%	1,268	939	326	3	0	25.95%	2	2	0	0	0	0.00%
33 NM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
34 NV	38	29	8	1	0	23.68%	38	29	8	1	0	23.68%	0	0	0	0	0	0
35 NY	1,586	1,261	325	0	0	20.49%	1,578	1,253	325	0	0	20.60%	8	8	0	0	0	0.00%
36 OH	1,246	989	257	0	0	20.63%	1,246	989	257	0	0	20.63%	0	0	0	0	0	0
37 OK	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
38 OR	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
39 PA	768	616	151	1	0	19.79%	767	615	151	1	0	19.82%	1	1	0	0	0	0.00%
40 RI	505	424	77	4	0	16.04%	505	424	77	4	0	16.04%	0	0	0	0	0	0
41 SC	1,158	940	214	4	0	18.83%	1,154	936	214	4	0	18.89%	4	4	0	0	0	0.00%
42 SD	145	117	28	0	0	19.31%	145	117	28	0	0	19.31%	0	0	0	0	0	0
43 TN	360	272	85	3	0	24.44%	356	268	85	3	0	24.72%	4	4	0	0	0	0.00%
44 TX	1,764	1,539	209	16	0	12.76%	1,763	1,538	209	16	0	12.76%	1	1	0	0	0	0.00%
45 UT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
46 VA	156	127	29	0	0	18.59%	156	127	29	0	0	18.59%	0	0	0	0	0	0
47 VT	238	215	23	0	0	9.66%	238	215	23	0	0	9.66%	0	0	0	0	0	0
48 WA	1,468	1,187	274	7	0	19.14%	1,467	1,186	274	7	0	19.15%	1	1	0	0	0	0.00%
49 WI	824	671	153	0	0	18.57%	823	670	153	0	0	18.59%	1	1	0	0	0	0.00%
50 WV	1,203	1,109	86	8	0	7.81%	1,203	1,109	86	8	0	7.81%	0	0	0	0	0	0
51 WY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>TOTAL</b>	<b>40,104</b>	<b>33,951</b>	<b>6,009</b>	<b>144</b>	<b>0</b>	<b>15.34%</b>	<b>40,031</b>	<b>33,878</b>	<b>6,009</b>	<b>144</b>	<b>0</b>	<b>15.37%</b>	<b>73</b>	<b>73</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0.00%</b>

### Analysis of FDA Compliance Check Data

#### FFY 2022 By Month

as of 03/31/2022

		FFY 2022 TOTAL ALL TYPES OF INSPECTIONS					FFY 2022 INSPECTIONS <i>Involving a Minor</i>					FFY 2022 INSPECTIONS <i>NOT Involving a Minor</i>				
Year	Month	Total Compliance Checks	Number of "NO Violations"	Number of Warning Letters	Number of Civil Money Penalties	Violation Rate	Total Compliance Checks	Number of "NO Violations"	Number of Warning Letters	Number of Civil Money Penalties	Violation Rate	Total Compliance Checks	Number of "NO Violations"	Number of Warning Letters	Number of Civil Money Penalties	Violation Rate
2021	Oct	5,870	4,755	1,115	0	18.99%	5,840	4,725	1,115	0	19.09%	30	30	0	0	0.00%
2021	Nov	6,216	5,086	1,130	0	18.18%	6,206	5,076	1,130	0	18.21%	10	10	0	0	0.00%
2021	Dec	6,777	5,482	1,294	1	19.11%	6,765	5,470	1,294	1	19.14%	12	12	0	0	0.00%
2022	Jan	6,761	5,417	1,339	5	19.88%	6,753	5,409	1,339	5	19.90%	8	8	0	0	0.00%
2022	Feb	7,294	6,112	1,130	52	16.21%	7,285	6,103	1,130	52	16.23%	9	9	0	0	0.00%
2022	Mar	7,186	7,099	1	86	1.21%	7,182	7,095	1	86	1.21%	4	4	0	0	0.00%
2022	Apr	0	0	0	0		0	0	0	0		0	0	0	0	
2022	May	0	0	0	0		0	0	0	0		0	0	0	0	
2022	Jun	0	0	0	0		0	0	0	0		0	0	0	0	
2022	Jul	0	0	0	0		0	0	0	0		0	0	0	0	
2022	Aug	0	0	0	0		0	0	0	0		0	0	0	0	
2022	Sep	0	0	0	0		0	0	0	0		0	0	0	0	
<b>TOTAL</b>		<b>40,104</b>	<b>33,951</b>	<b>6,009</b>	<b>144</b>	<b>15.34%</b>	<b>40,031</b>	<b>33,878</b>	<b>6,009</b>	<b>144</b>	<b>15.37%</b>	<b>73</b>	<b>73</b>	<b>0</b>	<b>0</b>	<b>0.00%</b>

**We Card's Analysis of FDA Compliance Check Data  
FFY 2022 - October 2021 to September 2022**

as of 3/31/22

**SUMMARY  
By PRODUCT TYPE**

Product Type	Warning		Civil Money Penalty		Grand Total	%	% of Overall Violation Rate
	Letter	%	Penalty	%			
Cigar(s)	2,632	43.85%	65	45.14%	2,697	43.88%	6.73%
Cigarette tobacco	2	0.03%	0	0.00%	2	0.03%	0.00%
garettes in a package	1,586	26.42%	34	23.61%	1,620	26.36%	4.04%
ENDS / E-liquid	1,674	27.89%	43	29.86%	1,717	27.94%	4.28%
N/A	8	0.13%	0	0.00%	8	0.13%	0.02%
Single cigarette	9	0.15%	1	0.69%	10	0.16%	0.02%
Smokeless tobacco	91	1.52%	1	0.69%	92	1.50%	0.23%
<b>Grand Total</b>	<b>6,002</b>	<b>100.00%</b>	<b>144</b>	<b>100.00%</b>	<b>6,146</b>	<b>100.00%</b>	<b>15.33%</b>



