

**SUMMARY Analysis of FDA Compliance Check Data**

**FFY 2011-2022**  
through 07/31/2022

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	73,058	60,766	11,404	888	0	16.82%
		<b>990,350</b>	<b>861,652</b>	<b>102,759</b>	<b>25,939</b>	<b>168</b>	<b>13.00%</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	1	0	5.64%
	FFY2021	7,780	7,767	12	1	0	0.17%
	FFY2022	113	112	1	0	0	0.88%
		<b>286,259</b>	<b>281,087</b>	<b>5,166</b>	<b>6</b>	<b>0</b>	<b>1.81%</b>
<b>TOTAL</b>	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	30,565	26,495	4,059	11	1	13.32%
	FFY2021	73,171	60,878	11,405	888	0	16.80%
		<b>1,276,609</b>	<b>1,142,739</b>	<b>107,925</b>	<b>25,945</b>	<b>168</b>	<b>10.49%</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 publically available raw data posted online at [fda.gov](http://fda.gov). Calculations of Total Compliance Checks and Violation Rate were computed by The We Card Program. Inspections Data FFY 2011-July 2022, accessed 08/14/22.

**Analysis of FDA Compliance Check Data  
FFY 2022 By State through 07/31/2022**

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	
2 AL	1,522	1,424	97	1	0	6.44%	1,520	1,422	97	1	0	6.45%	2	2	0	0	0	0.00%
3 AR	1,814	1,722	80	12	0	5.07%	1,814	1,722	80	12	0	5.07%	0	0	0	0	0	0.00%
4 AZ	995	852	142	1	0	14.37%	994	851	142	1	0	14.39%	1	1	0	0	0	0.00%
5 CA	2,334	2,069	239	26	0	11.35%	2,331	2,066	239	26	0	11.37%	3	3	0	0	0	0.00%
6 CO	2,100	1,863	206	31	0	11.29%	2,097	1,860	206	31	0	11.30%	3	3	0	0	0	0.00%
7 CT	2,278	1,721	524	33	0	24.45%	2,277	1,720	524	33	0	24.46%	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	0.00%
9 DE	574	507	63	4	0	11.67%	574	507	63	4	0	11.67%	0	0	0	0	0	0.00%
10 FL	4,157	2,862	1,172	123	0	31.15%	4,151	2,856	1,172	123	0	31.20%	6	6	0	0	0	0.00%
11 GA	2,221	2,210	11	0	0	0.50%	2,216	2,205	11	0	0	0.50%	5	5	0	0	0	0.00%
12 HI	433	419	13	1	0	3.23%	433	419	13	1	0	3.23%	0	0	0	0	0	0.00%
13 IA	2,326	2,144	152	30	0	7.82%	2,326	2,144	152	30	0	7.82%	0	0	0	0	0	0.00%
14 ID	511	490	21	0	0	4.11%	504	483	21	0	0	4.17%	7	7	0	0	0	0.00%
15 IL	3,865	3,076	717	72	0	20.41%	3,859	3,070	717	72	0	20.45%	6	6	0	0	0	0.00%
16 IN	1,300	1,072	220	8	0	17.54%	1,300	1,072	220	8	0	17.54%	0	0	0	0	0	0.00%
17 KS	1,287	1,199	84	4	0	6.84%	1,284	1,196	84	4	0	6.85%	3	3	0	0	0	0.00%
18 KY	2,867	2,557	304	6	0	10.81%	2,867	2,557	304	6	0	10.81%	0	0	0	0	0	0.00%
19 LA	1,371	949	413	9	0	30.78%	1,364	942	413	9	0	30.94%	7	7	0	0	0	0.00%
20 MA	3,437	2,953	452	32	0	14.08%	3,437	2,953	452	32	0	14.08%	0	0	0	0	0	0.00%
21 MD	613	536	77	0	0	12.56%	611	534	77	0	0	12.60%	2	2	0	0	0	0.00%
22 ME	920	895	24	1	0	2.72%	920	895	24	1	0	2.72%	0	0	0	0	0	0.00%
23 MI	1,968	1,446	482	40	0	26.52%	1,966	1,444	482	40	0	26.55%	2	2	0	0	0	0.00%
24 MN	3,409	2,921	453	35	0	14.32%	3,407	2,919	453	35	0	14.32%	2	2	0	0	0	0.00%
25 MO	2,711	2,287	374	50	0	15.64%	2,707	2,283	374	50	0	15.66%	4	4	0	0	0	0.00%
26 MS	2,404	2,181	206	17	0	9.28%	2,402	2,179	206	17	0	9.28%	2	2	0	0	0	0.00%
27 MT	408	392	14	2	0	3.92%	408	392	14	2	0	3.92%	0	0	0	0	0	0.00%
28 NC	2,241	1,750	458	33	0	21.91%	2,239	1,748	458	33	0	21.93%	2	2	0	0	0	0.00%
29 ND	81	65	16	0	0	19.75%	79	63	16	0	0	20.25%	2	2	0	0	0	0.00%
30 NE	421	377	40	4	0	10.45%	421	377	40	4	0	10.45%	0	0	0	0	0	0.00%
31 NH	389	300	83	6	0	22.88%	387	298	83	6	0	23.00%	2	2	0	0	0	0.00%
32 NJ	2,406	1,714	675	17	0	28.76%	2,397	1,705	675	17	0	28.87%	9	9	0	0	0	0.00%
33 NM	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0	
34 NV	40	29	8	3	0	27.50%	40	29	8	3	0	27.50%	0	0	0	0	0	0.00%
35 NY	2,709	2,062	606	41	0	23.88%	2,698	2,052	605	41	0	23.94%	11	10	1	0	0	9.09%
36 OH	2,418	1,864	536	18	0	22.91%	2,418	1,864	536	18	0	22.91%	0	0	0	0	0	0.00%
37 OK	315	255	60	0	0	19.05%	299	239	60	0	0	20.07%	16	16	0	0	0	0.00%
38 OR	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0	
39 PA	1,479	1,079	393	7	0	27.05%	1,478	1,078	393	7	0	27.06%	1	1	0	0	0	0.00%
40 RI	741	633	98	10	0	14.57%	740	632	98	10	0	14.59%	1	1	0	0	0	0.00%
41 SC	1,174	941	227	6	0	19.85%	1,170	937	227	6	0	19.91%	4	4	0	0	0	0.00%
42 SD	158	122	33	3	0	22.78%	158	122	33	3	0	22.78%	0	0	0	0	0	0.00%
43 TN	851	662	185	4	0	22.21%	846	657	185	4	0	22.34%	5	5	0	0	0	0.00%
44 TX	3,128	2,640	386	102	0	15.60%	3,127	2,639	386	102	0	15.61%	1	1	0	0	0	0.00%
45 UT	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0	
46 VA	584	450	134	0	0	22.95%	584	450	134	0	0	22.95%	0	0	0	0	0	0.00%
47 VT	543	498	43	2	0	8.29%	543	498	43	2	0	8.29%	0	0	0	0	0	0.00%
48 WA	2,365	1,871	448	46	0	20.89%	2,364	1,870	448	46	0	20.90%	1	1	0	0	0	0.00%
49 WI	1,548	1,253	281	14	0	19.06%	1,546	1,251	281	14	0	19.08%	2	2	0	0	0	0.00%
50 WV	1,749	1,560	155	34	0	10.81%	1,749	1,560	155	34	0	10.81%	0	0	0	0	0	0.00%
51 WY	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0	
<b>TOTAL</b>	<b>73,171</b>	<b>60,878</b>	<b>11,405</b>	<b>888</b>	<b>0</b>	<b>16.80%</b>	<b>73,058</b>	<b>60,766</b>	<b>11,404</b>	<b>888</b>	<b>0</b>	<b>16.82%</b>	<b>113</b>	<b>112</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0.88%</b>

