

SUMMARY Analysis of FDA Compliance Check Data

FFY 2011-2020
through 4/30/2020

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
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	62,845	55,949	4,644	2,252	19	10.97%
		894,333	782,142	87,228	24,963	154	12.54%
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	2,249	2,139	110		0	4.89%
		278,347	273,207	5,136	4	0	1.85%
TOTAL	FFY2011	24,404	23,381	1,022		1	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	65,094	58,088	4,754	2,252	19	10.76%
		1,172,680	1,055,349	92,364	24,967	154	10.01%

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-April 2020, accessed 05/21/20.

**Analysis of FDA Compliance Check Data
FFY 2020 By State through 4/30/2020**

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		Checks	Violations"	Letters	Penalties		Checks	Violations"	Letters	Penalties				
1 AK	124	109	11	4	12.10%	124	109	11	4	12.10%	0	0	0	0	0			
2 AL	1,385	1,241	123	21	10.40%	1,350	1,206	123	21	10.67%	35	35	0	0	0.00%			
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	837	717	83	37	14.34%	789	670	82	37	15.08%	48	47	1	0	2.08%			
5 CA	1,711	1,586	106	19	7.31%	1,667	1,542	106	19	7.50%	44	44	0	0	0.00%			
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	1,843	1,717	95	31	6.84%	1,795	1,678	86	31	6.52%	48	39	9	0	18.75%			
8 DC	366	322	28	16	12.02%	316	280	20	16	11.39%	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	5,964	5,049	626	289	15.34%	5,911	4,999	623	289	15.43%	53	50	3	0	5.66%			
11 GA	1,613	1,586	24	3	1.67%	1,565	1,542	20	3	1.47%	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	2,728	2,426	236	66	11.07%	2,680	2,383	231	66	11.08%	48	43	5	0	10.42%			
16 IN	1,765	1,591	115	59	9.86%	1,714	1,543	112	59	9.98%	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	1,763	1,679	77	7	4.76%	1,716	1,635	74	7	4.72%	47	44	3	0	6.38%			
19 LA	1,707	1,482	132	93	13.18%	1,671	1,447	131	93	13.41%	36	35	1	0	2.78%			
20 MA	2,391	2,245	115	31	6.11%	2,343	2,197	115	31	6.23%	48	48	0	0	0.00%			
21 MD	1,457	1,254	127	76	13.93%	1,415	1,214	125	76	14.20%	42	40	2	0	4.76%			
22 ME	409	383	21	5	6.36%	367	342	20	5	6.81%	42	41	1	0	2.38%			
23 MI	2,093	1,672	275	146	20.11%	2,045	1,626	273	146	20.49%	48	46	2	0	4.17%			
24 MN	1,531	1,414	85	32	7.64%	1,483	1,369	82	32	7.69%	48	45	3	0	6.25%			
25 MO	2,013	1,778	126	109	11.67%	1,968	1,740	119	109	11.59%	45	38	7	0	15.56%			
26 MS	1,289	1,222	53	14	5.20%	1,247	1,181	52	14	5.29%	42	41	1	0	2.38%			
27 MT	425	423	1	1	0.47%	379	377	1	1	0.53%	46	46	0	0	0.00%			
28 NC	1,780	1,349	248	183	24.21%	1,732	1,313	236	183	24.19%	48	36	12	0	25.00%			
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	2,368	2,137	185	46	9.76%	2,324	2,095	183	46	9.85%	44	42	2	0	4.55%			
33 NM	390	345	27	18	11.54%	342	298	26	18	12.87%	48	47	1	0	2.08%			
34 NV	525	459	63	3	12.57%	483	417	63	3	13.66%	42	42	0	0	0.00%			
35 NY	3,157	2,992	117	48	5.23%	3,108	2,943	117	48	5.31%	49	49	0	0	0.00%			
36 OH	448	253	28	167	43.53%	398	205	26	167	48.49%	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	1,973	1,740	146	87	11.81%	1,923	1,692	144	87	12.01%	50	48	2	0	4.00%			
40 RI	460	420	26	14	8.70%	409	369	26	14	9.78%	51	51	0	0	0.00%			
41 SC	2,077	1,769	241	67	14.83%	2,027	1,722	238	67	15.05%	50	47	3	0	6.00%			
42 SD	209	178	25	6	14.83%	160	131	23	6	18.13%	49	47	2	0	4.08%			
43 TN	1,633	1,364	168	101	16.47%	1,583	1,317	165	101	16.80%	50	47	3	0	6.00%			
44 TX	2,639	2,396	167	76	9.21%	2,593	2,358	159	76	9.06%	46	38	8	0	17.39%			
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	2,157	1,906	165	86	11.64%	2,106	1,855	165	86	11.92%	51	51	0	0	0.00%			
49 WI	1,608	1,337	179	92	16.85%	1,559	1,290	177	92	17.25%	49	47	2	0	4.08%			
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	65,094	58,088	4,754	2,252	10.76%	62,845	55,949	4,644	2,252	10.97%	2,249	2,139	110	0	4.89%			

