

SUMMARY Analysis of FDA Compliance Check Data

FFY 2022-2023
through 01/31/2023

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
<i>Where Minors were involved.</i> (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	31,467	27,112	3,385	970	0	13.84%
			1,040,208	902,461	110,451	27,296	168
<i>Adult Inspectors Only</i> (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	56	56	0	0	0	0.00%
			286,322	281,150	5,166	6	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	31,523	27,168	3,385	970	0	13.82%
			1,326,530	1,183,611	115,617	27,302	168

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-December 2023, accessed 02/14/23.

**Analysis of FDA Compliance Check Data
FFY 2023 By State through 01/31/2023**

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	18	18	0	0	0	0.00%	17	17	0	0	0	0.00%	1	1	0	0	0
2 AL	505	454	48	3	0	10.10%	491	440	48	3	0	10.39%	14	14	0	0	0	0.00%
3 AR	614	568	37	9	0	7.49%	614	568	37	9	0	7.49%	0	0	0	0	0	0
4 AZ	485	449	35	1	0	7.42%	485	449	35	1	0	7.42%	0	0	0	0	0	0
5 CA	1,067	957	86	24	0	10.31%	1,067	957	86	24	0	10.31%	0	0	0	0	0	0
6 CO	1,063	937	107	19	0	11.85%	1,063	937	107	19	0	11.85%	0	0	0	0	0	0
7 CT	1,096	949	112	35	0	13.41%	1,096	949	112	35	0	13.41%	0	0	0	0	0	0
8 DC	16	15	1	0	0	6.25%	16	15	1	0	0	6.25%	0	0	0	0	0	0
9 DE	333	317	13	3	0	4.80%	333	317	13	3	0	4.80%	0	0	0	0	0	0
10 FL	2,876	2,192	600	84	0	23.78%	2,875	2,191	600	84	0	23.79%	1	1	0	0	0	0.00%
11 GA	1,077	1,053	23	1	0	2.23%	1,077	1,053	23	1	0	2.23%	0	0	0	0	0	0
12 HI	119	113	5	1	0	5.04%	119	113	5	1	0	5.04%	0	0	0	0	0	0
13 IA	1,031	989	21	21	0	4.07%	1,030	988	21	21	0	4.08%	1	1	0	0	0	0.00%
14 ID	209	195	14	0	0	6.70%	206	192	14	0	0	6.80%	3	3	0	0	0	0.00%
15 IL	1,353	1,174	111	68	0	13.23%	1,353	1,174	111	68	0	13.23%	0	0	0	0	0	0
16 IN	348	291	33	24	0	16.38%	348	291	33	24	0	16.38%	0	0	0	0	0	0
17 KS	310	299	11	0	0	3.55%	310	299	11	0	0	3.55%	0	0	0	0	0	0
18 KY	729	662	42	25	0	9.19%	727	660	42	25	0	9.22%	2	2	0	0	0	0.00%
19 LA	522	402	102	18	0	22.99%	522	402	102	18	0	22.99%	0	0	0	0	0	0
20 MA	1,284	1,171	84	29	0	8.80%	1,284	1,171	84	29	0	8.80%	0	0	0	0	0	0
21 MD	232	182	50	0	0	21.55%	232	182	50	0	0	21.55%	0	0	0	0	0	0
22 ME	340	331	9	0	0	2.65%	340	331	9	0	0	2.65%	0	0	0	0	0	0
23 MI	856	662	152	42	0	22.66%	856	662	152	42	0	22.66%	0	0	0	0	0	0
24 MN	1,366	1,220	112	34	0	10.69%	1,366	1,220	112	34	0	10.69%	0	0	0	0	0	0
25 MO	1,578	1,379	131	68	0	12.61%	1,577	1,378	131	68	0	12.62%	1	1	0	0	0	0.00%
26 MS	796	743	38	15	0	6.66%	796	743	38	15	0	6.66%	0	0	0	0	0	0
27 MT	313	300	12	1	0	4.15%	313	300	12	1	0	4.15%	0	0	0	0	0	0
28 NC	1,024	879	110	35	0	14.16%	1,024	879	110	35	0	14.16%	0	0	0	0	0	0
29 ND	74	68	6	0	0	8.11%	74	68	6	0	0	8.11%	0	0	0	0	0	0
30 NE	276	244	31	1	0	11.59%	276	244	31	1	0	11.59%	0	0	0	0	0	0
31 NH	341	284	39	18	0	16.72%	341	284	39	18	0	16.72%	0	0	0	0	0	0
32 NJ	833	646	120	67	0	22.45%	831	644	120	67	0	22.50%	2	2	0	0	0	0.00%
33 NM	103	100	3	0	0	2.91%	103	100	3	0	0	2.91%	0	0	0	0	0	0
34 NV	37	33	4	0	0	10.81%	37	33	4	0	0	10.81%	0	0	0	0	0	0
35 NY	855	595	222	38	0	30.41%	855	595	222	38	0	30.41%	0	0	0	0	0	0
36 OH	675	550	102	23	0	18.52%	675	550	102	23	0	18.52%	0	0	0	0	0	0
37 OK	204	173	24	7	0	15.20%	180	149	24	7	0	17.22%	24	24	0	0	0	0.00%
38 OR	112	100	12	0	0	10.71%	110	98	12	0	0	10.91%	2	2	0	0	0	0.00%
39 PA	537	388	130	19	0	27.75%	536	387	130	19	0	27.80%	1	1	0	0	0	0.00%
40 RI	257	235	13	9	0	8.56%	257	235	13	9	0	8.56%	0	0	0	0	0	0
41 SC	446	372	51	23	0	16.59%	444	370	51	23	0	16.67%	2	2	0	0	0	0.00%
42 SD	10	6	4	0	0	40.00%	10	6	4	0	0	40.00%	0	0	0	0	0	0
43 TN	1,046	908	123	15	0	13.19%	1,045	907	123	15	0	13.21%	1	1	0	0	0	0.00%
44 TX	1,505	1,305	114	86	0	13.29%	1,505	1,305	114	86	0	13.29%	0	0	0	0	0	0
45 UT	28	27	1	0	0	3.57%	28	27	1	0	0	3.57%	0	0	0	0	0	0
46 VA	200	167	30	3	0	16.50%	200	167	30	3	0	16.50%	0	0	0	0	0	0
47 VT	225	195	25	5	0	13.33%	225	195	25	5	0	13.33%	0	0	0	0	0	0
48 WA	900	732	119	49	0	18.67%	899	731	119	49	0	18.69%	1	1	0	0	0	0.00%
49 WI	475	383	72	20	0	19.37%	475	383	72	20	0	19.37%	0	0	0	0	0	0
50 WV	820	752	41	27	0	8.29%	820	752	41	27	0	8.29%	0	0	0	0	0	0
51 WY	4	4	0	0	0	0.00%	4	4	0	0	0	0.00%	0	0	0	0	0	0
TOTAL	31,523	27,168	3,385	970	0	13.82%	31,467	27,112	3,385	970	0	13.84%	56	56	0	0	0	0.00%

