

SUMMARY Analysis of FDA Compliance Check Data

FFY 2011-2020
through 6/30/2020

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	62,996	55,960	4,722	2,314	21	11.17%
		894,484	782,153	87,306	25,025	156	12.56%
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	2,267	2,140	127	0	0	5.60%
		278,365	273,208	5,153	4	0	1.85%
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	65,263	58,100	4,849	2,314	21	10.98%
		1,172,849	1,055,361	92,459	25,029	156	10.02%

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-June 2020, accessed 07/21/20.

**Analysis of FDA Compliance Check Data
FFY 2020 By State through 6/30/2020**

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	124	109	11	4	12.10%	124	109	11	4	12.10%	0	0	0	0				
2 AL	1,388	1,241	125	22	10.59%	1,352	1,206	124	22	10.80%	36	35	1	0	2.78%			
3 AR	1,344	1,294	31	19	3.72%	1,294	1,245	30	19	3.79%	50	49	1	0	2.00%			
4 AZ	838	717	85	36	14.44%	790	670	84	36	15.19%	48	47	1	0	2.08%			
5 CA	1,718	1,588	108	22	7.57%	1,673	1,544	107	22	7.71%	45	44	1	0	2.22%			
6 CO	1,466	1,384	65	17	5.59%	1,416	1,338	61	17	5.51%	50	46	4	0	8.00%			
7 CT	1,845	1,718	96	31	6.88%	1,797	1,679	87	31	6.57%	48	39	9	0	18.75%			
8 DC	367	322	29	16	12.26%	317	280	21	16	11.67%	50	42	8	0	16.00%			
9 DE	74	72	0	2	2.70%	26	24	0	2	7.69%	48	48	0	0	0.00%			
10 FL	5,985	5,049	632	304	15.64%	5,931	4,999	628	304	15.71%	54	50	4	0	7.41%			
11 GA	1,614	1,586	25	3	1.73%	1,566	1,542	21	3	1.53%	48	44	4	0	8.33%			
12 HI	168	156	9	3	7.14%	119	111	5	3	6.72%	49	45	4	0	8.16%			
13 IA	1,195	1,152	30	13	3.60%	1,147	1,104	30	13	3.75%	48	48	0	0	0.00%			
14 ID	335	308	21	6	8.06%	299	273	20	6	8.70%	36	35	1	0	2.78%			
15 IL	2,745	2,426	252	67	11.62%	2,697	2,383	247	67	11.64%	48	43	5	0	10.42%			
16 IN	1,766	1,591	116	59	9.91%	1,715	1,543	113	59	10.03%	51	48	3	0	5.88%			
17 KS	901	856	34	11	4.99%	865	823	31	11	4.86%	36	33	3	0	8.33%			
18 KY	1,765	1,679	78	8	4.87%	1,718	1,635	75	8	4.83%	47	44	3	0	6.38%			
19 LA	1,712	1,484	133	95	13.32%	1,676	1,449	132	95	13.54%	36	35	1	0	2.78%			
20 MA	2,392	2,245	115	32	6.15%	2,344	2,197	115	32	6.27%	48	48	0	0	0.00%			
21 MD	1,458	1,254	128	76	13.99%	1,416	1,214	126	76	14.27%	42	40	2	0	4.76%			
