FFY 2011-2023
through 09/30/2023

| FDA Inspection Type | Year | Total Compliance Checks | Number of "NO Violations" | Number of Warning Letters | Number of Civil Money Penalties | Number of No-TobaccoSale Orders | Violation 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 | FFY2014 | 68,233 | 60,286 | 6,871 | 1,076 |  | 11.65\% |
| advertision or 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 Dat

FDA raw data now enables the reporting of:
Federal Fiscal Year (FFY) statistics, which is Oct. 1-Sep. 30- 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, EDA conducts two types of inspections of retail stores

- Inspections of retail stores where minors are involved. These inspections involve an
atempted 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 mach ines, banned single cigarertet sales also known as "loosies", banned advertising of
product, such as "lights" or banned characterizing flavors.

The raw data tie
Retailer Name
Street Address City, State, Ziip
Deeicision Type -- (No Violation, Warring Letter or Civil Money Penalty) Minor Involved - - Yes or No
Sale to Minor - - Yes or No
Sale to Minor-- - -e orvo
Decision Date --The date FDA determined a Decision Type from a
previously completed fDA inspection.
Link --- link to eithera Warning Letter or a Civil Money Penalty Inspection Date - - for data with violations
Product \& Brand - - only aviilable for Warning Letter
and Civil Money Penalty data.
NO Perid

Data Analysis: This analysis was completed by The
We Card Program, Inc We Card Program, Inc. using publically available raw
data a osted olline a fada.gov. Calculations of Total
Complance Cheectate Compliance Checks and Violation Rate wer
computed by The ewe Card rogram. Inspe FFY 2011-2023, accessed 10/15/23.


| FY 2023 <br> TOTAL ALL TYPES OF INSPECTIO |  |  |  |  |  |  | FFY 2023 <br> INSPECTIONS Involving a Minor |  |  |  |  | FFY 2023 |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Year | Month | Total Compliance Checks | Number of "NO Violations" | Number of Warning Letters | Number of Civil Money Penalties | Violation | Total Compliance Checks | Number of <br> "NO <br> Violations" | Number of Warning Letters | Number of Civil Money Penalties | Violation | $\begin{aligned} & \text { Total } \\ & \text { Compliance } \\ & \text { Checks } \end{aligned}$ | 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 | 8,014 | 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\% |

By PRODUCT TYPE
$\left.\begin{array}{rrrrrrrrr} & & & & & & & \begin{array}{c}\text { \% of } \\ \text { Overall }\end{array} \\ \text { Violation }\end{array}\right]$

## 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) <br> 3,882 \# of Civil Money Penalties (CMP) <br> 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 violation
- Violations of SMOKELESS TOBACCO products sold to minors represent less than $1 \%$ of all violation
- 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.

By PRODUCT TYPE \& BRAND

| Product Type | Brand | Warning Letter | \% | Civil <br> Money <br> Penalty | \% | Grand <br> 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 Total |  | 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 |  |  | 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\% |

