SUMMARY Analysis of FDA Compliance Check Data

FFY 2011-2023 through 09/30/2023

FDA		Total	Number of	Number of	Number of	Number of	
Inspection		Compliance	"NO	Warning	Civil Money	No-Tobacco-	Violation
Туре	Year	Checks	Violations"	Letters	Penalties	Sale Orders	Rate
Where Minors were involved.	FFY2011	11,049	10,271	777	1		7.04%
(Example: Violations may be a sale to a	FFY2012	43,245	39,419	3,443	383		8.85%
minor, but may be other violations, such as	FFY2013	52,027	46,651	4,843	533		10.33%
observed banned self-service racks or other advertision or merchandising violations.)	FFY2014	68,233	60,286	6,871	1,076		11.65%
advertision of merchandising violations.	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	105,336	89,038	12,438	3,860	1	15.47%
		1,114,077	964,387	119,504	30,186	169	13.44%
Adult Inspectors Only	FFY2011	13,355	13,110	245	0		1.83%
(Example: Violations observed by an adult	FFY2012	44,217	43,553	664	0		1.50%
inspector may include banned self-service	FFY2013	57,833	56,683	1,149	1		1.99%
racks, vending machine, "loosies", banned	FFY2014	55,485	54,253	1,232	0		2.22%
advertising such as "light", etc.)	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	147	22	0	21.07%
		287,068	281,727	5,313	28	0	1.86%
	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%
TOTAL	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	106,138	89,671	12,585	3,882	1	15.51%
		1,401,145	1,246,114	124,817	30,214	169	11.06%

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:

- \bullet 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 2011-2023, accessed 10/15/23.

Analysis of FDA Compliance Check Data FFY 2023 By State through 09/30/2023

•	. FFY 2023 TOTAL ALL TYPES OF INSPECTIONS						•	IN	FFY 2 SPECTIONS Inv	023 olving a Minor	FFY 2023 inor INSPECTIONS NOT Involving a Minor								
	Total	Number of	Number of	Number of	Number of			Total	Number of	Number of	-	Number of No-	_	Total	Number of	Number of	-	Number of No-	
	Compliance	"NO	Warning		No-Tobacco-	Violation		Compliance	"NO	Warning	Civil Money	Tobacco-Sale		Compliance	"NO	Warning	Civil Money		Violation
9	tate Checks	Violations"	Letters	Penalties	Sale Orders	Rate		Checks	Violations"	Letters	Penalties	Orders	Rate	Checks	Violations"	Letters	Penalties	Orders	Rate
1 A	. 65	61	4	0	0	6.15%		63	59	4	0	C	6.35%	2	2	0	0	0	0.00%
2 AL	2,553	2,266	265	22	0	11.24%		2,521	2,241	258	22	C	11.11%	32	25	7	0	0	21.88%
3 AF	2,769	2,643	110	16	0	4.55%		2,756	2,631	109	16	C	4.54%	13	12	1	0	0	7.69%
4 A2	1,610	1,432	166	12	0	11.06%		1,585	1,416	157	12	C	10.66%	25	16	9	0	0	36.00%
5 C/				55	0	10.05%		2,024	1,817	152	55	C	10.23%	35	35	0	0	0	0.00%
6 CC	3,749	3,278	366	105	0	12.56%		3,729	3,268	356	105	C	12.36%	20	10	10	0	0	50.00%
7 C1				216	0			3,359	2,777	366	216			29	22	7	0	0	24.14%
8 D				0				166	111	55	0			0		0	0	0	
9 DI				14				830	770	46	14			14	10	4	0	0	
10 FL	7,154			394				7,094	5,086	1,622	386	C		60	38	14	8	0	
11 G/				7	-	,		3,736	3,691	39	6	C		2	1	0	1	0	50.00%
12 HI				8				342	317	17	8			0		0	0	0	0.000/
13 IA	3,218			44				3,217	3,050	123	44			1	1	0	0	0	0.00%
14 ID 15 IL	857 4,176			163				830 4,166	765 3,489	63 514	2 163	C		27 10	25 9	2	0	0	7.41% 10.00%
16 IN				76				1,274	1,038	160	76			0		0	0	0	10.00%
17 KS				3	0			1,706	1,626	77	3			0	0	0	0	0	
17 K3				96				3,075	2,715	264	96	C		22	21	1	0	0	4.55%
19 LA				86				1,849	1,516	249	84	C		25	15	8	2	0	
20 M				92				4,088	3,615	381	92	C		0		0	0	0	40.0070
21 M				5				2,669	2,324	340	5	C		41	35	6	0	0	14.63%
22 M				2				1,206	1,171	33	2			0	0	0	0	0	11.05/0
23 M				200				2,496	1,866	430	200			0	0	0	0	0	
24 M				143				4,146	3,645	358	143			1	1	0	0	0	0.00%
25 M				208				4,560	3,971	382	207	C		34	24	9	1	0	
26 M				49				2,259	2,083	129	47	C		5		0	2	0	
27 M				8				1,121	1,069	44	8	C		0	0	0	0	0	
28 N				93	0	18.16%		2,268	1,860	316	92	C	17.99%	23	15	7	1	0	34.78%
29 NI	107	90	16	1	0	15.89%		107	90	16	1	C	15.89%	0	0	0	0	0	
30 NI	772	664	92	16	0	13.99%		762	655	91	16	C	14.04%	10	9	1	0	0	10.00%
31 NI	H 849	698	107	44	0	17.79%		844	695	106	43	C	17.65%	5	3	1	1	0	40.00%
32 N.	3,296	2,431	553	312	0	26.24%		3,272	2,407	553	312	C	26.44%	24	24	0	0	0	0.00%
33 NI	и 548	475	71	2	0	13.32%		509	436	71	2	C	14.34%	39	39	0	0	0	0.00%
34 N	/ 320	293	27	0	0	8.44%		320	293	27	0	C	8.44%	0	0	0	0	0	
35 N	4,407	3,155	1,007	245	0	28.41%		4,390	3,140	1,005	245	C	28.47%	17	15	2	0	0	11.76%
36 OI				130		25.04%		1,699	1,272	297	130	C	25.13%	14	12	2	0	0	
37 OI				42	0	17.71%		838	682	115	41	C		71	66	4	1	0	7.04%
38 OI				1				653	573	79	1			4		0	0	0	
39 PA				76				2,271	1,858	338	75			10	9	0	1	0	10.00%
40 RI	765			33		-		764	638	93	33			1	1	0	0	0	0.0070
41 SC				58				1,584	1,318	208	58			19	15	4	0	0	
42 SE				1				104	88	15	1			0		0	0	0	
43 TN				112				3,321	2,766	445	110			34	24	8	2	0	
44 TX				308				5,427	4,545	575	307	1		37	23	13	1	0	
45 U				0				244	238	6	0	C		1	1	0	0	0	
46 V/	,			36		00.0		1,424	948	440	36		0011071	34	21	13	0	0	38.24%
47 VT 48 W				15				238	195 2,011	28 326	15 163	C		33	0 29	0	0	0	12.12%
48 W 49 W				163 83				2,500 2,201	1,744	326	163	C		15	9	5	1	0	
50 W				85				2,201	2,277	179	82	0		10	6	4	0	0	
50 W				85				188	182	6	85	0		3	3	0	0	0	0.00%
	TAL 106,138			3,882				105,336	89,038	12,438	3,860		15.47%	802		147	22	-	
	100,130	. 05,071	12,303	3,882	-	13.31/6		103,330	05,038	12,430	3,300	-	13.47/0	302	333	147	22	·	21.07/8