22 ME	410	383	22	5	6.59%	367	342	20	5	6.81%	43	41	2	0	4.65%			
23 MI	2,101	1,673	278	150	20.37%	2,052	1,627	275	150	20.71%	49	46	3	0	6.12%			
24 MN	1,534	1,415	85	34	7.76%	1,486	1,370	82	34	7.81%	48	45	3	0	6.25%			
25 MO	2,013	1,778	127	108	11.67%	1,967	1,740	119	108	11.54%	46	38	8	0	17.39%			
26 MS	1,294	1,222	58	14	5.56%	1,252	1,181	57	14	5.67%	42	41	1	0	2.38%			
27 MT	426	423	2	1	0.70%	379	377	1	1	0.53%	47	46	1	0	2.13%			
28 NC	1,794	1,350	256	188	24.75%	1,745	1,314	243	188	24.70%	49	36	13	0	26.53%			
29 ND	216	195	13	8	9.72%	173	154	11	8	10.98%	43	41	2	0	4.65%			
30 NE	509	477	25	7	6.29%	470	438	25	7	6.81%	39	39	0	0	0.00%			
31 NH	311	261	31	19	16.08%	261	212	30	19	18.77%	50	49	1	0	2.00%			
32 NJ	2,376	2,137	189	50	10.06%	2,331	2,095	186	50	10.12%	45	42	3	0	6.67%			
33 NM	391	345	27	19	11.76%	343	298	26	19	13.12%	48	47	1	0	2.08%			
34 NV	526	459	64	3	12.74%	483	417	63	3	13.66%	43	42	1	0	2.33%			
35 NY	3,163	2,992	118	53	5.41%	3,114	2,943	118	53	5.49%	49	49	0	0	0.00%			
36 OH	449	253	30	166	43.65%	399	205	28	166	48.62%	50	48	2	0	4.00%			
37 OK	812	669	93	50	17.61%	764	624	90	50	18.32%	48	45	3	0	6.25%			
38 OR	656	594	54	8	9.45%	621	559	54	8	9.98%	35	35	0	0	0.00%			
39 PA	1,976	1,741	147	88	11.89%	1,926	1,693	145	88	12.10%	50	48	2	0	4.00%			
40 RI	461	420	27	14	8.89%	410	369	27	14	10.00%	51	51	0	0	0.00%			
41 SC	2,085	1,769	243	73	15.16%	2,034	1,722	239	73	15.34%	51	47	4	0	7.84%			
42 SD	211	178	27	6	15.64%	162	131	25	6	19.14%	49	47	2	0	4.08%			
43 TN	1,639	1,364	171	104	16.78%	1,589	1,317	168	104	17.12%	50	47	3	0	6.00%			
44 TX	2,645	2,396	171	78	9.41%	2,595	2,358	159	78	9.13%	50	38	12	0	24.00%			
45 UT	320	306	13	1	4.38%	272	259	12	1	4.78%	48	47	1	0	2.08%			
46 VA	0	0	0	0		0	0	0	0		0	0	0	0				
47 VT	648	619	26	3	4.48%	605	576	26	3	4.79%	43	43	0	0	0.00%			
48 WA	2,182	1,907	183	92	12.60%	2,130	1,856	182	92	12.86%	52	51	1	0	1.92%			
49 WI	1,614	1,339	181	94	17.04%	1,563	1,291	178	94	17.40%	51	48	3	0	5.88%			
50 WV	1,145	1,069	51	25	6.64%	1,105	1,029	51	25	6.88%	40	40	0	0	0.00%			
51 WY	156	135	14	7	13.46%	116	95	14	7	18.10%	40	40	0	0	0.00%			
TOTAL	65,263	58,100	4,849	2,314	10.98%	62,996	55,960	4,722	2,314	11.17%	2,267	2,140	127	0	5.60%			

