

**Department of Health and Human Services  
DEPARTMENTAL APPEALS BOARD  
Civil Remedies Division**

Center for Tobacco Products,  
Complainant

v.

Auto Valet, Inc.  
d/b/a Finest Car Wash,  
Respondent.

Docket No. T-17-3153  
FDA Docket No. FDA-2017-H-1867

Decision No. TB2571

Date: March 29, 2018

**DECISION**

Found:

- 1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1)<sup>1</sup> on July 21, 2015 and October 23, 2016 as charged in the complaint; and
- 2) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(2)(i) on July 21, 2015 and October 23, 2016 as charged in the complaint; and
- 3) Respondent committed three (3) violations in a twenty-four (24) month period as set forth hereinabove.
- 4) Respondent is hereby assessed a civil penalty in the amount of \$550.

Glossary:

ALJ	administrative law judge <sup>2</sup>
CTP/Complainant	Center for Tobacco Products
FDCA	Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9)
FDA	Food and Drug Administration

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<sup>1</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

<sup>2</sup> See 5 C.F.R. § 930.204.

HHS	Dept. of Health and Human Services
OSC	Order to Show Cause
PO	Procedural Order
POS	UPS Proof of Service
Respondent	Auto Valet, Inc. d/b/a Finest Car Wash
TCA	The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009)

## I. JURISDICTION

I have jurisdiction to hear this case pursuant to my appointment by the Secretary of Health and Human Services and my authority under the Administrative Procedure Act (5 U.S.C. §§ 554-556), 5 U.S.C.A. § 3106, 21 U.S.C. § 333(f)(5), 5 C.F.R. §§ 930.201 et seq. and 21 C.F.R. Part 17.<sup>3</sup>

## II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) filed a complaint dated April 3, 2017 alleging that FDA documented three (3) violations within a twenty-four (24) month period.

Auto Valet, Inc. d/b/a Finest Car Wash was served with process on April 6, 2017 by United Parcel Service. Respondent filed an Answer dated May 5, 2017 in which it denied the allegations.

I conducted a hearing on December 5, 2017. The parties filed post-hearing briefs on February 16, 2017.

The matter is now ready for decision (21 C.F.R. § 17.45 (c)).

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<sup>3</sup> See also *Butz v. Economou*, 438 U.S. 478 at 513, 98 S.Ct. 2894, 57 L.Ed.2d 895 (1978); *Marshall v. Jerrico, Inc.*, 446 U.S. 238 (1980); *Federal Maritime Com'n v. South Carolina State Ports Authority*, 535 U.S. 743, 744 (2002).

### III. BURDEN OF PROOF

CTP as the petitioning party has the burden of proof (21 C.F.R. § 17.33).

### IV. LAW

21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i).

### V. ISSUES

Did Respondent violate 21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i) as alleged in the complaint?

If so, is a civil money penalty in the amount of \$550 appropriate?

### VI. ALLEGATIONS

#### A. Complainant's Recitation of facts

CTP alleged that Respondent owned an establishment, doing business under the name Finest Car Wash, located at 36 Pleasant Valley Parkway, Providence, Rhode Island 02908. Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

CTP's complaint further alleged that on August 27, 2015, CTP issued a Warning Letter to Respondent <sup>4</sup>, alleging that Respondent committed the following violations:

- a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a)(1).

Specifically, a person younger than 18 years of age was able to purchase a package of Newport Box 100s on July 21, 2015, at approximately 2:43 PM;  
and

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<sup>4</sup> In the Warning Letter, Respondent was identified as Irving #1 Finest Car Wash.

- b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on July 21, 2015, at approximately 2:43 PM.

Further, during a subsequent inspection of Finest Car Wash conducted on October 23, 2016, an FDA-commissioned inspector documented the following violations:

- a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a)(1). Specifically, a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes on October 23, 2016, at approximately 11:51 AM; and
- b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on October 23, 2016, at approximately 11:51 AM.

B. Respondent's recitation of facts

In its Answer, Respondent denied the allegations contained in the complaint. Respondent argued that its actions were not intentional, that it promptly took remedial measures, and it discharged the employee in question.