Analysis of FDA Compliance Check Data FFY 2023 By Month

. FFY 2023 TOTAL ALL TYPES OF INSPECTIONS							INSPECTIO	FFY 2023 ONS Involving	a Minor		FFY 2023 INSPECTIONS NOT Involving a Minor						
		Total	Number of	Number of	Number of			Total	Number of	Number of	Number of		Total	Number of	Number of	Number of	
		Compliance	"NO	Warning	Civil Money	Violation		Compliance	"NO	Warning	Civil Money	Violation	Compliance	"NO	Warning	Civil Money	Violation
Year	Month	Checks	Violations"	Letters	Penalties	Rate		Checks	Violations"	Letters	Penalties	Rate	Checks	Violations"	Letters	Penalties	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	7,690	6,463	971	256	15.96%		7,668	6,441	971	256	16.00%	22	22	0	0	0.00%
2023	Jan	8,927	7,467	1,223	237	16.35%		8,911	7,451	1,223	237	16.38%	16	16	0	0	0.00%
2023	Feb	8,770	7,419	1,112	239	15.40%		8,696	7,348	1,109	239	15.50%	74	71	3	0	4.05%
2023	Mar	9,848	8,355	1,089	404	15.16%		9,755	8,265	1,086	404	15.27%	93	90	3	0	3.23%
2023	Apr	9,275	7,817	1,104	354	15.72%		9,219	7,761	1,104	354	15.82%	56	56	0	0	0.00%
2023	May	9,946	8,188	1,357	401	17.68%		9,746	8,067	1,278	401	17.23%	200	121	79	0	39.50%
2023	Jun	8,296	6,815	1,110	371	17.85%		8,286	6,807	1,108	371	17.85%	10	8	2	0	20.00%
2023	Jul	9,491	8,039	1,090	362	15.30%		9,478	8,026	1,090	362	15.32%	13	13	0	0	0.00%
2023	Aug	10,436	8,739	1,275	422	16.26%		10,170	8,533	1,215	422	16.10%	266	206	60	0	22.56%
2023	Sep	7,580	7,131	67	382	5.92%		7,546	7,119	67	360	5.66%	34	12	0	22	64.71%
	TOTAL	106,138	89,671	12,585	3,882	15.51%		105,336	89,038	12,438	3,860	15.47%	802	633	147	22	21.07%

