

**SUMMARY Analysis of FDA Compliance Check Data**

**FFY 2011-2020**  
through 2/29/2020

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	55,944	49,965	3,920	2,059	9	10.69%
		<b>887,432</b>	<b>776,158</b>	<b>86,504</b>	<b>24,770</b>	<b>144</b>	<b>12.54%</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	1,534	1,533	1	0	0	0.07%
		<b>277,632</b>	<b>272,601</b>	<b>5,027</b>	<b>4</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	57,478	51,498	3,921	2,059	9	10.40%
		<b>1,165,064</b>	<b>1,048,759</b>	<b>91,531</b>	<b>24,774</b>	<b>144</b>	<b>9.98%</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. Calculations of Total Compliance Checks and Violation Rate were computed by The We Card Program. Inspections Data FFY 2011-February 2020, accessed 03/12/20.

**Analysis of FDA Compliance Check Data  
FFY 2020 By State through 2/29/2020**

State	FFY 2020 TOTAL ALL TYPES OF INSPECTIONS						FFY 2020 INSPECTIONS <i>Involving a Minor</i>						FFY 2020 INSPECTIONS <i>NOT Involving a Minor</i>					
	Total Compliance	Number of "NO Violations"	Number of Warning Letters	Number of Civil Money Penalties	Violation Rate	Total Compliance	Number of "NO Violations"	Number of Warning Letters	Number of Civil Money Penalties	Violation Rate	Total Compliance	Number of "NO Violations"	Number of Warning Letters	Number of Civil Money Penalties	Violation Rate			
	Checks	Violations"	Letters	Penalties	Rate	Checks	Violations"	Letters	Penalties	Rate	Checks	Violations"	Letters	Penalties	Rate			
1 AK	106	96	6	4	9.43%	106	96	6	4	9.43%	0	0	0	0	0.00%			
2 AL	1,155	1,040	97	18	9.96%	1,132	1,017	97	18	10.16%	23	23	0	0	0.00%			
3 AR	1,140	1,096	26	18	3.86%	1,114	1,070	26	18	3.95%	26	26	0	0	0.00%			
4 AZ	763	653	76	34	14.42%	722	612	76	34	15.24%	41	41	0	0	0.00%			
5 CA	1,550	1,445	89	16	6.77%	1,519	1,414	89	16	6.91%	31	31	0	0	0.00%			
6 CO	1,271	1,208	49	14	4.96%	1,233	1,171	48	14	5.03%	38	37	1	0	2.63%			
7 CT	1,709	1,613	76	20	5.62%	1,670	1,574	76	20	5.75%	39	39	0	0	0.00%			
8 DC	325	294	16	15	9.54%	299	268	16	15	10.37%	26	26	0	0	0.00%			
9 DE	72	70	0	2	2.78%	26	24	0	2	7.69%	46	46	0	0	0.00%			
10 FL	5,513	4,685	560	268	15.02%	5,473	4,645	560	268	15.13%	40	40	0	0	0.00%			
11 GA	1,502	1,484	17	1	1.20%	1,474	1,456	17	1	1.22%	28	28	0	0	0.00%			
12 HI	118	111	4	3	5.93%	74	67	4	3	9.46%	44	44	0	0	0.00%			
13 IA	1,127	1,087	29	11	3.55%	1,091	1,051	29	11	3.67%	36	36	0	0	0.00%			
14 ID	322	297	19	6	7.76%	295	270	19	6	8.47%	27	27	0	0	0.00%			
15 IL	2,468	2,216	193	59	10.21%	2,437	2,185	193	59	10.34%	31	31	0	0	0.00%			
16 IN	1,544	1,401	86	57	9.26%	1,519	1,376	86	57	9.41%	25	25	0	0	0.00%			