## VII. FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

The “relevant statute” in this case is actually a combination of statutes and regulations: The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111 31, 123 Stat. 1776 (2009) (TCA), amended the Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9) (FDCA) and created a new subchapter of that Act that dealt exclusively with tobacco products, (21 U.S.C. §§ 387-387u), and it also modified other parts of the FDCA explicitly to include tobacco products among the regulated products whose misbranding can give rise to civil, and in some cases criminal, liability. The 2009 amendments to the FDCA contained within the TCA also charged the Secretary of Health and Human Services with, among other things, creating regulations to govern tobacco sales. The Secretary’s regulations on tobacco products appear in Part 1140 of title 21, Code of Federal Regulations.

Under the FDCA, “[a] tobacco product shall be deemed to be misbranded if, in the case of any tobacco product sold or offered for sale in any State, it is sold or distributed in violation of regulations prescribed under section 387f(d).” 21 U.S.C. § 387c(a)(7)(B) (2012). Section 387 a-1 directed FDA to re-issue, with some modifications, regulations previously passed in 1996. 21 U.S.C. § 387 a-1(a)(2012). These regulations were passed pursuant to section 387f(d), which authorizes FDA to promulgate regulations on the sale and distribution of tobacco products. 75 Fed. Reg. 13,225 (March 19, 2010), codified at 21 C.F.R. Part 1140 (2015); 21 U.S.C. § 387f(d)(1) (2012). Accordingly, 21 C.F.R. § 1140.1(b) provides that “failure to comply with any applicable provision in this part in

the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.”

Under 21 U.S.C. § 331(k), “[t]he alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded” is a prohibited act under 21 U.S.C. § 331. Thus, when a Retailer such as Respondent misbrands a tobacco product by violating a requirement of 21 C.F.R. Part 1140, that misbranding in turn violates the FDCA, specifically 21 U.S.C. § 331(k). FDA may seek a civil money penalty from “any person who violates a requirement of this chapter which relates to tobacco products.” 21 U.S.C. § 333(f)(9)(A) (2012). Penalties are set by 21 U.S.C. § 333 note and 21 C.F.R. § 17.2. Under current FDA policy, the first time FDA finds violations of 21 C.F.R. Part 1140 at an establishment, FDA only counts one violation regardless of the number of specific regulatory requirements that were actually violated, but if FDA finds violations on subsequent occasions, it will count violations of specific regulatory requirements individually in computing any civil money penalty sought. This policy is set forth in detail, with examples to illustrate, at *U.S. Food & Drug Admin., Guidance for Industry and FDA Staff, Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers, Responses to Frequently Asked Questions (Revised) (2015)*, available at

<http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/U>

[CM447310.pdf](#) [hereinafter *Guidance for Industry*], at 13-15. So, for instance, if a retailer sells a tobacco product on a particular occasion to a minor without checking for photographic identification, in violation of 21 C.F.R. §§ 1140.14(a)(1) and (a)(2)(i), this will count as two separate violations for purposes of computing the civil money penalty, unless it is the first time violations were observed at that particular establishment. This policy of counting violations has been determined by the HHS Departmental Appeals Board (Board) to be consistent with the language of the FDCA and its implementing regulations, *see CTP v. Orton Motor Company*, Departmental Appeals Board Decision number 2717 of June 30, 2016. The Board's decision was upheld on appeal. *see Orton Motor, Inc. d/b/a Orton's Bagley v. United States Department of Health and Human Services*, No. 16-1299, WL 1386141, (D.C. Cir. Mar. 20, 2018). In *Orton*, the court held that the FDCA permits multiple violations where multiple regulations were breached. *Id.* at 14. The regulations authorize the FDA to impose penalties for each violation of the tobacco sale restrictions arising during a single inspection. *Id.* at 11.

## VIII. HEARING

A hearing was held on December 5, 2017 by telephone as set forth in my October 3, 2017 Order of the Court. Samantha Hong, Esquire, appeared on behalf of Complainant. Scott J. Summer, Esquire, appeared on behalf of Respondent.

