

SUMMARY Analysis of FDA Compliance Check Data

FFY 2023-2024
through 07/31/2024

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 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	20,625	18,728	1,887	10	1	9.20%
	* FFY2022	92,166	74,460	16,442	1,264	0	19.21%
	* FFY2023	106,832	89,038	13,949	3,845	7	16.66%
	* FFY2024	95,294	81,271	10,317	3,706	3	14.72%
		1,209,424	1,045,655	129,903	33,866	178	13.54%
* Data based upon FDA's "Decision Date".							
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	7,772	7,767	4	1		0.06%
	FFY2022	128	119	9		0	7.03%
	FFY2023	800	633	147	20		20.88%
	FFY2024	972	710	147	115		26.95%
		288,038	282,437	5,460	141	0	1.94%
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	5,982	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	28,397	26,495	1,891	11	1	6.70%
	FFY2022	92,294	74,579	16,451	1,264	0	19.19%
	FFY2023	107,632	89,671	14,096	3,865	7	16.69%
	FFY2024	96,266	81,981	10,464	3,821	3	14.84%
		1,497,462	1,328,092	135,363	34,007	178	11.31%

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-July 2024, accessed 08/13/24.

**Analysis of FDA Compliance Check Data
FFY 2024 By State through 07/31/2024**

State	FFY 2024 TOTAL ALL TYPES OF INSPECTIONS							FFY 2024 INSPECTIONS Involving a Minor							FFY 2024 INSPECTIONS NOT Involving a Minor						
	Total Compliance	Number of "NO Violations"	Number of Warning Letters	Number of Civil Money Penalties	Number of Tobacco-Sale Orders	Violation Rate	Total Compliance	Number of "NO Violations"	Number of Warning Letters	Number of Civil Money Penalties	Number of Tobacco-Sale Orders	Violation Rate	Total Compliance	Number of "NO Violations"	Number of Warning Letters	Number of Civil Money Penalties	Number of Tobacco-Sale Orders	Violation Rate			
	Checks	Violations	Letters	Penalties	Orders	Rate	Checks	Violations	Letters	Penalties	Orders	Rate	Checks	Violations	Letters	Penalties	Orders	Rate			
1 AK	64	61	3	0	0	4.69%	58	55	3	0	0	5.17%	6	6	0	0	0	0.00%			
2 AL	2,955	2,602	312	41	0	11.95%	2,954	2,601	312	41	0	11.95%	1	1	0	0	0	0.00%			
3 AR	2,837	2,664	157	16	0	6.10%	2,835	2,664	157	14	0	6.03%	2	0	0	2	0	100.00%			
4 AZ	1,501	1,315	159	27	0	12.39%	1,465	1,297	145	23	0	11.47%	36	18	14	4	0	50.00%			
5 CA	1,806	1,603	142	61	0	11.24%	1,777	1,581	137	59	0	11.03%	29	22	5	2	0	24.14%			
6 CO	2,832	2,573	172	87	0	9.15%	2,813	2,566	166	81	0	8.78%	19	7	6	6	0	63.16%			
7 CT	2,399	1,988	280	131	0	17.13%	2,376	1,969	278	129	0	17.13%	23	19	2	2	0	17.39%			
8 DC	320	235	84	1	0	26.56%	320	235	84	1	0	26.56%	0	0	0	0	0	0			
9 DE	620	580	29	11	0	6.45%	597	560	26	11	0	6.20%	23	20	3	0	0	13.04%			
10 FL	4,619	3,591	827	201	0	22.26%	4,518	3,515	820	183	0	22.20%	101	76	7	18	0	24.75%			
11 GA	2,056	2,017	36	3	0	1.90%	2,037	2,001	33	3	0	1.77%	19	16	3	0	0	15.79%			
12 HI	391	363	23	5	0	7.16%	391	363	23	5	0	7.16%	0	0	0	0	0	0			
13 IA	2,261	2,124	111	26	0	6.06%	2,260	2,123	111	26	0	6.06%	1	1	0	0	0	0.00%			
14 ID	732	672	51	9	0	8.20%	729	671	51	7	0	7.96%	3	1	0	2	0	66.67%			
