

SUMMARY Analysis of FDA Compliance Check Data

FFY 2022-2023
through 05/31/2023

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	63,019	55,965	4,724	2,330	32	11.19%
	FFY2021	22,785	18,728	4,047	10	1	17.81%
	FFY2022	91,449	74,463	15,711	1,275	0	18.57%
	FFY2023	68,941	58,553	8,036	2,352	1	15.07%
		1,077,682	933,902	115,102	28,678	169	13.34%
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	0		1.83%
	FFY2012	44,217	43,553	664	0		1.50%
	FFY2013	57,833	56,683	1,149	1		1.99%
	FFY2014	55,485	54,253	1,232	0		2.22%
	FFY2015	35,222	34,429	793	0		2.25%
	FFY2016	31,563	31,100	463	0		1.47%
	FFY2017	30,868	30,497	371	0		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	120	119	1	0	0	0.83%
	FFY2023	400	394	6	0	0	1.50%
		286,666	281,488	5,172	6	0	1.81%
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	65,287	58,105	4,851	2,331	32	11.00%
	FFY2021	30,565	26,495	4,059	11	1	13.32%
	FFY2022	91,569	74,582	15,712	1,275	0	18.55%
	FFY2023	69,341	58,947	8,042	2,352	1	14.99%
		1,364,348	1,215,390	120,274	28,684	169	10.92%

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-May 2023, accessed 06/17/23.