## IX. SUMMARY OF TESTIMONY AND EVIDENCE

### A. Complainant's case

Complainant submitted evidence and testimony in form of written declarations and photographs. Complainant offered CTP Exhibits 1 through 21, inclusive, the exhibits were marked for identification. Respondent did not object to any of Complainant's exhibits. I admit Complainant's Exhibits 1 through 21, inclusive.

#### i. Inspector David Tejada

Witness David Tejada, the FDA-commissioned Inspector who conducted the inspection of Respondent's establishment on July 21, 2015 testified on behalf of Complainant. Complainant provided Inspector Tejada's written direct testimony as CTP Ex. 4.

Inspector Tejada testified that on July 21, 2015, at approximately 2:43 PM, he and a minor conducted an undercover buy (UB) compliance check inspection at Respondent's establishment, Finest Car Wash, located at 36 Pleasant Valley Parkway, Providence, Rhode Island 02908. CTP Ex. 4 at 2. Before the inspection, Inspector Tejada confirmed that the minor left his/her photographic identification (ID) in the car and that the minor did not have any tobacco products in his/her possession. CTP Ex. 4 at 2.

According to his testimony, Inspector Tejada parked his car near Respondent's establishment and he and the minor exited the vehicle. He took a position where he had a clear, unobstructed view of the service window and the minor, and watched the minor approach the transaction kiosk at Respondent's establishment. CTP Ex. 4 at 2. Inspector Tejada testified that he observed the minor purchase a package of cigarettes from an

employee at Respondent's establishment, and prior to the purchase the minor did not present any identification to the employee. CTP Ex. 4 at 3. The employee did not provide the minor with a receipt after the purchase. *Id.*

After the transaction, Inspector Tejada and the minor returned to the vehicle where immediately upon entering, the minor handed the inspector the package of cigarettes. Inspector Tejada observed that the package of cigarettes were Newport Box 100s cigarettes. Inspector Tejada processed the evidence according to procedure and completed a narrative report. CTP Ex. 4 at 3; *see* CTP Exs. 7-8. Inspector Tejada also testified that CTP Exhibits 7 and 10 were true and accurate copies. CTP Ex. 4 at 3.

ii. Inspector Derek Shields

Witness Derek Shields, the FDA-commissioned Inspector who conducted the inspection of Respondent's establishment on October 23, 2016 testified on behalf of Complainant. Complainant provided Inspector Shields' written direct testimony as CTP Ex. 5.

Inspector Shields testified that on October 23, 2016, at approximately 11:51 AM, he and a minor conducted the follow-up UB compliance check inspection at Respondent's establishment. CTP Ex. 5 at 2. Before the inspection, Inspector Shields confirmed that the minor left his/her photographic identification (ID) in the car and that the minor did not have any tobacco products in his/her possession. CTP Ex. 5 at 2.

According to his testimony, Inspector Shields parked his car near Respondent's establishment and the minor exited the vehicle. Inspector Shields remained inside his vehicle and watched the minor approach the transaction kiosk window at Respondent's

establishment. CTP Ex. 5 at 2. The minor completed the transaction, returned to the Inspector's vehicle, and handed Inspector Shields a package of cigarettes. Inspector Shields observed that the package of cigarettes were Marlboro cigarettes. The minor reported to Inspector Shields that during the inspection, the minor was able to purchase a package of cigarettes from an employee at the establishment. The minor also reported to Inspector Shields that prior to the purchase the minor did not present any identification to the employee, and the employee did not provide a receipt to the minor after the purchase. CTP Ex. 5 at 3.

Inspector Shields processed the evidence according to procedure and completed a narrative report. CTP Ex. 5 at 3; *see* CTP Exs. 14-15. Inspector Shields also testified that CTP Exhibits 14 and 17 were true and accurate copies. CTP Ex. 5 at 3.

iii. Ms. Laurie Sternberg

Witness Laurie Sternberg, Senior Regulatory Counsel, Office of Compliance and Enforcement, CTP, FDA, testified on behalf of Complainant. Complainant provided Ms. Sternberg's written direct testimony as CTP Ex. 3.

