

SUMMARY Analysis of FDA Compliance Check Data

FFY 2023-2024
through 02/29/2024

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 advertision 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	106,215	89,038	13,327	3,850	4	16.17%
	FFY2024	45,360	39,104	4,444	1,812	1	13.79%
			1,160,316	1,003,491	124,837	31,988	173
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	802	633	148	21	0	21.07%
	FFY2024	496	411	2	83	0	17.14%
			287,564	282,138	5,316	110	0
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	107,017	89,671	13,475	3,871	4	16.21%
	FFY2024	45,856	39,515	4,446	1,895	1	13.83%
			1,447,880	1,285,629	130,153	32,098	173

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 2024, accessed 03/16/24.

**Analysis of FDA Compliance Check Data
FFY 2024 By State through 02/29/2024**

State	FFY 2024 TOTAL ALL TYPES OF INSPECTIONS						FFY 2024 INSPECTIONS Involving a Minor						FFY 2024 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	1,761	1,599	150	12	0	9.20%	1,760	1,598	150	12	0	9.20%	1	1	0	0	0	0.00%
3 AR	1,236	1,179	49	8	0	4.61%	1,234	1,179	49	6	0	4.46%	2	0	0	2	0	100.00%
4 AZ	715	656	48	11	0	8.25%	700	642	48	10	0	8.29%	15	14	0	1	0	6.67%
5 CA	1,144	1,034	82	28	0	9.62%	1,130	1,020	82	28	0	9.73%	14	14	0	0	0	0.00%
6 CO	1,404	1,267	74	63	0	9.76%	1,398	1,267	74	57	0	9.37%	6	0	0	6	0	100.00%
7 CT	1,186	997	133	56	0	15.94%	1,166	978	133	55	0	16.12%	20	19	0	1	0	5.00%
8 DC	149	113	35	1	0	24.16%	149	113	35	1	0	24.16%	0	0	0	0	0	0
9 DE	317	302	11	4	0	4.73%	297	282	11	4	0	5.05%	20	20	0	0	0	0.00%
10 FL	2,281	1,756	426	99	0	23.02%	2,224	1,711	426	87	0	23.07%	57	45	0	12	0	21.05%
11 GA	1,145	1,129	14	2	0	1.40%	1,129	1,113	14	2	0	1.42%	16	16	0	0	0	0.00%
12 HI	260	238	18	4	0	8.46%	260	238	18	4	0	8.46%	0	0	0	0	0	0
13 IA	1,116	1,057	48	11	0	5.29%	1,116	1,057	48	11	0	5.29%	0	0	0	0	0	0
14 ID	354	335	14	5	0	5.37%	352	334	14	4	0	5.11%	2	1	0	1	0	50.00%
15 IL	1,828	1,499	188	141	0	18.00%	1,812	1,485	188	139	0	18.05%	16	14	0	2	0	12.50%
16 IN	433	353	55	25	0	18.48%	433	353	55	25	0	18.48%	0	0	0	0	0	0
17 KS	630	575	48	7	0	8.73%	628	574	48	6	0	8.60%	2	1	0	1	0	50.00%
18 KY	1,436	1,287	116	33	0	10.38%	1,426	1,277	116	33	0	10.45%	10	10	0	0	0	0.00%
19 LA	777	682	63	32	0	12.23%	756	670	63	23	0	11.38%	21	12	0	9	0	42.86%