**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	8,023	6,716	1,081	226	16.29%	8,011	6,704	1,081	226	16.32%	12	12	0	0	0.00%
2022	Dec	7,681	6,463	957	261	15.86%	7,659	6,441	957	261	15.90%	22	22	0	0	0.00%
2023	Jan	7,954	7,467	243	244	6.12%	7,938	7,451	243	244	6.14%	16	16	0	0	0.00%
2023	Feb	0	0	0	0		0	0	0	0		0	0	0	0	
2023	Mar	0	0	0	0		0	0	0	0		0	0	0	0	
2023	Apr	0	0	0	0		0	0	0	0		0	0	0	0	
2023	May	0	0	0	0		0	0	0	0		0	0	0	0	
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	31,523	27,168	3,385	970	13.82%	31,467	27,112	3,385	970	13.84%	56	56	0	0	0.00%

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

as of 1/31/23

**SUMMARY
By PRODUCT TYPE**

Product Type	Warning		Civil Money		Grand Total	% of Overall Violation Rate
	Letter	%	Penalty	%		
Cigar(s)	1,583	47.16%	452	46.60%	2,035	47.03%
Cigarette tobacco	7	0.21%	0	0.00%	7	0.16%
Cigarettes in a package	684	20.38%	202	20.82%	886	20.48%
ENDS / E-liquid	1,011	30.12%	297	30.62%	1,308	30.23%
N/A	8	0.24%	6	0.62%	14	0.32%
Single cigarette	10	0.30%	2	0.21%	12	0.28%
Smokeless tobacco	54	1.61%	11	1.13%	65	1.50%
Grand Total	3,357	100.00%	970	100.00%	4,327	13.73%