We Card's Analysis of FDA Compliance Check Data
FFY 2020 - October 2019 to September 2020
through 6-30-20

SUMMARY
By PRODUCT TYPE

Product Ty	Warning Letter		Civil Money Penalty		Grand Total		% of Overall Violation Rate
	Letter	%	Penalty	%	Total	%	
Cigar(s)	2,049	41.81%	1,158	50.04%	3,207	44.45%	4.91%
Cigarette tobacco	2	0.04%	0	0.00%	2	0.03%	0.00%
Cigarettes in a package	1,345	27.44%	594	25.67%	1,939	26.87%	2.97%
ENDS / E-liquid	1,166	23.79%	475	20.53%	1,641	22.74%	2.51%
N/A	212	4.33%	42	1.82%	254	3.52%	0.39%
Single cigarette	6	0.12%	4	0.17%	10	0.14%	0.02%
Smokeless tobacco	121	2.47%	41	1.77%	162	2.25%	0.25%
Grand Total	4,901	100.00%	2,314	100.00%	7,215	100.00%	11.06%



By PRODUCT TYPE & BRAND

Product Type	Brand	Warning Letter		Civil Money Penalty		Grand Total		% Of ALL
		Letter	%	Penalty	%	Total	%	
Cigar(s)	Swisher	1,069	52.17%	595	51.38%	1,664	51.89%	
Cigar(s)	Black & Mild	535	26.11%	280	24.18%	815	25.41%	
Cigar(s)	Other	170	8.30%	112	9.67%	282	8.79%	
Cigar(s)	White Owl	101	4.93%	56	4.84%	157	4.90%	
Cigar(s)	Game	173	8.44%	115	9.93%	288	8.98%	
Cigar(s)	Phillies	1	0.05%	0	0.00%	1	0.03%	
Cigar(s)		0	0.00%	0	0.00%	0	0.00%	
Cigar(s) Total		2,049	100.00%	1,158	100.00%	3,207	100.00%	44.45%
Cigarette tobacco	Other	2				2		0.03%
Cigarettes in a package	Marlboro	680	50.56%	287	48.32%	967	49.87%	
Cigarettes in a package	Newport	428	31.82%	192	32.32%	620	31.98%	
Cigarettes in a package	Camel	146	10.86%	69	11.62%	215	11.09%	
Cigarettes in a package	Other	54	4.01%	24	4.04%	78	4.02%	
Cigarettes in a package	Kool	10	0.74%	11	1.85%	21	1.08%	
Cigarettes in a package	Pall Mall	12	0.89%	10	1.68%	22	1.13%	
Cigarettes in a package	Doral	12	0.89%	1	0.17%	13	0.67%	
Cigarettes in a package	Winston	3	0.22%	0	0.00%	3	0.15%	
Cigarettes in a package Total		1,345	100.00%	594	100.00%	1,939	100.00%	26.87%
ENDS / E-liquid	JUUL	535	45.88%	189	39.79%	724	44.12%	
ENDS / E-liquid	Other	279	23.93%	66	13.89%	345	21.02%	
ENDS / E-liquid	Vuse	195	16.72%	145	30.53%	340	20.72%	
ENDS / E-liquid	blu	136	11.66%	73	15.37%	209	12.74%	
ENDS / E-liquid	NJOY	11	0.94%	1	0.21%	12	0.73%	
ENDS / E-liquid	Logic	9	0.77%	1	0.21%	10	0.61%	
ENDS / E-liquid	MarkTen	1	0.09%	0	0.00%	1	0.06%	
ENDS / E-liquid Total		1,166	100.00%	475	100.00%	1,641	100.00%	22.74%
N/A	N/A	212		42		254		3.52%
Single cigarette	N/A	6		4		10		0.14%
Smokeless tobacco	Grizzly	74	6.35%	22	4.63%	96	5.85%	
Smokeless tobacco	Copenhagen	23	1.97%	11	2.32%	34	2.07%	
Smokeless tobacco	Skoal	8	0.69%	4	0.84%	12	0.73%	
Smokeless tobacco	Longhorn	7	0.60%	2	0.42%	9	0.55%	
Smokeless tobacco	Kayak	3	0.26%	1	0.21%	4	0.24%	
Smokeless tobacco	Other	2	0.17%	0	0.00%	2	0.12%	
Smokeless tobacco	Red Seal	2	0.17%	1	0.21%	3	0.18%	
Smokeless tobacco	Stokers	1	0.09%	0	0.00%	1	0.06%	
Smokeless tobacco	Kodiak	1	0.09%	0	0.00%	1	0.06%	
Smokeless tobacco Total		121	10.38%	41	8.63%	162	9.87%	2.25%
Grand Total		4,901		2,314		7,215		100.00%

Highlights of Oct 2019-September 2020 - FFY2020 - through 6-30-20

65,263 Total Compliance Checks
 58,100 # of Compliance Checks with NO VIOLATIONS

 4,849 # of Warning Letters (WL)
2,314 # of Civil Money Penalties (CMP)
 7,163 Total of WL and CMP

10.98% 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 27% of all violations.
- Violations of ENDS / E-liquid products sold to minors represent less than 23% 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 0.14% of all violations

Important Unknowns about the publicly available FDA enforcement Data

- An Important 'unknown' are the Products and Brands associated with the 58,100 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.