

# SUMMARY Analysis of FDA Compliance Check Data

FFY 2011-2015  
through 1/31/15

FDA Inspection Type	Year	Total Compliance Checks	Number of "NO Violations"	Number of Warning Letters	Number of Civil Money Penalties	Violation Rate
<b>Where Minors were Involved.</b>  (Example: Violations may be a sale to a minor, but may be other violations, such as observed banned self-service racks or other advertising 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	68,232	60,285	6,871	1,076	11.65%
	FFY2015	31,602	27,323	3,416	863	13.54%
			206,155	183,949	19,350	2,856
<b>Adult Inspectors Only</b>  (Example: Violations observed by an adult inspector may include banned self-service racks, vending machine, "loosies," banned advertising such as "lights," etc.)	FFY2011	13,355	13,110	245	-	1.83%
	FFY2012	44,217	43,553	664	-	1.50%
	FFY2013	57,833	56,683	1,149	1	1.99%
	FFY2014	55,486	54,254	1,232	-	2.22%
	FFY2015	11,025	10,795	230	-	2.09%
			181,916	178,395	3,520	1
<b>TOTAL</b>	FFY2011	24,404	23,381	1,022	1	4.19%
	FFY2012	87,462	82,972	4,107	383	5.13%
	FFY2013	109,860	103,334	5,992	534	5.94%
	FFY2014	123,718	114,539	8,103	1,076	7.42%
	FFY2015	42,627	38,118	3,646	863	10.58%
			388,071	362,344	22,870	2,857

## Information about FDA publicly available Enforcement Data

In June 2014, FDA provided additional data fields in the raw data it makes publicly available at fda.gov. This new data allows for greater analysis. FDA raw data now enables the reporting of:

Federal Fiscal Year (FFY) statistics, which is Oct. 1-Sept. 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)



**Data Analysis:** This analysis was completed by The We Card Program, Inc. using publicly 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-Jan. 2015, accessed 2/12/15.

