

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

Center for Tobacco Products,
Complainant

v.

Shreeji Investments, LLC
d/b/a Marathon / Sunrise Food Mart,
Respondent

FDA Docket No. FDA-2017-H-3501
CRD Docket No. T-17-4632

Decision No. TB2800

Date: June 15, 2018

INITIAL DECISION

Found:

- 1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i) as charged in the complaint; and
- 2) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) as charged in the prior complaint; and
- 3) Respondent committed four violations in a 24-month period as set forth hereinabove.
- 4) Respondent is hereby assessed a civil penalty in the amount of \$2,236.

Glossary:

| | |
|-----------------|---------------------------------------|
| ALJ | administrative law judge ¹ |
| CMP | civil money penalty |
| CTP/Complainant | Center for Tobacco Products |
| DJ | Default Judgment |

¹ See 5 C.F.R. § 930.204.

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| FDCA | Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9) |
| DN | UPS Delivery Notification |
| FDA | Food and Drug Administration |
| HHS | Dept. of Health and Human Services |
| OSC | Order to Show Cause |
| POS | UPS Proof of Service |
| SOP | Service of Process |
| Respondent | Shreeji Investments, LLC d/b/a Marathon / Sunrise Food Mart |
| 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 17.²

II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) filed a complaint on June 16, 2017, alleging that FDA documented four violations within a 24-month period.

There is a presumption Shreeji Investments, LLC d/b/a Marathon / Sunrise Food Mart (Respondent or Marathon / Sunrise Food Mart) was served with process on June 15, 2017, by United Parcel Service. Respondent filed an answer on July 13, 2017.

² 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).

CTP filed its pre-hearing exchange, containing a brief (CTP Br.), a list of proposed witnesses and exhibits, and 13 exhibits (CTP Exs. 1-13), including the written direct testimony of two proposed witnesses (CTP Exs. 4-5).³ Respondent did not file a pre-hearing exchange, submit any proposed exhibits, or object to CTP's proposed exhibits.⁴

I conducted a hearing on March 7, 2018. Transcript (Tr.) 1.

CTP filed a post-hearing brief (CTP Post-Hrg. Br.) accompanied by one exhibit, I will identify as CTP Post-Hrg. Ex. 1.

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

III. BURDEN OF PROOF

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

IV. LAW

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

V. ISSUES

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

If so, is a civil money penalty in the amount of \$2,236 appropriate?

³ The transcript incorrectly indicates that I stated, "Now I have that CTP has submitted Exhibits 1 through 13 and Ms. Svonkin has submitted nothing." The transcript should instead read, "Now I have that CTP has submitted Exhibits 1 through 13 and Respondent has submitted nothing." Tr. 4.

⁴ On November 28, 2017, Respondent filed a letter, which I construed as a late-filed response to my order to show cause. CTP did not object.

VI. ALLEGATIONS

A. Agency's recitation of facts

CTP alleged that Respondent owned an establishment, doing business under the name Marathon / Sunrise Food Mart, located at 1606 Northwest 13th Street, Gainesville, Florida 32609. Respondent's establishment receives tobacco products in interstate commerce and holds them for sale after shipment in interstate commerce.

During an inspection of Marathon / Sunrise Food Mart conducted on April 1, 2017, an FDA-commissioned inspector documented the following violations:

- a. Selling cigarettes or smokeless tobacco 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 Gold Pack cigarettes on April 1, 2017, at approximately 1:37 PM; 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 April 1, 2017, at approximately 1:37 PM.

B. Respondent's recitation of facts

Respondent does not specifically deny these allegations, but argues that CTP has not provided sufficient evidence to prove Respondent's liability. Respondent also challenges CTP's inspection methodology and argues that it should not be responsible for the civil money penalty. Answer; Respondent's (R's) Nov. 28, 2017 filing; Tr. 6-8, 11.

VII. PRIOR VIOLATIONS

On January 13, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-1546, FDA Docket Number FDA-2017-H-0096, against Respondent for two violations of 21 C.F.R. pt. 1140 within a 12-month period. CTP alleged those violations to have occurred at Respondent's business establishment located at 1606 Northwest 13th Street, Gainesville, Florida 32609, on April 10, 2016, and June 23, 2016.

The previous action concluded when Respondent admitted the allegations contained in the complaint issued by CTP, and agreed to pay a monetary penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions."

Respondent conceded the violations asserted in the prior complaints. Those cases were closed and became administratively final 30 days thereafter. I find and conclude Respondent committed two violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) based on the conduct set forth in the prior complaint. CTP Exs. 2-3.

VIII. 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. pt. 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) (2016)*, available at <http://www.fda.gov/downloads/TobaccoProducts/Labeling/Rules/RegulationsGuidance/UCM447310.pdf> [hereinafter *Guidance for Industry*], at 13-14. 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 to be consistent with the language of the FDCA

and its implementing regulations. *See Orton Motor Co. d/b/a Orton's Bagley v. HHS*, 884 F.3d 1205 (D.C. Cir. 2018).