**By PRODUCT TYPE & BRAND**

Product Type	Brand	Warning		Civil Money Penalty		Grand Total	%	% Of ALL
		Letter	%	Penalty	%			
Cigar(s)	Swisher	1,301	49.43%	39	60.00%	1,340	49.68%	
Cigar(s)	Black & Mild	419	15.92%	11	16.92%	430	15.94%	
Cigar(s)	Other	395	15.01%	4	6.15%	399	14.79%	
Cigar(s)	Game	310	11.78%	7	10.77%	317	11.75%	
Cigar(s)	White Owl	204	7.75%	4	6.15%	208	7.71%	
Cigar(s)	Phillies	3	0.11%		0.00%	3	0.11%	
Cigar(s)			0.00%		0.00%	0	0.00%	
<b>Cigar(s) Total</b>		<b>2,632</b>	<b>100.00%</b>	<b>65</b>	<b>100.00%</b>	<b>2,697</b>	<b>100.00%</b>	<b>43.88%</b>
Cigarette tobacco		2				2		0.03%
Cigarettes in a package	Marlboro	801	50.50%	23	67.65%	824	50.86%	
Cigarettes in a package	Newport	523	32.98%	6	17.65%	529	32.65%	
Cigarettes in a package	Camel	171	10.78%	4	11.76%	175	10.80%	
Cigarettes in a package	Other	60	3.78%	1	2.94%	61	3.77%	
Cigarettes in a package	Pall Mall	12	0.76%		0.00%	12	0.74%	
Cigarettes in a package	Kool	9	0.57%		0.00%	9	0.56%	
Cigarettes in a package	Winston	6	0.38%		0.00%	6	0.37%	
Cigarettes in a package	Decade	4	0.25%		0.00%	4	0.25%	
<b>Cigarettes in a package Total</b>		<b>1,586</b>	<b>100.00%</b>	<b>34</b>	<b>100.00%</b>	<b>1,620</b>	<b>100.00%</b>	<b>26.36%</b>
ENDS / E-liquid	JUUL	713	42.59%	23	53.49%	736	42.87%	
ENDS / E-liquid	Other	554	33.09%	11	25.58%	565	32.91%	
ENDS / E-liquid	Vuse	329	19.65%	8	18.60%	337	19.63%	
ENDS / E-liquid	blu	53	3.17%	1	2.33%	54	3.15%	
ENDS / E-liquid	Logic	19	1.14%		0.00%	19	1.11%	
ENDS / E-liquid	NJOY	6	0.36%		0.00%	6	0.35%	
ENDS / E-liquid			0.00%		0.00%	0	0.00%	
<b>ENDS / E-liquid Total</b>		<b>1,674</b>	<b>100.00%</b>	<b>43</b>	<b>100.00%</b>	<b>1,717</b>	<b>100.00%</b>	<b>27.94%</b>
N/A		8				8		0.13%
Single cigarette		9		1		10		0.16%
Smokeless tobacco	Grizzly	44	2.63%		0.00%	44	2.56%	
Smokeless tobacco	Copenhagen	25	1.49%		0.00%	25	1.46%	
Smokeless tobacco	Skool	7	0.42%		0.00%	7	0.41%	
Smokeless tobacco	Other	6	0.36%		0.00%	6	0.35%	
Smokeless tobacco	Red Seal	5	0.30%		0.00%	5	0.29%	
Smokeless tobacco	Longhorn	4	0.24%	1	100.00%	5	0.29%	
Smokeless tobacco			0.00%		0.00%	0	0.00%	
Smokeless tobacco			0.00%		0.00%	0	0.00%	
Smokeless tobacco			0.00%		0.00%	0	0.00%	
<b>Smokeless tobacco Total</b>		<b>91</b>	<b>5.44%</b>	<b>1</b>	<b>100.00%</b>	<b>92</b>	<b>5.36%</b>	<b>1.50%</b>
<b>Grand Total</b>		<b>6,002</b>		<b>144</b>		<b>6,146</b>		<b>100.00%</b>

**Highlights of Oct 2021-September 2022 - FFY2022**

40,104 Total Compliance Checks  
33,951 # of Compliance Checks with NO VIOLATIONS

6,009 # of Warning Letters (WL)  
144 # of Civil Money Penalties (CMP)

6,153 Total of WL and CMP

15.34% Calculated Violation Rate

- Violations of CIGAR products sold to minors represent 44% of all violations.
- Violations of CIGARETTES IN A PACKAGE products sold to minors represent more than 26% of all violations.
- Violations of ENDS / E-liquid products sold to minors represent less than 28% of all violations
- Violations of SMOKELESS TOBACCO products sold to minors represent less than 1% of all violations
- Violations of SINGLE CIGARETTE products (LOOSIES) represent 0.16% of all violations

**Important Unknowns about the publicly available FDA enforcement Data**

- An Important 'unknown' are the Products and Brands associated with the 33,951 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.