Ms. Sternberg testified that Newport brand cigarettes, the tobacco product purchased during the July 21, 2015 inspection, were manufactured or processed for commercial distribution at facilities in North Carolina and Virginia. CTP Ex. 3 at 2-3. The manufacturer of Newport brand cigarettes does not have any production facilities in Rhode Island, where the tobacco product at issue was purchased. CTP Ex. 3 at 3. Ms. Sternberg further testified that Marlboro brand cigarettes, the tobacco product purchased during the October 23, 2016 inspection, were manufactured or processed for commercial

distribution at facilities in Virginia. CTP Ex. 3 at 3. The manufacturer of Marlboro brand cigarettes does not have any production facilities in Rhode Island, where the tobacco product at issue was purchased. CTP Ex. 3 at 3.

B. Respondent's case

Respondent submitted five exhibits marked as R. Ex. 1 through 5. Complainant did not object to any of Respondent's exhibits. I admit Respondent's Exhibits 1 through 5, inclusive.

i. Peter Montaquila, Jr.

Witness Peter Montaquila, Jr., Respondent's owner, testified on behalf of Respondent. Respondent offered Mr. Montaquilia's written direct testimony as R Ex. 1.

Mr. Montaquila testified that it was his understanding that after receiving the warning letter regarding the July 21, 2015 violations, Respondent's General Manager met with all cashiers and confirmed that they understood the rules regarding tobacco sales to minors. R. Ex. 1 at 2. The manager also met with the attendant involved in the July 21, 2015 violations and warned that "she could lose her job if she again made the mistake of selling to a minor." *Id.* After receiving the notice regarding the October 23, 2016 violations, Respondent fired the cashier involved. *Id.*

C. Credibility determinations

I find and conclude testimony and evidence by both parties was credible.

X. ANALYSIS OF EVIDENCE AND TESTIMONY

A. Complainant's case

Complainant offered and I admitted into evidence Exhibits 1 through 21, inclusive. Pursuant to 21 C.F.R. § 17.33(b) in order to prevail, CTP must prove Respondent's liability and the appropriateness of the penalty under the applicable statute by a preponderance of the evidence.

I must determine whether the allegations in the complaint are true, and if so, whether Respondent's actions identified in the complaint violated the law. 21 C.F.R. § 14.45(b)(1).

B. Respondent's case

Respondent offered and I admitted into evidence Exhibits 1 through 5, inclusive. Pursuant to 21 C.F.R. § 17.33(c) Respondent must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

C. Analysis

- i. I find and conclude that CTP has shown by a preponderance of the evidence that Respondent violated 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i) when it impermissibly sold cigarettes to a minor and failed to verify the minor's age by means of photographic identification on July 21, 2015, at approximately 2:43 PM.

On July 21, 2015, Inspector Tejada and the confidential state-contracted minor conducted an undercover buy compliance check inspection of Respondent's

establishment at approximately 2:43 PM. CTP Ex. 7 at 1. Inspector Tejada confirmed that the minor left his/her photographic identification in the car, and that the minor did not possess any tobacco products on his/her person before the inspection. *Id.*

The inspector had a clear, unobstructed view of the service window and the minor, and observed the minor approach the transaction kiosk at Respondent's establishment. CTP Ex. 4 at 2. Inspector Tejada observed the minor purchase a package of Newport Box 100s cigarettes from one of Respondent's employees, and the minor did not provide an identification to the employee prior to the purchase. CTP Ex. 7 at 1. I find Inspector Tejada's testimony to be credible and unbiased. I find that it, in conjunction with the corroborating documentary evidence (e.g. the contemporaneous report) and physical evidence (e.g. photographs of the Newport 100s cigarettes purchased on that date), CTP has satisfied its burden of proving that Respondent violated 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i) on July 21, 2015 at 2:43 PM by a preponderance of the evidence.

- ii. I find and conclude that CTP has shown by a preponderance of the evidence that Respondent violated 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i) when it impermissibly sold cigarettes to a minor and failed to verify the minor's age by means of photographic identification on October 23, 2016, at approximately 11:51 AM.