IX. HEARING

I conducted a hearing on March 7, 2018, by telephone.

Michele Svonkin, Esquire, appeared on behalf of Complainant.

Pradeep Gandhi appeared pro se on behalf of Respondent.

Witnesses Laurie Sternberg and Michael Barnes provided written direct testimony (CTP Exs. 4-5) on behalf of CTP; however, Respondent elected not to cross-examine either witness during the hearing. Tr. 6.

X. SUMMARY OF TESTIMONY AND EVIDENCE

A. Complainant's case

CTP submitted documentary evidence and testimony in form of written declarations. CTP Exs. 1-13; CTP Post-Hrg. Ex. 1. Respondent did not object to CTP's exhibits.

i. Inspector Michael Barnes

Witness Michael Barnes, the FDA-commissioned Inspector who conducted the inspection at issue on April 1, 2017, testified on behalf of Complainant. Complainant provided Inspector Barnes' written direct testimony as CTP Ex. 5.

Inspector Barnes testified that on April 1, 2017, at approximately 1:37 PM, he and the minor conducted the follow-up compliance inspection at Respondent's establishment, Marathon / Sunrise Food Mart, located at 1606 Northwest 13th Street, Gainesville,

Florida. Before the inspection, Inspector Barnes confirmed that the minor had his or her photographic identification (ID) and did not have any tobacco products in his or her possession. Inspector Barnes testified that CTP's Ex. 6 is a true and accurate redacted copy of the minor's Learner License and confirmed that the minor was under the age of 18 when the minor participated in this inspection. CTP Ex. 5 at 2.

According to his testimony, Inspector Barnes watched the minor enter Respondent's establishment and followed the minor inside the establishment. The inspector testified that from his location, he had a "clear, unobstructed view of the sales counter and [the minor]." CTP Ex. 5 at 3. Inspector Barnes observed the minor purchase a package of cigarettes from an employee at Respondent's establishment. The inspector testified that prior to the purchase, he observed that the minor did not present any identification to the employee. The employee did not provide the minor with a receipt. CTP Ex. 5 at 3.

Inspector Barnes testified that after the minor exited Respondent's establishment, he and the minor returned to the vehicle where immediately upon entering, the minor handed the inspector the package of Marlboro Gold Pack cigarettes. Inspector Barnes labeled the cigarettes as evidence, photographed the evidence (CTP Exs. 9-10), and processed the evidence in accordance with standard procedures at the time of the inspection. CTP Ex. 5 at 3.

According to Inspector Barnes, he recorded the inspection shortly thereafter in the FDA's Tobacco Inspection Management System (CTP Ex. 8) and created a

contemporaneous Narrative Report (CTP Ex. 7). Inspector Barnes also testified that CTP Exs. 7 through 10, inclusive, were true and accurate copies. CTP Ex. 5 at 3.

Respondent elected not to cross-examine Inspector Barnes. Tr. at 6.

ii. Attorney Laurie Sternberg

Witness Laurie Sternberg, Senior Regulatory Counsel in the Office of Compliance and Enforcement, CTP, FDA, testified on behalf of CTP. CTP offered Ms. Sternberg's written direct testimony as CTP Ex. 4.

Ms. Sternberg testified that Marlboro brand cigarettes, the tobacco product purchased during the April 1, 2017 inspection, are manufactured at facilities in Virginia. CTP Ex. 4 at 2-3; *see* CTP Exs. 9-10, 13. The manufacturer of Marlboro brand cigarettes does not have any production facilities in Florida, where the tobacco product at issue was purchased. CTP Ex. 4 at 2-3; *see* CTP Exs. 9-10, 13.

B. Respondent's case

Respondent did not submit written direct testimony or documentary evidence. *See* February 1, 2018 Order Scheduling Telephone Hearing; March 2, 2018 Order.

In its Post-Hearing Brief, CTP asks that I exclude Respondent's "testimony." CTP Post-Hrg. Br. at 2-5. It is CTP's position that Pradeep Gandhi, who appeared pro se on behalf of Respondent, testified during the March 7, 2018 hearing. However, the statements that CTP seeks to exclude are argument, not testimony under oath or affirmation. 21 C.F.R. § 17.37. Mr. Gandhi's statements during the hearing were essentially an argument of his position. I have the authority to regulate the conduct of the

parties in order to conduct a fair and impartial hearing. 21 C.F.R. §§ 17.19(a), (b)(8), (17). During this hearing, I permitted Respondent to provide argument, within appropriate limits. Accordingly, I deny CTP's request.

C. Credibility determinations

I find and conclude that the testimony and evidence provided was credible.

