SOUTH CAROLINA FDA TOBACCO INSPECTION PROGRAM

MAY 4, 2017
PREVENTION QUARTERLY
PROGRAM NUMBERS

• OVER 52,000 INSPECTIONS COMPLETED
• 2,644 WARNING LETTERS ISSUED
• 647 CIVIL MONEY PENALTIES
• 1 NO SALE ORDER

*AS OF 5/3/17 PER FDA INSPECTION DATABASE
## CIVIL MONEY PENALTIES

<table>
<thead>
<tr>
<th>NUMBER OF REGULATION VIOLATIONS</th>
<th>CMP AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>$0 (WARNING LETTER SENT BY CTP)</td>
</tr>
<tr>
<td>2 WITHIN A 12-MONTH PERIOD</td>
<td>$279</td>
</tr>
<tr>
<td>3 WITHIN A 24-MONTH PERIOD</td>
<td>$559</td>
</tr>
<tr>
<td>4 WITHIN A 24-MONTH PERIOD</td>
<td>$2,236</td>
</tr>
<tr>
<td>5 WITHIN A 36-MONTH PERIOD</td>
<td>$5,591</td>
</tr>
<tr>
<td>6 WITHIN A 48-MONTH PERIOD</td>
<td>$11,182</td>
</tr>
</tbody>
</table>

*amounts adjusted for inflation each year

https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm232109.htm#civilmoneypenalty
FY17 INSPECTIONS

- 4,384 INSPECTIONS ADJUDICATED SO FAR IN FY17 (OCTOBER-PRESENT)
- 3,890 NO VIOLATIONS
- 340 WARNING LETTERS
- 153 CIVIL MONEY PENALTIES
- 1 NO SALE ORDER

*AS OF 5/3/17 PER FDA INSPECTION DATABASE
FY 17 WARNING LETTERS ISSUED

As of May 3, 2017

*Includes both A&L & UB Inspections
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RESOURCES

FDA WEBSITE

https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm

- DATA ON INSPECTIONS, VIOLATIONS, CMPs, NO SALE ORDERS
- RETAIL EDUCATION
- REPORT POTENTIAL VIOLATIONS

FDA EXCHANGE LAB

https://digitalmedia.hhs.gov/tobacco

- TOBACCO RELATED DIGITAL AND PRINT MEDIA
CONTACT INFORMATION

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