On October 23, 2016, Inspector Shields and the confidential state-contracted minor conducted a follow-up undercover buy compliance check inspection of Respondent's establishment at approximately 11:51 AM. CTP Ex. 5 at 2. Inspector Shields confirmed that the minor left his/her photographic identification in the car, and

that the minor did not possess any tobacco products on his/her person before the inspection. *Id.*

The inspector remained inside his vehicle and observed the minor approach the transaction kiosk at Respondent's establishment. CTP Ex. 5 at 2. The minor completed the transaction, returned to the inspector's vehicle, and handed Inspector Shields a package of Marlboro cigarettes. I find Inspector Shield's testimony to be credible and unbiased. I find that it, in conjunction with the corroborating documentary evidence (e.g. the contemporaneous report) and physical evidence (e.g. photographs of the Marlboro cigarettes purchased on that date), CTP has satisfied its burden of proving that Respondent violated 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i) on October 23, 2016 at 11:51 AM by a preponderance of the evidence.

- iii. Respondent offered no affirmative proof to rebut the evidence of noncompliance presented by CTP.

In its Answer, Respondent stated that its "actions were neither flagrant nor intentional; [Respondent] took measures, promptly, and discharged the employee in question." However, Respondent has not offered anything to rebut CTP's evidence of noncompliance, and has not put forth anything to refute the sworn testimony of Inspectors Tejada and Inspector Shields that it sold tobacco products to minors and failed to verify the minors' identification on July 21, 2015 and October 23, 2016.

Respondent argues it was denied due process because CTP failed to timely inform Respondent that the July 21, 2015 violations, which resulted in a Warning Letter, could be used as a basis to assess civil monetary penalties, therefore, it was denied a fair and effective opportunity to preserve evidence. R. Informal Brief at 5. A retailer has an opportunity to challenge the issuance of a first violation upon the later assessment of civil money penalties. *See Orton Motor, Inc. d/b/a Orton's Bagley v. United States Department of Health and Human Services*, No. 16-1299, WL 1386141, (D.C. Cir. Mar. 20, 2018). CTP's adjudication of the subsequent violation provides a meaningful opportunity for a retailer to be heard regarding the first violation. *Id* at 19. Because no opportunity for a hearing was provided before the Warning Letter was issued, Respondent had a right to challenge the July 21, 2015 allegations in the instant case.

Respondent's defense also focuses on whether it is reasonable for its staff to request identification. Respondent argues "there is no way for the Presiding Officer to determine whether or not it would be reasonable for the sales clerk to conclude that a tester "appeared to be" over 26 years old . . ." R. Post-Hearing Brief at 3. Section 1140.14(a)(2) requires retailers to verify by means of photographic identification that no person purchasing tobacco products is younger than 18 years of age. This verification is not required for any person over the age of 26. I am not required to make a determination whether it is reasonable for a retailer to conclude that a tobacco product purchaser appears to be over the age of 26. The regulations do not take into account a retailer's subjective inquiry about the appearance of tobacco product purchasers.

Finally, Respondent takes issue with CTP's method of counting violations. Respondent argues "each inspection upon which a sales clerk failed to check ID and sold to a minor should be counted as one violation, not the two violations that the Government proposes." R. Post-Hearing Brief at 3. As stated above, CTP's policy of counting violations has been held to be consistent with the language of the FDCA and its implementing regulations. *See Orton Motor, Inc. d/b/a Orton's Bagley v. United States Department of Health and Human Services*, No. 16-1299, WL 1386141, (D.C. Cir. Mar. 20, 2018).

Though I find Mr. Montaquila's testimony credible, it does nothing to rebut CTP's allegations. Respondent has not provided any affirmative proof to rebut the evidence of noncompliance presented by CTP. On the other hand, the testimony of Inspector Tejada and Inspector Shield's is believable and supported by evidence in the record.

I conclude that Respondent has not proved any affirmative defense by a preponderance of the evidence.

## XI. LIABILITY

When a retailer such as Respondent is found to have "misbranded" a tobacco product in interstate commerce, it can be liable to pay a civil monetary penalty. 21 U.S.C. §§ 331, 333.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R.

§ 1140.14(a)(1) on July 21, 2015 and October 23, 2016, in that a person younger than 18 years of age was able to purchase cigarettes as set forth in the complaint.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(2)(i) on those same dates, in that Respondent failed to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age

The conduct set forth above on July 21, 2015 and October 23, 2016 counts as three (3) violations under FDA policy for purposes of computing the civil money penalty. *See Guidance for Industry*, at 13-15.