15 IL	4,202	3,512	452	238	0	16.42%	4,169	3,488	445	236	0	16.33%	33	24	7	2	0	27.27%			
16 IN	1,252	995	210	47	0	20.53%	1,252	995	210	47	0	20.53%	0	0	0	0	0	0			
17 KS	1,238	1,125	90	23	0	9.13%	1,236	1,124	90	22	0	9.06%	2	1	0	1	0	50.00%			
18 KY	3,019	2,674	278	67	0	11.43%	2,992	2,651	277	64	0	11.40%	27	23	1	3	0	14.81%			
19 LA	1,871	1,625	197	49	0	13.15%	1,849	1,612	197	40	0	12.82%	22	13	0	9	0	40.91%			
20 MA	4,267	3,956	246	65	1	7.29%	4,267	3,956	246	65	1	7.29%	0	0	0	0	0	0			
21 MD	1,253	888	224	141	0	29.13%	1,236	874	223	139	0	29.29%	17	14	1	2	0	17.65%			
22 ME	963	927	34	2	0	3.74%	963	927	34	2	0	3.74%	0	0	0	0	0	0			
23 MI	1,931	1,461	345	125	0	24.34%	1,906	1,438	343	125	0	24.55%	25	23	2	0	0	8.00%			
24 MN	3,203	2,799	265	139	0	12.61%	3,187	2,788	260	139	0	12.52%	16	11	5	0	0	31.25%			
25 MO	3,887	3,464	298	125	0	10.88%	3,881	3,464	298	119	0	10.74%	6	0	0	6	0	100.00%			
26 MS	1,308	1,235	57	16	0	5.58%	1,305	1,232	57	16	0	5.59%	3	3	0	0	0	0.00%			
27 MT	976	923	49	4	0	5.43%	976	923	49	4	0	5.43%	0	0	0	0	0	0			
28 NC	1,395	960	261	174	0	31.18%	1,362	949	246	167	0	30.32%	33	11	15	7	0	66.67%			
29 ND	205	171	34	0	0	16.59%	205	171	34	0	0	16.59%	0	0	0	0	0	0			
30 NE	654	577	66	11	0	11.77%	653	576	66	11	0	11.79%	1	1	0	0	0	0.00%			
31 NH	627	523	73	31	0	16.59%	616	517	72	27	0	16.07%	11	6	1	4	0	45.45%			
32 NJ	6,308	4,885	1,100	323	0	22.56%	6,246	4,840	1,092	314	0	22.51%	62	45	8	9	0	27.42%			
33 NM	442	419	15	8	0	5.20%	441	418	15	8	0	5.22%	1	1	0	0	0	0.00%			
34 NV	95	80	15	0	0	15.79%	94	79	15	0	0	15.96%	1	1	0	0	0	0.00%			
35 NY	5,255	3,975	721	559	0	24.36%	5,229	3,953	719	557	0	24.40%	26	22	2	2	0	15.38%			
36 OH	1,886	1,495	315	76	0	20.73%	1,861	1,478	307	76	0	20.58%	25	17	8	0	0	32.00%			
37 OK	1,067	948	87	32	0	11.15%	897	795	80	22	0	11.37%	170	153	7	10	0	10.00%			
38 OR	795	719	72	4	0	9.56%	786	710	72	4	0	9.67%	9	9	0	0	0	0.00%			
39 PA	2,849	2,579	220	50	0	9.48%	2,795	2,533	215	47	0	9.37%	54	46	5	3	0	14.81%			
40 RI	856	735	85	36	0	14.14%	851	731	85	35	0	14.10%	5	4	0	1	0	20.00%			
41 SC	2,170	1,844	249	77	0	15.02%	2,162	1,837	249	76	0	15.03%	8	7	0	1	0	12.50%			
42 SD	252	227	24	1	0	9.92%	252	227	24	1	0	9.92%	0	0	0	0	0	0			
43 TN	2,650	2,272	290	88	0	14.26%	2,635	2,259	290	86	0	14.27%	15	13	0	2	0	13.33%			
44 TX	5,237	4,370	585	282	1	16.56%	5,186	4,344	564	278	1	16.24%	51	26	21	4	0	49.02%			
45 UT	92	92	0	0	0	0.00%	92	92	0	0	0	0.00%	0	0	0	0	0	0			
46 VA	1,825	1,259	372	194	0	31.01%	1,801	1,244	368	189	0	30.93%	24	15	4	5	0	37.50%			
47 VT	328	307	16	5	0	6.40%	328	307	16	5	0	6.40%	0	0	0	0	0	0			
48 WA	2,605	2,223	301	81	1	14.66%	2,604	2,223	301	80	1	14.63%	1	0	0	1	0	100.00%			
49 WI	1,784	1,433	270	81	0	19.67%	1,767	1,423	264	80	0	19.47%	17	10	6	1	0	41.18%			
50 WV	1,974	1,788	138	48	0	9.42%	1,931	1,765	124	42	0	8.60%	43	23	14	6	0	46.51%			
51 WY	152	128	24	0	0	15.79%	151	127	24	0	0	15.89%	1	1	0	0	0	0.00%			
TOTAL	96,266	81,981	10,464	3,821	3	14.84%	95,294	81,271	10,317	3,706	3	14.72%	972	710	147	115	0	26.95%			

