

SUMMARY Analysis of FDA Compliance Check Data

FFY 2024-2025
through 12/31/2024

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
<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	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	115,224	98,342	12,495	4,387	3	14.65%
	FFY2025	28,638	24,627	2,998	1,013		14.01%
		1,257,992	1,087,353	135,079	35,560	178	13.56%
<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	7,772	7,767	4	1		0.06%
	FFY2022	128	119	9		0	7.03%
	FFY2023	800	633	147	20		20.88%
	FFY2024	1,019	757	147	115		25.71%
	FFY2025	357	237	116	4		33.61%
		288,442	282,721	5,576	145	0	1.98%
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	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	116,243	99,099	12,642	4,502	3	14.75%
	FFY2025	28,995	24,864	3,114	1,017	0	14.25%
		1,546,434	1,370,074	140,655	35,705	178	11.40%

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 fd.gov. Calculations of Total Compliance Checks and Violation Rate were computed by The We Card Program. Inspections Data FFY 2011-December 31 2024, accessed 01/18/24.