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

SUMMARY By PRODUCT TYPE

By PRODUCT TYPE & BRAND

	Warning		Civil Money				% of Overall Violation
Product Ty	Letter	%	Penalty	%	Grand Total	%	Rate
Cigar(s)	5,592	45.73%	1,781	46.08%	7,373	45.81%	6.95%
Cigarette tobacco	6	0.05%	0	0.00%	6	0.04%	0.01%
garettes in a package	2,780	22.73%	813	21.03%	3,593	22.33%	3.39%
ENDS / E-liquid	3,275	26.78%	1,166	30.17%	4,441	27.60%	4.18%
N/A	400	3.27%	42	1.09%	442	2.75%	0.42%
Single cigarette	30	0.25%	8	0.21%	38	0.24%	0.04%
Smokeless tobacco	<u>145</u>	1.19%	<u>55</u>	1.42%	<u>200</u>	1.24%	0.19%
Grand Total	12,228	100.00%	3,865	100.00%	16,093	100.00%	15.16%



Highlights of Oct 2022-September 2023 - FFY2023

106,138 Total Compliance Checks

89,671 # of Compliance Checks with NO VIOLATIONS

12,585 # of Warning Letters (WL)

3,882 # of Civil Money Penalties (CMP)

16,467 Total of WL and CMP

15.51% 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 28% 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 0.24% of all violations

Important Unknowns about the pubicly available FDA enforcement Data

- An Important 'unknown' are the Products and Brands associated with the 89,671 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.

				Civil				
		Warning		Money		Grand		
Product Type	Brand	Letter	%	Penalty	%	Total	%	% Of ALL
Cigar(s)	Swisher	2,300	41.13%	851	47.78%	3,151	42.74%	
Cigar(s)	Black & Mild	1,783	31.88%	481	27.01%	2,264	30.71%	
Cigar(s)	Game	702	12.55%	228	12.80%	930	12.61%	
Cigar(s)	Other	493	8.82%	98	5.50%	591	8.02%	
Cigar(s)	White Owl	312	5.58%	121	6.79%	433	5.87%	
Cigar(s)	Phillies	2	0.04%	2	0.11%	4	0.05%	
Cigar(s)			0.00%		0.00%	0	0.00%	
Cigar(s) Total		5,592	100.00%	1,781	100.00%	7,373	100.00%	45.81%
Cigarette tobacco		6				6		0.04%
Cigarettes in a package	Marlboro	1,520	54.68%	379	46.62%	1,899	52.85%	
Cigarettes in a package	Newport	837	30.11%	277	34.07%	1,114	31.00%	
Cigarettes in a package	Camel	255	9.17%	94	11.56%	349	9.71%	
Cigarettes in a package	Other	110	3.96%	43	5.29%	153	4.26%	
Cigarettes in a package	Pall Mall	24	0.86%	9	1.11%	33	0.92%	
Cigarettes in a package	Kool	23	0.83%	6	0.74%	29	0.81%	
Cigarettes in a package	Winston	8	0.29%	2	0.25%	10	0.28%	
Cigarettes in a package	Salem	3	0.11%	3	0.37%	6	0.17%	
Cigarettes in a package Tot	al	2,780	100.00%	813	100.00%	3,593	100.00%	22.33%
ENDS / E-liquid	Other	2,076	63.39%	631	54.12%	2,707	60.95%	
ENDS / E-liquid	Vuse	590	18.02%	240	20.58%	830	18.69%	
ENDS / E-liquid	JUUL	512	15.63%	264	22.64%	776	17.47%	
ENDS / E-liquid	blu	51	1.56%	17	1.46%	68	1.53%	
ENDS / E-liquid	Logic	29	0.89%	7	0.60%	36	0.81%	
ENDS / E-liquid	NJOY	17	0.52%	7	0.60%	24	0.54%	
ENDS / E-liquid	14301	1,	0.00%	,	0.00%	0	0.00%	
ENDS / E-liquid Total		3,275	100.00%	1,166	100.00%	4,441	100.00%	27.60%
N/A		400		42		442		2.75%
Single cigarette		30		8		38		0.24%
Smokeless tobacco	Grizzly	67	2.05%	35	63.64%	102	2.30%	
Smokeless tobacco	Copenhagen	42	1.28%	5	9.09%	47	1.06%	
Smokeless tobacco	Other	13	0.40%	5	9.09%	18	0.41%	
Smokeless tobacco	Stokers	9	0.27%		0.00%	9	0.20%	
Smokeless tobacco	Longhorn	5	0.15%	2	3.64%	7	0.16%	
Smokeless tobacco	Skoal	5	0.15%	7	12.73%	12	0.27%	
Smokeless tobacco	Red Seal	3	0.09%	1	1.82%	4	0.09%	
Smokeless tobacco	Husky	1	0.03%		0.00%	1	0.02%	
Smokeless tobacco	•		0.00%		0.00%	0	0.00%	
Smokeless tobacco Total		145	4.43%	55	100.00%	200	4.50%	1.24%
Grand Total		12,228		3,865		16,093		100.00%