**Analysis of FDA Compliance Check Data
FFY 2024 By Month**

Year	Month	FFY 2024 TOTAL ALL TYPES OF INSPECTIONS					FFY 2024 INSPECTIONS <i>Involving a Minor</i>					FFY 2024 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
2023	Oct	9,585	7,950	1,236	399	17.06%	9,540	7,926	1,235	379	16.92%	45	24	1	20	46.67%
2023	Nov	9,357	7,922	1,077	358	15.34%	9,324	7,912	1,076	336	15.14%	33	10	1	22	69.70%
2023	Dec	8,819	7,562	899	358	14.25%	8,697	7,440	899	358	14.45%	122	122	0	0	0.00%
2024	Jan	9,373	7,798	1,189	386	16.80%	9,162	7,609	1,187	366	16.95%	211	189	2	20	10.43%
2024	Feb	9,653	8,298	970	385	14.04%	9,563	8,229	970	364	13.95%	90	69	0	21	23.33%
2024	Mar	9,949	8,461	1,110	378	14.96%	9,866	8,441	1,047	378	14.44%	83	20	63	0	75.90%
2024	Apr	9,975	8,460	1,100	415	15.19%	9,926	8,431	1,100	395	15.06%	49	29	0	20	40.82%
2024	May	9,850	8,544	909	397	13.26%	9,720	8,423	909	388	13.34%	130	121	0	9	6.92%
2024	Jun	9,618	8,358	916	344	13.10%	9,522	8,265	916	341	13.20%	96	93	0	3	3.13%
2024	Jul	10,087	8,628	1,058	401	14.46%	9,974	8,595	978	401	13.83%	113	33	80	0	70.80%
2024	Aug	0	0	0	0		0	0	0	0		0	0	0	0	
2024	Sep	0	0	0	0		0	0	0	0		0	0	0	0	
	TOTAL	96,266	81,981	10,464	3,821	14.84%	95,294	81,271	10,317	3,706	14.72%	972	710	147	115	26.95%

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

as of July 31, 2024

SUMMARY

By PRODUCT TYPE

Product Type	Warning		Civil Money Penalty		Grand Total	% of Overall Violation Rate	
	Letter	%		%		%	
Cigar(s)	4,764	45.53%	1,710	44.75%	6,474	45.32%	6.73%
Cigarette tobacco	6	0.06%	3	0.08%	9	0.06%	0.01%
Cigarettes in a package	2,535	24.23%	655	17.14%	3,190	22.33%	3.31%
ENDS / E-liquid	2,469	23.60%	1,133	29.65%	3,602	25.22%	3.74%
N/A	163	1.56%	129	3.38%	292	2.04%	0.30%
Single cigarette	28	0.27%	17	0.44%	45	0.32%	0.05%
Smokeless tobacco	96	0.92%	38	0.99%	134	0.94%	0.14%
Oral nicotine product	381	3.64%	127	3.32%	508	3.56%	0.53%
Hookah tobacco	22	0.21%	9	0.24%	31	0.22%	0.03%
Grand Total	10,464	100.00%	3,821	100.00%	14,285	100.00%	14.84%