20 MA	2,210	2,064	131	15	1	6.61%	2,210	2,064	131	15	1	6.61%	0	0	0	0	0	0
21 MD	652	477	132	43	0	26.84%	637	463	132	42	0	27.32%	15	14	0	1	0	6.67%
22 ME	514	489	23	2	0	4.86%	514	489	23	2	0	4.86%	0	0	0	0	0	0
23 MI	873	638	149	86	0	26.92%	852	617	149	86	0	27.58%	21	21	0	0	0	0.00%
24 MN	1,815	1,591	136	88	0	12.34%	1,814	1,590	136	88	0	12.35%	1	1	0	0	0	0.00%
25 MO	1,957	1,771	120	66	0	9.50%	1,951	1,771	120	60	0	9.23%	6	0	0	6	0	100.00%
26 MS	748	704	37	7	0	5.88%	745	701	37	7	0	5.91%	3	3	0	0	0	0.00%
27 MT	433	423	9	1	0	2.31%	433	423	9	1	0	2.31%	0	0	0	0	0	0
28 NC	687	492	95	100	0	28.38%	675	485	95	95	0	28.15%	12	7	0	5	0	41.67%
29 ND	82	72	10	0	0	12.20%	82	72	10	0	0	12.20%	0	0	0	0	0	0
30 NE	324	288	30	6	0	11.11%	323	287	30	6	0	11.15%	1	1	0	0	0	0.00%
31 NH	431	356	51	24	0	17.40%	421	350	51	20	0	16.86%	10	6	0	4	0	40.00%
32 NJ	2,752	2,194	447	111	0	20.28%	2,720	2,167	447	106	0	20.33%	32	27	0	5	0	15.63%
33 NM	160	152	7	1	0	5.00%	159	151	7	1	0	5.03%	1	1	0	0	0	0.00%
34 NV	80	74	6	0	0	7.50%	79	73	6	0	0	7.59%	1	1	0	0	0	0.00%
35 NY	2,174	1,610	289	275	0	25.94%	2,163	1,600	289	274	0	26.03%	11	10	0	1	0	9.09%
36 OH	840	652	139	49	0	22.38%	831	643	139	49	0	22.62%	9	9	0	0	0	0.00%
37 OK	294	248	22	24	0	15.65%	262	226	22	14	0	13.74%	32	22	0	10	0	31.25%
38 OR	233	215	17	1	0	7.73%	232	214	17	1	0	7.76%	1	1	0	0	0	0.00%
39 PA	1,263	1,165	69	29	0	7.76%	1,218	1,122	68	28	0	7.88%	45	43	1	1	0	4.44%
40 RI	490	438	38	14	0	10.61%	485	434	38	13	0	10.52%	5	4	0	1	0	20.00%
41 SC	789	661	84	44	0	16.22%	782	655	84	43	0	16.24%	7	6	0	1	0	14.29%
42 SD	109	105	4	0	0	3.67%	109	105	4	0	0	3.67%	0	0	0	0	0	0
43 TN	1,391	1,260	102	29	0	9.42%	1,377	1,247	102	28	0	9.44%	14	13	0	1	0	7.14%
44 TX	2,535	2,129	250	156	0	16.02%	2,512	2,109	250	153	0	16.04%	23	20	0	3	0	13.04%
45 UT	38	38	0	0	0	0.00%	38	38	0	0	0	0.00%	0	0	0	0	0	0
46 VA	773	513	184	76	0	33.64%	754	498	184	72	0	33.95%	19	15	0	4	0	21.05%
47 VT	98	93	5	0	0	5.10%	98	93	5	0	0	5.10%	0	0	0	0	0	0
48 WA	1,155	974	131	50	0	15.67%	1,154	974	131	49	0	15.60%	1	0	0	1	0	100.00%
49 WI	712	589	96	27	0	17.28%	710	588	96	26	0	17.18%	2	1	0	1	0	50.00%
50 WV	1,024	937	58	29	0	8.50%	1,003	920	57	26	0	8.28%	21	17	1	3	0	19.05%
51 WY	48	45	3	0	0	6.25%	47	44	3	0	0	6.38%	1	1	0	0	0	0.00%
TOTAL	45,856	39,515	4,446	1,895	1	13.83%	45,360	39,104	4,444	1,812	1	13.79%	496	411	2	83	0	17.14%