**Analysis of FDA Compliance Check Data
FFY 2023 By State through 05/31/2023**

State	FFY 2023 TOTAL ALL TYPES OF INSPECTIONS						FFY 2023 INSPECTIONS Involving a Minor						FFY 2023 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	23	21	2	0	0	8.70%	21	19	2	0	0	9.52%	2	2	0	0	0
2 AL	1,596	1,429	156	11	0	10.46%	1,578	1,411	156	11	0	10.58%	18	18	0	0	0	0.00%
3 AR	1,827	1,726	91	10	0	5.53%	1,815	1,715	90	10	0	5.51%	12	11	1	0	0	8.33%
4 AZ	1,104	991	110	3	0	10.24%	1,092	980	109	3	0	10.26%	12	11	1	0	0	8.33%
5 CA	1,505	1,331	122	52	0	11.56%	1,484	1,310	122	52	0	11.73%	21	21	0	0	0	0.00%
6 CO	2,502	2,194	248	60	0	12.31%	2,497	2,189	248	60	0	12.33%	5	5	0	0	0	0.00%
7 CT	2,288	1,921	252	115	0	16.04%	2,273	1,906	252	115	0	16.15%	15	15	0	0	0	0.00%
8 DC	97	71	26	0	0	26.80%	97	71	26	0	0	26.80%	0	0	0	0	0	0
9 DE	597	558	33	6	0	6.53%	597	558	33	6	0	6.53%	0	0	0	0	0	0
10 FL	5,510	4,072	1,215	223	0	26.10%	5,489	4,051	1,215	223	0	26.20%	21	21	0	0	0	0.00%
11 GA	2,262	2,229	31	2	0	1.46%	2,262	2,229	31	2	0	1.46%	0	0	0	0	0	0
12 HI	231	218	8	5	0	5.63%	231	218	8	5	0	5.63%	0	0	0	0	0	0
13 IA	2,021	1,924	67	30	0	4.80%	2,020	1,923	67	30	0	4.80%	1	1	0	0	0	0.00%
14 ID	501	454	47	0	0	9.38%	489	442	47	0	0	9.61%	12	12	0	0	0	0.00%
15 IL	2,832	2,342	354	136	0	17.30%	2,823	2,333	354	136	0	17.36%	9	9	0	0	0	0.00%
16 IN	830	680	94	56	0	18.07%	830	680	94	56	0	18.07%	0	0	0	0	0	0
17 KS	1,250	1,210	40	0	0	3.20%	1,250	1,210	40	0	0	3.20%	0	0	0	0	0	0
18 KY	1,915	1,708	139	68	0	10.81%	1,911	1,704	139	68	0	10.83%	4	4	0	0	0	0.00%
19 LA	923	725	142	56	0	21.45%	915	717	142	56	0	21.64%	8	8	0	0	0	0.00%
20 MA	2,672	2,327	283	62	0	12.91%	2,672	2,327	283	62	0	12.91%	0	0	0	0	0	0
21 MD	1,440	1,280	157	3	0	11.11%	1,418	1,258	157	3	0	11.28%	22	22	0	0	0	0.00%
22 ME	753	735	18	0	0	2.39%	753	735	18	0	0	2.39%	0	0	0	0	0	0
23 MI	1,622	1,252	272	98	0	22.81%	1,622	1,252	272	98	0	22.81%	0	0	0	0	0	0
24 MN	3,073	2,711	278	84	0	11.78%	3,073	2,711	278	84	0	11.78%	0	0	0	0	0	0
25 MO	3,011	2,615	253	143	0	13.15%	2,993	2,598	252	143	0	13.20%	18	17	1	0	0	5.56%
26 MS	1,558	1,425	100	33	0	8.54%	1,558	1,425	100	33	0	8.54%	0	0	0	0	0	0
27 MT	798	762	30	6	0	4.51%	798	762	30	6	0	4.51%	0	0	0	0	0	0
28 NC	2,044	1,714	269	61	0	16.14%	2,029	1,701	267	61	0	16.17%	15	13	2	0	0	13.33%
29 ND	94	78	15	1	0	17.02%	94	78	15	1	0	17.02%	0	0	0	0	0	0
30 NE	555	474	69	12	0	14.59%	555	474	69	12	0	14.59%	0	0	0	0	0	0
31 NH	564	473	63	28	0	16.13%	564	473	63	28	0	16.13%	0	0	0	0	0	0
32 NJ	2,024	1,492	288	244	0	26.28%	2,018	1,486	288	244	0	26.36%	6	6	0	0	0	0.00%
33 NM	363	315	47	1	0	13.22%	325	277	47	1	0	14.77%	38	38	0	0	0	0.00%
34 NV	54	50	4	0	0	7.41%	54	50	4	0	0	7.41%	0	0	0	0	0	0
35 NY	2,212	1,556	592	64	0	29.66%	2,205	1,550	591	64	0	29.71%	7	6	1	0	0	14.29%
36 OH	1,161	883	196	82	0	23.94%	1,161	883	196	82	0	23.94%	0	0	0	0	0	0
37 OK	621	534	66	21	0	14.01%	558	471	66	21	0	15.59%	63	63	0	0	0	0.00%
38 OR	391	346	45	0	0	11.51%	389	344	45	0	0	11.57%	2	2	0	0	0	0.00%
39 PA	1,414	1,110	260	44	0	21.50%	1,407	1,103	260	44	0	21.61%	7	7	0	0	0	0.00%
40 RI	564	486	56	22	0	13.83%	564	486	56	22	0	13.83%	0	0	0	0	0	0
41 SC	1,056	880	134	42	0	16.67%	1,054	878	134	42	0	16.70%	2	2	0	0	0	0.00%
42 SD	80	68	12	0	0	15.00%	80	68	12	0	0	15.00%	0	0	0	0	0	0
43 TN	2,245	1,859	327	59	0	17.19%	2,226	1,840	327	59	0	17.34%	19	19	0	0	0	0.00%
44 TX	3,381	2,860	341	180	1	15.41%	3,364	2,843	341	180	1	15.49%	17	17	0	0	0	0.00%
45 UT	115	112	3	0	0	2.61%	115	112	3	0	0	2.61%	0	0	0	0	0	0
46 VA	590	440	140	10	0	25.42%	582	432	140	10	0	25.77%	8	8	0	0	0	0.00%
47 VT	238	195	28	15	0	18.07%	238	195	28	15	0	18.07%	0	0	0	0	0	0
48 WA	1,751	1,436	217	98	0	17.99%	1,726	1,411	217	98	0	18.25%	25	25	0	0	0	0.00%
49 WI	1,140	906	185	49	0	20.53%	1,135	901	185	49	0	20.62%	5	5	0	0	0	0.00%
50 WV	1,880	1,707	116	57	0	9.20%	1,877	1,704	116	57	0	9.22%	3	3	0	0	0	0.00%
51 WY	63	62	1	0	0	1.59%	60	59	1	0	0	1.67%	3	3	0	0	0	0.00%
TOTAL	69,341	58,947	8,042	2,352	1	14.99%	68,941	58,553	8,036	2,352	1	15.07%	400	394	6	0	0	1.50%