17 KS	763	729	24	10	4.46%	740	706	24	10	4.59%	23	23	0	0	0.00%			
18 KY	1,543	1,474	62	7	4.47%	1,518	1,449	62	7	4.55%	25	25	0	0	0.00%			
19 LA	1,555	1,351	113	91	13.12%	1,538	1,334	113	91	13.26%	17	17	0	0	0.00%			
20 MA	2,124	2,015	85	24	5.13%	2,082	1,973	85	24	5.24%	42	42	0	0	0.00%			
21 MD	1,297	1,129	103	65	12.95%	1,261	1,093	103	65	13.32%	36	36	0	0	0.00%			
22 ME	302	286	13	3	5.30%	268	252	13	3	5.97%	34	34	0	0	0.00%			
23 MI	1,752	1,400	217	135	20.09%	1,709	1,357	217	135	20.60%	43	43	0	0	0.00%			
24 MN	1,366	1,259	78	29	7.83%	1,335	1,228	78	29	8.01%	31	31	0	0	0.00%			
25 MO	1,778	1,577	102	99	11.30%	1,741	1,540	102	99	11.55%	37	37	0	0	0.00%			
26 MS	1,134	1,075	45	14	5.20%	1,097	1,038	45	14	5.38%	37	37	0	0	0.00%			
27 MT	380	378	1	1	0.53%	334	332	1	1	0.60%	46	46	0	0	0.00%			
28 NC	1,627	1,234	218	175	24.15%	1,620	1,227	218	175	24.26%	7	7	0	0	0.00%			
29 ND	177	166	7	4	6.21%	161	150	7	4	6.83%	16	16	0	0	0.00%			
30 NE	406	375	24	7	7.64%	386	355	24	7	8.03%	20	20	0	0	0.00%			
31 NH	265	217	29	19	18.11%	260	212	29	19	18.46%	5	5	0	0	0.00%			
32 NJ	1,988	1,806	140	42	9.15%	1,973	1,791	140	42	9.22%	15	15	0	0	0.00%			
33 NM	335	294	24	17	12.24%	305	264	24	17	13.44%	30	30	0	0	0.00%			
34 NV	481	422	56	3	12.27%	439	380	56	3	13.44%	42	42	0	0	0.00%			
35 NY	2,814	2,677	94	43	4.87%	2,778	2,641	94	43	4.93%	36	36	0	0	0.00%			
36 OH	239	73	17	149	69.46%	198	32	17	149	83.84%	41	41	0	0	0.00%			
37 OK	701	576	78	47	17.83%	672	547	78	47	18.60%	29	29	0	0	0.00%			
38 OR	577	520	49	8	9.88%	564	507	49	8	10.11%	13	13	0	0	0.00%			
39 PA	1,660	1,466	114	80	11.69%	1,633	1,439	114	80	11.88%	27	27	0	0	0.00%			
40 RI	387	359	15	13	7.24%	344	316	15	13	8.14%	43	43	0	0	0.00%			
41 SC	2,003	1,712	225	66	14.53%	1,958	1,667	225	66	14.86%	45	45	0	0	0.00%			
42 SD	176	151	20	5	14.20%	137	112	20	5	18.25%	39	39	0	0	0.00%			
43 TN	1,462	1,233	137	92	15.66%	1,430	1,201	137	92	16.01%	32	32	0	0	0.00%			
44 TX	2,248	2,052	127	69	8.72%	2,212	2,016	127	69	8.86%	36	36	0	0	0.00%			
45 UT	269	259	9	1	3.72%	241	231	9	1	4.15%	28	28	0	0	0.00%			
46 VA	0	0	0	0		0	0	0	0		0	0	0	0				
47 VT	591	564	24	3	4.57%	575	548	24	3	4.70%	16	16	0	0	0.00%			
48 WA	1,866	1,642	145	79	12.00%	1,823	1,599	145	79	12.29%	43	43	0	0	0.00%			
49 WI	1,356	1,141	130	85	15.86%	1,323	1,108	130	85	16.25%	33	33	0	0	0.00%			
50 WV	1,029	965	43	21	6.22%	1,000	936	43	21	6.40%	29	29	0	0	0.00%			
51 WY	142	125	10	7	11.97%	105	88	10	7	16.19%	37	37	0	0	0.00%			
<b>TOTAL</b>	<b>57,478</b>	<b>51,498</b>	<b>3,921</b>	<b>2,059</b>	<b>10.40%</b>	<b>55,944</b>	<b>49,965</b>	<b>3,920</b>	<b>2,059</b>	<b>10.69%</b>	<b>1,534</b>	<b>1,533</b>	<b>1</b>	<b>0</b>	<b>0.07%</b>			