**Analysis of FDA Compliance Check Data  
FFY 2015 By State through 1/31/15**

	FFY 2015 TOTAL ALL TYPES OF INSPECTIONS						FFY 2015 INSPECTIONS Involving a Minor					FFY 2015 INSPECTIONS NOT Involving a Minor				
	State	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
1	AK	84	83	1	0	1.19%	84	83	1	-	1.19%	0	-	-	-	0.00%
2	AL	485	464	21	0	4.33%	72	60	12	-	16.67%	413	404	9	-	2.18%
3	AR	678	645	19	14	4.87%	494	462	18	14	6.48%	184	183	1	-	0.54%
4	AZ	764	646	106	12	15.45%	757	640	105	12	15.46%	7	6	1	-	14.29%
5	CA	1,221	1,184	36	1	3.03%	1,005	978	26	1	2.69%	216	206	10	-	4.63%
6	CO	555	499	38	18	10.09%	412	362	32	18	12.14%	143	137	6	-	4.20%
7	CT	642	507	81	54	21.03%	625	498	73	54	20.32%	17	9	8	-	47.06%
8	DC	81	78	3	0	3.70%	0	-	-	-	0.00%	81	78	3	-	3.70%
9	DE	6	1	5	0	83.33%	6	1	5	-	83.33%	0	-	-	-	0.00%
10	FL	5,379	4,472	907	0	16.86%	5,355	4,448	907	-	16.94%	24	24	-	-	0.00%
11	GA	713	668	43	2	6.31%	511	466	43	2	8.81%	202	202	-	-	0.00%
12	HI	50	49	1	0	2.00%	44	43	1	-	2.27%	6	6	-	-	0.00%
13	IA	692	674	15	3	2.60%	445	432	10	3	2.92%	247	242	5	-	2.02%
14	ID	534	505	21	8	5.43%	289	260	21	8	10.03%	245	245	-	-	0.00%
15	IL	614	533	49	32	13.19%	429	364	33	32	15.15%	185	169	16	-	8.65%
16	IN	2,182	2,000	154	28	8.34%	1,862	1,684	150	28	9.56%	320	316	4	-	1.25%
17	KS	871	843	28	0	3.21%	744	716	28	-	3.76%	127	127	-	-	0.00%
18	KY	783	760	23	0	2.94%	606	583	23	-	3.80%	177	177	-	-	0.00%
19	LA	20	8	0	12	60.00%	19	7	-	12	63.16%	1	1	-	-	0.00%
20	MA	2,287	2,141	111	35	6.38%	1,579	1,435	109	35	9.12%	708	706	2	-	0.28%
21	MD	778	680	42	56	12.60%	459	363	40	56	20.92%	319	317	2	-	0.63%
22	ME	193	188	5	0	2.59%	22	17	5	-	22.73%	171	171	-	-	0.00%
23	MI	954	754	94	106	20.96%	928	729	93	106	21.44%	26	25	1	-	3.85%
24	MN	2,006	1,879	108	19	6.33%	1,451	1,331	101	19	8.27%	555	548	7	-	1.26%
25	MO	1,185	928	157	100	21.69%	1,093	846	147	100	22.60%	92	82	10	-	10.87%
26	MS	1,477	1,442	30	5	2.37%	817	784	28	5	4.04%	660	658	2	-	0.30%
27	MT	503	487	15	1	3.18%	48	43	4	1	10.42%	455	444	11	-	2.42%
28	NC	118	63	26	29	46.61%	90	36	25	29	60.00%	28	27	1	-	3.57%
29	ND	110	105	5	0	4.55%	110	105	5	-	4.55%	0	-	-	-	0.00%
30	NE	581	555	26	0	4.48%	581	555	26	-	4.48%	0	-	-	-	0.00%
31	NH	88	79	4	5	10.23%	40	31	4	5	22.50%	48	48	-	-	0.00%
32	NJ	1,832	1,622	154	56	11.46%	1,363	1,156	151	56	15.19%	469	466	3	-	0.64%
33	NM	45	45	0	0	0.00%	0	-	-	-	0.00%	45	45	-	-	0.00%
34	NV	1	1	0	0	0.00%	0	-	-	-	0.00%	1	1	-	-	0.00%
35	NY	385	370	15	0	3.90%	384	369	15	-	3.91%	1	1	-	-	0.00%
36	OH	147	31	116	0	78.91%	142	29	113	-	79.58%	5	2	3	-	60.00%
37	OK	270	230	30	10	14.81%	222	182	30	10	18.02%	48	48	-	-	0.00%
38	OR	548	502	46	0	8.39%	548	502	46	-	8.39%	0	-	-	-	0.00%
39	PA	1,647	1,353	253	41	17.85%	1,220	947	232	41	22.38%	427	406	21	-	4.92%
40	RI	183	168	4	11	8.20%	59	45	3	11	23.73%	124	123	1	-	0.81%
41	SC	2,688	2,505	102	81	6.81%	1,051	896	74	81	14.75%	1,637	1,609	28	-	1.71%
42	SD	635	491	144	0	22.68%	635	491	144	-	22.68%	0	-	-	-	0.00%
43	TN	422	335	85	2	20.62%	315	249	64	2	20.95%	107	86	21	-	19.63%
44	TX	2,069	1,927	131	11	6.86%	1,683	1,543	129	11	8.32%	386	384	2	-	0.52%
45	UT	0	0	0	0	0.00%	0	-	-	-	0.00%	0	-	-	-	0.00%
46	VA	444	425	6	13	4.28%	84	66	5	13	21.43%	360	359	1	-	0.28%
47	VT	368	352	16	0	4.35%	199	183	16	-	8.04%	169	169	-	-	0.00%
48	WA	2,752	2,447	228	77	11.08%	1,671	1,389	205	77	16.88%	1,081	1,058	23	-	2.13%
49	WI	588	539	42	7	8.33%	129	108	14	7	16.28%	459	431	28	-	6.10%
50	WV	927	821	92	14	11.43%	878	772	92	14	12.07%	49	49	-	-	0.00%
51	WY	42	34	8	0	19.05%	42	34	8	-	19.05%	0	-	-	-	0.00%
	<b>TOTAL</b>	<b>42,627</b>	<b>38,118</b>	<b>3,646</b>	<b>863</b>	<b>10.58%</b>	<b>31,602</b>	<b>27,323</b>	<b>3,416</b>	<b>863</b>	<b>13.54%</b>	<b>11,025</b>	<b>10,795</b>	<b>230</b>	<b>0</b>	<b>2.09%</b>