**Analysis of FDA Compliance Check Data
FFY 2023 By Month**

Year	Month	FFY 2023 TOTAL ALL TYPES OF INSPECTIONS					FFY 2023 INSPECTIONS <i>Involving a Minor</i>					FFY 2023 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
2022	Oct	7,865	6,522	1,104	239	17.08%	7,859	6,516	1,104	239	17.09%	6	6	0	0	0.00%
2022	Nov	8,014	6,716	1,083	215	16.20%	8,002	6,704	1,083	215	16.22%	12	12	0	0	0.00%
2022	Dec	7,689	6,463	970	256	15.94%	7,667	6,441	970	256	15.99%	22	22	0	0	0.00%
2023	Jan	8,925	7,467	1,221	237	16.34%	8,909	7,451	1,221	237	16.37%	16	16	0	0	0.00%
2023	Feb	8,769	7,419	1,110	240	15.40%	8,695	7,348	1,107	240	15.49%	74	71	3	0	4.05%
2023	Mar	9,845	8,355	1,086	404	15.13%	9,752	8,265	1,083	404	15.25%	93	90	3	0	3.23%
2023	Apr	9,259	7,817	1,085	357	15.57%	9,203	7,761	1,085	357	15.67%	56	56	0	0	0.00%
2023	May	8,975	8,188	383	404	8.77%	8,854	8,067	383	404	8.89%	121	121	0	0	0.00%
2023	Jun	0	0	0	0		0	0	0	0		0	0	0	0	
2023	Jul	0	0	0	0		0	0	0	0		0	0	0	0	
2023	Aug	0	0	0	0		0	0	0	0		0	0	0	0	
2023	Sep	0	0	0	0		0	0	0	0		0	0	0	0	
	TOTAL	69,341	58,947	8,042	2,352	14.99%	68,941	58,553	8,036	2,352	15.07%	400	394	6	0	1.50%

We Card's Analysis of FDA Compliance Check Data FFY 2023 - October 2022 to September 2023

as of 5/31/23

SUMMARY By PRODUCT TYPE

Product Ty	Warning		Civil		Grand Total	%	% of Overall Violation Rate
	Letter	%	Money Penalty	%			
Cigar(s)	3,666	46.75%	1,075	45.74%	4,741	46.52%	6.84%
Cigarette tobacco	7	0.09%	0	0.00%	7	0.07%	0.01%
garettes in a package	1,836	23.41%	524	22.30%	2,360	23.16%	3.40%
ENDS / E-liquid	2,165	27.61%	708	30.13%	2,873	28.19%	4.14%
N/A	29	0.37%	10	0.43%	39	0.38%	0.06%
Single cigarette	14	0.18%	2	0.09%	16	0.16%	0.02%
<u>Smokeless tobacco</u>	<u>125</u>	<u>1.59%</u>	<u>31</u>	<u>1.32%</u>	<u>156</u>	<u>1.53%</u>	<u>0.22%</u>
Grand Total	7,842	100.00%	2,350	100.00%	10,192	100.00%	14.70%