We Card's Analysis of FDA Compliance Check Data
FFY 2020 - October 2019 to September 2020
 through 4/30/2020

SUMMARY

By PRODUCT TYPE

Product Type	Warning		Civil Money		Grand Total		% of Overall Violation Rate
	Letter	%	Penalty	%	Total	%	
Cigar(s)	2,031	42.31%	1,123	49.84%	3,154	44.72%	4.85%
Cigarette tobacco	2	0.04%	0	0.00%	2	0.03%	0.00%
Cigarettes in a package	1,334	27.79%	581	25.79%	1,915	27.15%	2.94%
ENDS / E-liquid	1,124	23.42%	461	20.46%	1,585	22.47%	2.43%
N/A	182	3.79%	42	1.86%	224	3.18%	0.34%
Single cigarette	6	0.13%	4	0.18%	10	0.14%	0.02%
Smokeless tobacco	121	2.52%	42	1.86%	163	2.31%	0.25%
Grand Total	4,800	100.00%	2,253	100.00%	7,053	100.00%	10.84%



By PRODUCT TYPE & BRAND

Product Type	Brand	Warning		Civil Money		Grand Total		% Of ALL
		Letter	%	Penalty	%	Total	%	
Cigar(s)	Swisher	1,060	52.19%	584	52.00%	1,644	52.12%	
Cigar(s)	Black & Mild	530	26.10%	269	23.95%	799	25.33%	
Cigar(s)	Other	168	8.27%	106	9.44%	274	8.69%	
Cigar(s)	White Owl	100	4.92%	56	4.99%	156	4.95%	
Cigar(s)	Game	172	8.47%	108	9.62%	280	8.88%	
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		2,031	100.00%	1,123	100.00%	3,154	100.00%	44.72%
Cigarette tobacco	Other	2				2		0.03%
Cigarettes in a package	Marlboro	674	50.52%	278	47.85%	952	49.71%	
Cigarettes in a package	Newport	425	31.86%	191	32.87%	616	32.17%	
Cigarettes in a package	Camel	144	10.79%	68	11.70%	212	11.07%	
Cigarettes in a package	Other	54	4.05%	22	3.79%	76	3.97%	
Cigarettes in a package	Kool	10	0.75%	11	1.89%	21	1.10%	
Cigarettes in a package	Pall Mall	12	0.90%	10	1.72%	22	1.15%	
Cigarettes in a package	Doral	12	0.90%	1	0.17%	13	0.68%	
Cigarettes in a package	Winston	3	0.22%	0	0.00%	3	0.16%	
Cigarettes in a package Total		1,334	100.00%	581	100.00%	1,915	100.00%	27.15%
ENDS / E-liquid	JUUL	515	45.82%	184	39.91%	699	44.10%	
ENDS / E-liquid	Other	261	23.22%	60	13.02%	321	20.25%	
ENDS / E-liquid	Vuse	195	17.35%	145	31.45%	340	21.45%	
ENDS / E-liquid	blu	132	11.74%	70	15.18%	202	12.74%	
ENDS / E-liquid	NJOY	11	0.98%	1	0.22%	12	0.76%	
ENDS / E-liquid	Logic	9	0.80%	1	0.22%	10	0.63%	
ENDS / E-liquid	MarkTen	1	0.09%	0	0.00%	1	0.06%	
ENDS / E-liquid Total		1,124	100.00%	461	100.00%	1,585	100.00%	22.47%
N/A	N/A	182		42		224		3.18%
Single cigarette	N/A	6		4		10		0.14%
Smokeless tobacco	Grizzly	74	6.58%	23	4.99%	97	6.12%	
Smokeless tobacco	Copenhagen	23	2.05%	11	2.39%	34	2.15%	
Smokeless tobacco	Skoal	8	0.71%	4	0.87%	12	0.76%	
Smokeless tobacco	Longhorn	7	0.62%	2	0.43%	9	0.57%	
Smokeless tobacco	Kayak	3	0.27%	1	0.22%	4	0.25%	
Smokeless tobacco	Other	2	0.18%	0	0.00%	2	0.13%	
Smokeless tobacco	Red Seal	2	0.18%	1	0.22%	3	0.19%	
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	10.77%	42	9.11%	163	10.28%	2.31%
Grand Total		4,800		2,253		7,053		100.00%

Highlights of Oct 2019-September 2020 - FFY2020

65,094 Total Compliance Checks
 58,088 # of Compliance Checks with NO VIOLATIONS

4,754 # of Warning Letters (WL)
 2,252 # of Civil Money Penalties (CMP)

7,006 Total of WL and CMP

10.76% Calculated Violation Rate

- Violations of CIGAR products sold to minors represent 45% 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 22% 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 58,088 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.