**Analysis of FDA Compliance Check Data  
FFY 2022 By Month**

Year	Month	FFY 2021 TOTAL ALL TYPES OF INSPECTIONS					FFY 2021 INSPECTIONS <i>Involving a Minor</i>					FFY 2021 INSPECTIONS <i>NOT Involving a Minor</i>				
		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	6,217	5,086	1,131	0	18.19%	6,207	5,076	1,131	0	18.22%	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	6,768	5,417	1,346	5	19.96%	6,760	5,409	1,346	5	19.99%	8	8	0	0	0.00%
2022	Feb	7,600	6,134	1,414	52	19.29%	7,580	6,115	1,413	52	19.33%	20	19	1	0	5.00%
2022	Mar	8,869	7,127	1,656	86	19.64%	8,860	7,118	1,656	86	19.66%	9	9	0	0	0.00%
2022	Apr	8,257	6,749	1,418	90	18.26%	8,251	6,743	1,418	90	18.28%	6	6	0	0	0.00%
2022	May	8,654	7,039	1,466	149	18.66%	8,651	7,036	1,466	149	18.67%	3	3	0	0	0.00%
2022	Jun	7,448	6,662	529	257	10.55%	7,442	6,656	529	257	10.56%	6	6	0	0	0.00%
2022	Jul	6,711	6,427	36	248	4.23%	6,702	6,418	36	248	4.24%	9	9	0	0	0.00%
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>73,171</b>	<b>60,878</b>	<b>11,405</b>	<b>888</b>	<b>16.80%</b>	<b>73,058</b>	<b>60,766</b>	<b>11,404</b>	<b>888</b>	<b>16.82%</b>	<b>113</b>	<b>112</b>	<b>1</b>	<b>0</b>	<b>0.88%</b>

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

as of 7-31-22

### SUMMARY

#### By PRODUCT TYPE

Product Type	Warning		Civil		Grand Total	% of Overall	% of Overall Violation Rate
	Letter	%	Penalty	%			
Cigar(s)	5,046	44.32%	361	40.65%	5,407	44.05%	7.39%
Cigarette tobacco	3	0.03%	0	0.00%	3	0.02%	0.00%
Cigarettes in a package	2,924	25.68%	204	22.97%	3,128	25.48%	4.27%
ENDS / E-liquid	3,209	28.18%	294	33.11%	3,503	28.54%	4.79%
N/A	14	0.12%	7	0.79%	21	0.17%	0.03%
Single cigarette	25	0.22%	3	0.34%	28	0.23%	0.04%
Smokeless tobacco	165	1.45%	19	2.14%	184	1.50%	0.25%
<b>Grand Total</b>	<b>11,386</b>	<b>100.00%</b>	<b>888</b>	<b>100.00%</b>	<b>12,274</b>	<b>100.00%</b>	<b>16.77%</b>