## XII. PENALTY

There being liability under the relevant statute, I must now determine the amount of penalty to impose. Pursuant to 21 U.S.C. § 333(f)(9), Respondent is liable for a civil money penalty not to exceed the amounts listed in FDA's civil money penalty regulations at 21 C.F.R. § 17.2. In its complaint, CTP sought to impose the maximum penalty amount, \$550, against Respondent for three (3) violations of the Act and its implementing regulations within a twenty-four (24) month period. Complaint ¶ 1-2. Respondent denies any obligation to pay a civil money penalty arguing that CTP has not met its burden of proof. Respondent's Informal Brief at 2.

As discussed, I found that CTP met its burden by a preponderance of the evidence and concluded that Respondent committed three (3) violations of the Act and its

implementing regulations within a twenty-four (24) month period. When determining the amount of a civil money penalty, I am required to take into account “the nature, circumstances, extent and gravity of the violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.”

21 U.S.C. § 333(f)(5)(B).

A. The Nature, Circumstances, Extent and Gravity of the Violations

I have found that Respondent specifically committed (2) violations of selling tobacco products to minors, and two (2) violations for failure to verify, by means of photo identification containing a purchaser’s date of birth, that no tobacco product purchasers are younger than 18 years of age, totaling three (3) violations<sup>5</sup> of the tobacco regulations. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the civil money penalty amount should be set accordingly.

B. Respondent’s Ability to Pay And Effect on Ability to do Business

On July 27, 2017, the parties stipulated that Respondent has the financial means to pay \$550, and that payment will not constitute a financial hardship for Respondent. *See* Stipulation of Fact, Dkt. No. 10.

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<sup>5</sup> Two violations were documented on July 21, 2015, and two on October 23, 2016. In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

C. History of Prior Violations

The current action is the first civil money penalty action brought against Respondent for violations of the Act and its implementing regulations.

D. Degree of Culpability

I find Respondent committed three (3) violations as alleged in complaint, and I hold it fully culpable for all three (3) violations of the Act and its implementing regulations.

E. Additional Mitigating Factors

Mitigation is an affirmative defense for which Respondent bears the burden of proof (21 C.F.R. § 17.33(c)). Respondent has posted signage, trained employees, and “added software that requires a clerk to enter the date of birth of the customer before the register will allow the sale of cigarettes.” R. Ex. 1 at 1-2. The purpose of the TCA to prevent unlawful sales of tobacco products to minors. Tobacco is a highly addictive and dangerous product. The reason that sales of tobacco products to minors is unlawful is that consumption of these products at an early age can lead to a lifetime of addiction, to illness, and ultimately to premature death. Sales of tobacco products to minors are unlawful because younger individuals often lack the maturity and judgment to make informed decisions about whether to consume such inherently dangerous and addictive products. Selling tobacco products to these individuals puts them at risk for all of the adverse consequences that addiction can cause.

I find and conclude there is no reason to consider mitigation of the penalty herein.

F. Penalty

Based on the foregoing reasoning, I conclude a penalty amount of \$550 to be appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).

XIII. CONCLUSION

Respondent committed three (3) violations in a twenty-four (24) month period as set forth in the complaint.

Respondent is liable for a civil money penalty of \$550. *See* 21 C.F.R. § 17.2.

WHEREFORE, evidence having read and considered it be and is hereby

ORDERED as follows:

- a. I find Respondent was served with process herein and is subject to this forum.
- b. I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) on July 21, 2015 and October 23, 2016, in that a person younger than 18 years of age was able to purchase cigarettes as set forth in the complaint.
- c. I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(2)(i) on July 21, 2015 and October 23, 2016, in that Respondent failed to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age; and
- d. I find and conclude Respondent committed three (3) violations of the regulations within a twenty-four (24) month period; and
- e. I assess a monetary penalty in the amount of \$550.

\_\_\_\_\_/s/\_\_\_\_\_  
Richard C. Goodwin  
U.S. Administrative Law Judge