We Card's Analysis of FDA Compliance Check Data
FFY 2024 - October 2023 to September 2024

as of February 29, 2024

SUMMARY

By PRODUCT TYPE

Product Type	Warning Letter		Civil Money Penalty		Grand Total	% of Overall Violation Rate
	Letter	%	Penalty	%		
Cigar(s)	2,094	47.10%	851	44.91%	2,945	46.44%
Cigarette tobacco	1	0.02%	1	0.05%	2	0.03%
Cigarettes in a package	1,079	24.27%	322	16.99%	1,401	22.09%
ENDS / E-liquid	1,080	24.29%	550	29.02%	1,630	25.71%
N/A	12	0.27%	92	4.85%	104	1.64%
Single cigarette	13	0.29%	6	0.32%	19	0.30%
Smokeless tobacco	39	0.88%	21	1.11%	60	0.95%
Oral nicotine product	116	2.61%	46	2.43%	162	2.55%
Hookah tobacco	12	0.27%	6	0.32%	18	0.28%
Grand Total	4,446	100.00%	1,895	100.00%	6,341	100.00%



By PRODUCT TYPE & BRAND

Product Type	Brand	Warning Letter		Civil Money Penalty		Grand Total	% of ALL
		Letter	%	Penalty	%		
Cigar(s)	Swisher	857	40.93%	370	43.48%	1,227	41.66%
Cigar(s)	Black & Mild	835	39.88%	278	32.67%	1,113	37.79%
Cigar(s)	Game	167	7.98%	75	8.81%	242	8.22%
Cigar(s)	Other	146	6.97%	82	9.64%	228	7.74%
Cigar(s)	White Owl	87	4.15%	42	4.94%	129	4.38%
Cigar(s)	Phillies	2	0.10%	4	0.47%	6	0.20%
Cigar(s)			0.00%		0.00%	0	0.00%
Cigar(s) Total		2,094	100.00%	851	100.00%	2,945	100.00%
Cigarettes in a package	Marlboro	538	49.86%	137	42.55%	675	48.18%
Cigarettes in a package	Newport	360	33.36%	123	38.20%	483	34.48%
Cigarettes in a package	Camel	136	12.60%	39	12.11%	175	12.49%
Cigarettes in a package	Other	36	3.34%	17	5.28%	53	3.78%
Cigarettes in a package	Kool	5	0.46%	2	0.62%	7	0.50%
Cigarettes in a package	Decade	3	0.28%	2	0.62%	5	0.36%
Cigarettes in a package	Pall Mall	1	0.09%	1	0.31%	2	0.14%
Cigarettes in a package	Salem		0.00%	1	0.31%	1	0.07%
Cigarettes in a package Total		1,079	100.00%	322	100.00%	1,401	100.00%
ENDS / E-liquid	Other	744	68.89%	380	69.09%	1,124	68.96%
ENDS / E-liquid	Vuse	197	18.24%	91	16.55%	288	17.67%
ENDS / E-liquid	JUUL	131	12.13%	71	12.91%	202	12.39%
ENDS / E-liquid	blu	3	0.28%	1	0.18%	4	0.25%
ENDS / E-liquid	Logic	3	0.28%	4	0.73%	7	0.43%
ENDS / E-liquid	NJOY	2	0.19%	3	0.55%	5	0.31%
ENDS / E-liquid			0.00%		0.00%	0	0.00%
ENDS / E-liquid Total		1,080	100.00%	550	100.00%	1,630	100.00%
N/A		12	7.79%	92	60.93%	104	34.10%
Single cigarette		13	8.44%	6	3.97%	19	6.23%
Cigarette tobacco		1	0.65%	1	0.66%	2	0.66%
Hookah tobacco		12	7.79%	6	3.97%	18	5.90%
Oral nicotine product		116	75.32%	46	30.46%	162	53.11%
Misc. Total		154	100.00%	151	100.00%	305	100.00%
Smokeless tobacco	Grizzly	18	46.15%	14	66.67%	32	53.33%
Smokeless tobacco	Copenhagen	10	25.64%	2	9.52%	12	20.00%
Smokeless tobacco	Skoal	5	12.82%	1	4.76%	6	10.00%
Smokeless tobacco	Other	3	7.69%		0.00%	3	5.00%
Smokeless tobacco	Camel	1	2.56%	1	4.76%	2	3.33%
Smokeless tobacco	Longhorn	1	2.56%	3	14.29%	4	6.67%
Smokeless tobacco	Stokers	1	2.56%		0.00%	1	1.67%
Smokeless tobacco			0.00%		0.00%	0	0.00%
Smokeless tobacco Total		39	100.00%	21	100.00%	60	100.00%

Highlights of Oct 2023-September 2024 - FFY2024

45,856 Total Compliance Checks
 39,515 # of Compliance Checks with NO VIOLATIONS

4,446 # of Warning Letters (WL)
 1,895 # of Civil Money Penalties (CMP)

6,341 Total of WL and CMP

13.83% 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 22% of all violations.
- Violations of ENDS / E-liquid products sold to minors represent less than 26% 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 0.30% of all violations

Important Unknowns about the publicly available FDA enforcement Data

An Important 'unknown' are the Products and Brands associated with the 39,515 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.