**We Card's Analysis of FDA Compliance Check Data**  
**FFY 2020 - October 2019 to September 2020**

Data: 10/1/19 to 2/29/20

**SUMMARY**  
**By PRODUCT TYPE**

Product Ty	Warning		Civil Money		Grand		% of Overall Violation Rate
	Letter	%	Penalty	%	Total	%	
Cigar(s)	1,738	43.90%	1,025	49.76%	2,763	45.90%	4.81%
Cigarette tobacco	2	0.05%	0	0.00%	2	0.03%	0.00%
Cigarettes in a package	1,108	27.99%	520	25.24%	1,628	27.05%	2.83%
ENDS / E-liquid	989	24.98%	431	20.92%	1,420	23.59%	2.47%
N/A	14	0.35%	39	1.89%	53	0.88%	0.09%
Single cigarette	6	0.15%	4	0.19%	10	0.17%	0.02%
Smokeless tobacco	102	2.58%	41	1.99%	143	2.38%	0.25%
<b>Grand Total</b>	<b>3,959</b>	<b>100.00%</b>	<b>2,060</b>	<b>100.00%</b>	<b>6,019</b>	<b>100.00%</b>	<b>10.47%</b>



**By PRODUCT TYPE & BRAND**

Product Type	Brand	Warning		Civil Money		Grand		% Of ALL
		Letter	%	Penalty	%	Total	%	
Cigar(s)	Swisher	905	52.07%	536	52.29%	1,441	52.15%	
Cigar(s)	Black & Mild	461	26.52%	245	23.90%	706	25.55%	
Cigar(s)	Other	151	8.69%	100	9.76%	251	9.08%	
Cigar(s)	Game	139	8.00%	92	8.98%	231	8.36%	
Cigar(s)	White Owl	81	4.66%	52	5.07%	133	4.81%	
Cigar(s)	Phillies	1	0.06%	0	0.00%	1	0.04%	
Cigar(s)		0	0.00%	0	0.00%	0	0.00%	
<b>Cigar(s) Total</b>		<b>1,738</b>	<b>100.00%</b>	<b>1,025</b>	<b>100.00%</b>	<b>2,763</b>	<b>100.00%</b>	<b>45.90%</b>
Cigarette tobacco	Other	2				2		0.03%
Cigarettes in a package	Marlboro	572	51.62%	246	47.31%	818	50.25%	
Cigarettes in a package	Newport	337	30.42%	168	32.31%	505	31.02%	
Cigarettes in a package	Camel	123	11.10%	66	12.69%	189	11.61%	
Cigarettes in a package	Other	43	3.88%	19	3.65%	62	3.81%	
Cigarettes in a package	Doral	12	1.08%	1	0.19%	13	0.80%	
Cigarettes in a package	Pall Mall	11	0.99%	9	1.73%	20	1.23%	
Cigarettes in a package	Kool	9	0.81%	11	2.12%	20	1.23%	
Cigarettes in a package	Winston	1	0.09%	0	0.00%	1	0.06%	
<b>Cigarettes in a package Total</b>		<b>1,108</b>	<b>100.00%</b>	<b>520</b>	<b>100.00%</b>	<b>1,628</b>	<b>100.00%</b>	<b>27.05%</b>
ENDS / E-liquid	JUUL	452	45.70%	168	38.98%	620	43.66%	
ENDS / E-liquid	Other	225	22.75%	57	13.23%	282	19.86%	
ENDS / E-liquid	Vuse	180	18.20%	137	31.79%	317	22.32%	
ENDS / E-liquid	blu	113	11.43%	68	15.78%	181	12.75%	
ENDS / E-liquid	NJOY	11	1.11%	1	0.23%	12	0.85%	
ENDS / E-liquid	Logic	7	0.71%	0	0.00%	7	0.49%	
ENDS / E-liquid	MarkTen	1	0.10%	0	0.00%	1	0.07%	
<b>ENDS / E-liquid Total</b>		<b>989</b>	<b>100.00%</b>	<b>431</b>	<b>100.00%</b>	<b>1,420</b>	<b>100.00%</b>	<b>23.59%</b>
N/A	N/A	14		39		53		0.88%
Single cigarette	N/A	6		4		10		0.17%
Smokeless tobacco	Grizzly	67	6.77%	24	5.57%	91	6.41%	
Smokeless tobacco	Copenhagen	17	1.72%	9	2.09%	26	1.83%	
Smokeless tobacco	Longhorn	6	0.61%	2	0.46%	8	0.56%	
Smokeless tobacco	Skoal	4	0.40%	4	0.93%	8	0.56%	
Smokeless tobacco	Kayak	3	0.30%	1	0.23%	4	0.28%	
Smokeless tobacco	Other	2	0.20%	0	0.00%	2	0.14%	
Smokeless tobacco	Red Seal	2	0.20%	1	0.23%	3	0.21%	
Smokeless tobacco	Stokers	1	0.10%	0	0.00%	1	0.07%	
Smokeless tobacco		0	0.00%	0	0.00%	0	0.00%	
<b>Smokeless tobacco Total</b>		<b>102</b>	<b>10.31%</b>	<b>41</b>	<b>9.51%</b>	<b>143</b>	<b>10.07%</b>	<b>2.38%</b>
<b>Grand Total</b>		<b>3,959</b>		<b>2,060</b>		<b>6,019</b>		<b>100.00%</b>

**Highlights of Oct 2019-September 2020 - FFY2020**  
Data: 10/1/19 to 2/29/20

57,478 Total Compliance Checks  
51,498 # of Compliance Checks with NO VIOLATIONS

3,921 # of Warning Letters (WL)  
2,059 # of Civil Money Penalties (CMP)

5,980 Total of WL and CMP

10.40% Calculated Violation Rate

- Violations of CIGAR products sold to minors represent 46% of all violations.
- Violations of CIGARETTES IN A PACKAGE products sold to minors represent more than 27% of all violations.
- Violations of ENDS / E-liquid products sold to minors represent less than 24% 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 0.17% of all violations

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

- An Important 'unknown' are the Products and Brands associated with the 51,498 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.