By PRODUCT TYPE & BRAND

Product Type	Brand	Warning		Civil		Grand Total	%	% Of ALL
		Letter	%	Money Penalty	%			
Cigar(s)	Swisher	1,504	41.03%	537	49.95%	2,041	43.05%	
Cigar(s)	Black & Mild	1,080	29.46%	288	26.79%	1,368	28.85%	
Cigar(s)	Game	540	14.73%	142	13.21%	682	14.39%	
Cigar(s)	Other	333	9.08%	42	3.91%	375	7.91%	
Cigar(s)	White Owl	207	5.65%	66	6.14%	273	5.76%	
Cigar(s)	Phillies	2	0.05%	0	0.00%	2	0.04%	
Cigar(s)			0.00%		0.00%	0	0.00%	
Cigar(s) Total		3,666	100.00%	1,075	100.00%	4,741	100.00%	46.52%
Cigarette tobacco		7				7		0.07%
Cigarettes in a package	Marlboro	1,036	56.43%	244	46.56%	1,280	54.24%	
Cigarettes in a package	Newport	546	29.74%	181	34.54%	727	30.81%	
Cigarettes in a package	Camel	155	8.44%	55	10.50%	210	8.90%	
Cigarettes in a package	Other	67	3.65%	28	5.34%	95	4.03%	
Cigarettes in a package	Pall Mall	13	0.71%	7	1.34%	20	0.85%	
Cigarettes in a package	Kool	8	0.44%	4	0.76%	12	0.51%	
Cigarettes in a package	Winston	8	0.44%	2	0.38%	10	0.42%	
Cigarettes in a package	Salem	3	0.16%	3	0.57%	6	0.25%	
Cigarettes in a package Total		1,836	100.00%	524	100.00%	2,360	100.00%	23.16%
ENDS / E-liquid	Other	1,329	61.39%	358	50.56%	1,687	58.72%	
ENDS / E-liquid	Vuse	418	19.31%	142	20.06%	560	19.49%	
ENDS / E-liquid	JUUL	344	15.89%	189	26.69%	533	18.55%	
ENDS / E-liquid	blu	44	2.03%	11	1.55%	55	1.91%	
ENDS / E-liquid	Logic	18	0.83%	3	0.42%	21	0.73%	
ENDS / E-liquid	NJOY	12	0.55%	5	0.71%	17	0.59%	
ENDS / E-liquid			0.00%		0.00%	0	0.00%	
ENDS / E-liquid Total		2,165	100.00%	708	100.00%	2,873	100.00%	28.19%
N/A		29		10		39		0.38%
Single cigarette		14		2		16		0.16%
Smokeless tobacco	Grizzly	58	2.68%	21	67.74%	79	2.75%	
Smokeless tobacco	Copenhagen	35	1.62%	2	6.45%	37	1.29%	
Smokeless tobacco	Other	12	0.55%	3	9.68%	15	0.52%	
Smokeless tobacco	Stokers	9	0.42%	0	0.00%	9	0.31%	
Smokeless tobacco	Longhorn	4	0.18%	0	0.00%	4	0.14%	
Smokeless tobacco	Skoal	4	0.18%	5	16.13%	9	0.31%	
Smokeless tobacco	Red Seal	3	0.14%	0	0.00%	3	0.10%	
Smokeless tobacco			0.00%		0.00%	0	0.00%	
Smokeless tobacco			0.00%		0.00%	0	0.00%	
Smokeless tobacco Total		125	5.77%	31	100.00%	156	5.43%	1.53%
Grand Total		7,842		2,350		10,192		100.00%

Highlights of Oct 2022-September 2023 - FFY2023

69,341 Total Compliance Checks
58,947 # of Compliance Checks with NO VIOLATIONS

8,042 # of Warning Letters (WL)
2,352 # of Civil Money Penalties (CMP)

10,394 Total of WL and CMP

14.99% Calculated Violation Rate

- Violations of CIGAR products sold to minors represent 47% of all violations.
- Violations of CIGARETTES IN A PACKAGE products sold to minors represent more than 23% 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 2% 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 58,947 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.