By PRODUCT TYPE & BRAND

Product Type	Brand	Warning		Civil Money Penalty		Grand Total	% Of ALL	
		Letter	%		%		%	
Cigar(s)	Swisher	2,055	43.14%	666	38.95%	2,721	42.03%	
Cigar(s)	Black & Mild	1,774	37.24%	599	35.03%	2,373	36.65%	
Cigar(s)	Game	386	8.10%	165	9.65%	551	8.51%	
Cigar(s)	Other	353	7.41%	173	10.12%	526	8.12%	
Cigar(s)	White Owl	192	4.03%	100	5.85%	292	4.51%	
Cigar(s)	Phillies	4	0.08%	7	0.41%	11	0.17%	
Cigar(s) Total		4,764	100.00%	1,710	100.00%	6,474	100.00%	45.32%
Cigarettes in a package	Marlboro	1,304	51.44%	267	40.76%	1,571	49.25%	
Cigarettes in a package	Newport	822	32.43%	284	43.36%	1,106	34.67%	
Cigarettes in a package	Camel	282	11.12%	65	9.92%	347	10.88%	
Cigarettes in a package	Other	100	3.94%	30	4.58%	130	4.08%	
Cigarettes in a package	Kool	15	0.59%	3	0.46%	18	0.56%	
Cigarettes in a package	Decade	7	0.28%	3	0.46%	10	0.31%	
Cigarettes in a package	Pall Mall	5	0.20%	3	0.46%	8	0.25%	
Cigarettes in a package Total		2,535	100.00%	655	100.00%	3,190	100.00%	22.33%
ENDS / E-liquid	Other	1,676	67.88%	765	67.52%	2,441	67.77%	
ENDS / E-liquid	Vuse	491	19.89%	200	17.65%	691	19.18%	
ENDS / E-liquid	JUUL	267	10.81%	145	12.80%	412	11.44%	
ENDS / E-liquid	NJOY	17	0.69%	8	0.71%	25	0.69%	
ENDS / E-liquid	Logic	11	0.45%	10	0.88%	21	0.58%	
ENDS / E-liquid	blu	7	0.28%	5	0.44%	12	0.33%	
ENDS / E-liquid Total		2,469	100.00%	1,133	100.00%	3,602	100.00%	25.22%
Smokeless tobacco	Grizzly	47	48.96%	26	68.42%	73	54.48%	
Smokeless tobacco	Copenhagen	27	28.13%	4	10.53%	31	23.13%	
Smokeless tobacco	Skoal	10	10.42%	2	5.26%	12	8.96%	
Smokeless tobacco	Other	8	8.33%	3	7.89%	11	8.21%	
Smokeless tobacco	Longhorn	2	2.08%	3	7.89%	5	3.73%	
Smokeless tobacco	Kayak	2	2.08%		0.00%	2	1.49%	
Smokeless tobacco Total		96	100.00%	38	100.00%	134	100.00%	0.94%
Oral nicotine product	Zyn	332	87.14%	115	90.55%	447	87.99%	
Oral nicotine product	Velo	21	5.51%	5	3.94%	26	5.12%	
Oral nicotine product	On	15	3.94%	4	3.15%	19	3.74%	
Oral nicotine product	Rogue	7	1.84%	1	0.79%	8	1.57%	
Oral nicotine product	Other	6	1.57%	2	1.57%	8	1.57%	
Oral nicotine product Total		381	100.00%	127	100.00%	508	100.00%	3.56%
N/A		163		129		292		2.04%
Single cigarette		28		17		45		0.32%
Cigarette tobacco		6		3		9		0.06%
Hookah tobacco		22		9		31		0.22%
Grand Total		10,464		3,821		14,285		100.00%

Highlights of Oct 2023-September 2024 - FFY2024

96,266 Total Compliance Checks
81,981 # of Compliance Checks with NO VIOLATIONS

10,464 # of Warning Letters (WL)
3,821 # of Civil Money Penalties (CMP)

14,285 Total of WL and CMP

14.84% 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 22% of all violations.
- Violations of ENDS / E-liquid products sold to minors represent less than 25% 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 0.32% of all violations
- Violations of ORAL NICOTINE PRODUCT represent 3.56% of all violations

Important Unknowns about the publicly available FDA enforcement Data

An Important 'unknown' are the Products and Brands associated with the 81,981 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.