By PRODUCT TYPE & BRAND

Product Type	Brand	Warning		Civil Money		Grand Total	% of ALL
		Letter	%	Penalty	%		
Cigar(s)	Black & Mild	402	25.39%	77	17.04%	479	23.54%
Cigar(s)	Game	250	15.79%	52	11.50%	302	14.84%
Cigar(s)	Other	141	8.91%	28	6.19%	169	8.30%
Cigar(s)	Swisher	678	42.83%	252	55.75%	930	45.70%
Cigar(s)	White Owl	111	7.01%	43	9.51%	154	7.57%
Cigar(s)	Phillies	1	0.06%	0	0.00%	1	0.05%
Cigar(s)		0	0.00%	0	0.00%	0	0.00%
Cigar(s) Total		1,583	100.00%	452	100.00%	2,035	47.03%
Cigarette tobacco		7				7	0.16%
Cigarettes in a package	Marlboro	399	58.33%	97	48.02%	496	55.98%
Cigarettes in a package	Newport	203	29.68%	66	32.67%	269	30.36%
Cigarettes in a package	Camel	54	7.89%	24	11.88%	78	8.80%
Cigarettes in a package	Other	16	2.34%	11	5.45%	27	3.05%
Cigarettes in a package	Kool	5	0.73%	1	0.50%	6	0.68%
Cigarettes in a package	Winston	5	0.73%	1	0.50%	6	0.68%
Cigarettes in a package	Pall Mall	1	0.15%	2	0.99%	3	0.34%
Cigarettes in a package	Salem	1	0.15%	0	0.00%	1	0.11%
Cigarettes in a package Total		684	100.00%	202	100.00%	886	20.48%
ENDS / E-liquid	Other	602	59.55%	145	48.82%	747	57.11%
ENDS / E-liquid	Vuse	191	18.89%	53	17.85%	244	18.65%
ENDS / E-liquid	JUUL	171	16.91%	91	30.64%	262	20.03%
ENDS / E-liquid	blu	31	3.07%	5	1.68%	36	2.75%
ENDS / E-liquid	Logic	11	1.09%	1	0.34%	12	0.92%
ENDS / E-liquid	NJOY	5	0.49%	2	0.67%	7	0.54%
ENDS / E-liquid		0	0.00%	0	0.00%	0	0.00%
ENDS / E-liquid Total		1,011	100.00%	297	100.00%	1,308	30.23%
N/A		8		6		14	0.32%
Single cigarette		10		2		12	0.28%
Smokeless tobacco	Grizzly	22	2.18%	8	72.73%	30	2.29%
Smokeless tobacco	Copenhagen	10	0.99%	0	0.00%	10	0.76%
Smokeless tobacco	Other	9	0.89%	1	9.09%	10	0.76%
Smokeless tobacco	Stokers	8	0.79%	0	0.00%	8	0.61%
Smokeless tobacco	Longhorn	3	0.30%	0	0.00%	3	0.23%
Smokeless tobacco	Skoal	2	0.20%	2	18.18%	4	0.31%
Smokeless tobacco		0	0.00%	0	0.00%	0	0.00%
Smokeless tobacco		0	0.00%	0	0.00%	0	0.00%
Smokeless tobacco		0	0.00%	0	0.00%	0	0.00%
Smokeless tobacco Total		54	5.34%	11	100.00%	65	4.97%
Grand Total		3,357		970		4,327	100.00%

Highlights of Oct 2022-September 2023 - FFY2023

31,523 Total Compliance Checks
27,168 # of Compliance Checks with NO VIOLATIONS

3,385 # of Warning Letters (WL)
970 # of Civil Money Penalties (CMP)

4,355 Total of WL and CMP

13.82% 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 20% of all violations.
- Violations of ENDS / E-liquid products sold to minors represent less than 30% 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 0.28% of all violations

Important Unknowns about the publicly available FDA enforcement Data

- An Important 'unknown' are the Products and Brands associated with the 27,168 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.