#### By PRODUCT TYPE & BRAND

Product Type	Brand	Warning		Civil		Grand		% Of ALL
		Letter	%	Penalty	%	Total	%	
Cigar(s)	Swisher	2,577	51.07%	201	55.68%	2,778	51.38%	
Cigar(s)	Black & Mild	1,005	19.92%	56	15.51%	1,061	19.62%	
Cigar(s)	Game	613	12.15%	41	11.36%	654	12.10%	
Cigar(s)	Other	521	10.33%	35	9.70%	556	10.28%	
Cigar(s)	White Owl	321	6.36%	28	7.76%	349	6.45%	
Cigar(s)	Phillies	9	0.18%	0	0.00%	9	0.17%	
Cigar(s)			0.00%		0.00%	0	0.00%	
<b>Cigar(s) Total</b>		<b>5,046</b>	<b>100.00%</b>	<b>361</b>	<b>100.00%</b>	<b>5,407</b>	<b>100.00%</b>	<b>44.05%</b>
Cigarette tobacco		3				3		0.02%
Cigarettes in a package	Marlboro	1,378	47.13%	126	61.76%	1,504	48.08%	
Cigarettes in a package	Newport	1,044	35.70%	40	19.61%	1,084	34.65%	
Cigarettes in a package	Camel	318	10.88%	31	15.20%	349	11.16%	
Cigarettes in a package	Other	107	3.66%	7	3.43%	114	3.64%	
Cigarettes in a package	Pall Mall	33	1.13%	0	0.00%	33	1.05%	
Cigarettes in a package	Kool	17	0.58%	0	0.00%	17	0.54%	
Cigarettes in a package	Decade	16	0.55%	0	0.00%	16	0.51%	
Cigarettes in a package	Winston	11	0.38%	0	0.00%	11	0.35%	
<b>Cigarettes in a package Total</b>		<b>2,924</b>	<b>100.00%</b>	<b>204</b>	<b>100.00%</b>	<b>3,128</b>	<b>100.00%</b>	<b>25.48%</b>
ENDS / E-liquid	JUUL	1,329	41.41%	149	50.68%	1,478	42.19%	
ENDS / E-liquid	Other	1,107	34.50%	71	24.15%	1,178	33.63%	
ENDS / E-liquid	Vuse	634	19.76%	57	19.39%	691	19.73%	
ENDS / E-liquid	blu	104	3.24%	12	4.08%	116	3.31%	
ENDS / E-liquid	Logic	25	0.78%	3	1.02%	28	0.80%	
ENDS / E-liquid	NJOY	10	0.31%	2	0.68%	12	0.34%	
ENDS / E-liquid			0.00%		0.00%	0	0.00%	
<b>ENDS / E-liquid Total</b>		<b>3,209</b>	<b>100.00%</b>	<b>294</b>	<b>100.00%</b>	<b>3,503</b>	<b>100.00%</b>	<b>28.54%</b>
N/A		14		7		21		0.17%
Single cigarette		25		3		28		0.23%
Smokeless tobacco	Grizzly	81	2.52%	4	21.05%	85	2.43%	
Smokeless tobacco	Copenhagen	44	1.37%	7	36.84%	51	1.46%	
Smokeless tobacco	Other	13	0.41%	1	5.26%	14	0.40%	
Smokeless tobacco	Skoal	9	0.28%	1	5.26%	10	0.29%	
Smokeless tobacco	Red Seal	9	0.28%	3	15.79%	12	0.34%	
Smokeless tobacco	Longhorn	7	0.22%	2	10.53%	9	0.26%	
Smokeless tobacco	Camel	1	0.03%	0	0.00%	1	0.03%	
Smokeless tobacco	Kayak	1	0.03%	0	0.00%	1	0.03%	
Smokeless tobacco	Timber Wolf		0.00%	1	5.26%	1	0.03%	
<b>Smokeless tobacco Total</b>		<b>165</b>	<b>5.14%</b>	<b>19</b>	<b>100.00%</b>	<b>184</b>	<b>5.25%</b>	<b>1.50%</b>
<b>Grand Total</b>		<b>11,386</b>		<b>888</b>		<b>12,274</b>		<b>100.00%</b>

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

73,171 Total Compliance Checks  
60,878 # of Compliance Checks with NO VIOLATIONS

11,405 # of Warning Letters (WL)  
888 # of Civil Money Penalties (CMP)

12,293 Total of WL and CMP

16.80% 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 25% of all violations.
- Violations of ENDS / E-liquid products sold to minors represent less than 29% 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 0.23% of all violations

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

- An Important 'unknown' are the Products and Brands associated with the 60,878 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.