XI. ANALYSIS OF EVIDENCE AND TESTIMONY

A. Complainant's case

Complainant proposed CTP Exhibits 1 through 13, inclusive, and CTP Post-Hearing Exhibit 1.

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. § 17.45(b)(1).

B. Respondent's case

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.

It is Respondent's position that CTP has not submitted evidence sufficient to meet its burden of proof to prove Respondent's liability. Respondent has not offered any affirmative defenses to rebut the allegations in the Complaint.

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) when it impermissibly sold cigarettes to a minor on April 1, 2017, at approximately 1:37 PM.

On April 1, 2017, at approximately 1:37 PM, Inspector Barnes conducted a follow-up compliance check inspection of Respondent's establishment with a confidential state-contracted minor. Inspector Barnes confirmed that the minor did not possess any tobacco products in his or her possession before entering the establishment. CTP Ex. 5 at 2.

The inspector followed the minor into Respondent's establishment and took a position with a "clear, unobstructed view of the sales counter and [the minor]." CTP Ex. 5 at 3. Inspector Barnes observed the minor purchase a package of cigarettes from Respondent's sales clerk. Inspector Barnes observed that the minor did not provide any identification to the sales clerk prior to the purchase a package. The inspector followed the minor out of the store and the two returned to the vehicle. When they entered the vehicle, the minor immediately tendered the package of cigarettes to Inspector Barnes. Inspector Barnes labeled the cigarettes as evidence, documented the physical evidence (CTP Exs. 9-10) and contemporaneously recorded the transaction (CTP Exs. 7-8).

Inspector Barnes' testimony is additionally supported by physical evidence. CTP submitted a copy of the undercover minor's state photo identification (redacted), listing the date of birth as October 20, 2000, or 16 years old during the April 1, 2017 inspection.

CTP Ex. 6; *see* CTP Ex. 5 at 2. CTP also submitted copies of the photographs that Inspector Barnes took of the package of Marlboro Gold Pack cigarettes. CTP Exs. 9-10; *see* CTP Ex. 5 at 3.

I find Inspector Barnes' testimony to be credible and unbiased. I find that it, in conjunction with the corroborating documentary evidence (e.g. the contemporaneous reports) and physical evidence (e.g. photographs), is sufficient to satisfy CTP's burden of proving that Respondent violated 21 C.F.R. § 1140.14(a)(1) on April 1, 2017, at approximately 1:37 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)(2)(i) when it failed to verify, by means of photographic identification containing the purchaser's date of birth, that no cigarette purchaser is younger than 18 years of age, on April 1, 2017, at approximately 1:37 PM.

On April 1, 2017, at approximately 1:37 PM, Inspector Barnes conducted a follow-up compliance check inspection of Respondent's establishment with a confidential state-contracted minor. Prior to the inspection, Inspector Barnes confirmed that the minor had his or her photographic identification in the minor's possession. CTP Ex. 5 at 2. During the inspection, Inspector Barnes observed that the minor did not present any identification to the employee. Yet, the inspector also observed Respondent's staff sell the undercover minor a package of cigarettes. CTP Ex. 5 at 3.

I find Inspector Barnes' testimony to be credible and unbiased. I find that it, in conjunction with the corroborating documentary evidence (e.g. the contemporaneous reports) and physical evidence (e.g. photographs), is sufficient to satisfy CTP's burden of proving that Respondent violated 21 C.F.R. § 1140.14(a)(2)(i) on April 1, 2017, at approximately 1:37 PM by a preponderance of the evidence.

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

Respondent argues that the inspector should have immediately issued the citation in-person to Respondent's employee who committed the infraction. Respondent further complains that it did not receive notice of the violation until its camera system no longer retained footage from the date at issue. Answer.

I find these arguments to be without merit. How CTP conducts its inspections is irrelevant to the issue of Respondent's compliance. CTP's inspection methodology does not gainsay my finding that Respondent committed the violations that are at issue here.

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

XII. 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 evidence presented supports a finding that on April 1, 2017, at approximately 1:37 PM, Respondent violated 21 U.S.C. § 331, specifically

21 C.F.R. § 1140.14(a)(1), in that a person younger than 18 years of age was able to purchase a package of Marlboro Gold Pack cigarettes.

I find and conclude that the evidence presented supports a finding that on April 1, 2017, at approximately 1:37 PM, Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. §1140.14(a)(2)(i), 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 April 1, 2017 counts as *two additional violations* under FDA policy for purposes of computing the civil money penalty. *See Guidance for Industry*, at 13-15. Respondent previously admitted to two violations of FDA policy in the relevant timeframe. Accordingly, I find and conclude that Respondent is liable for four violations of FDA policy in a 24-month period.

XIII. 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, \$2,236, against Respondent for four violations of the Act and its implementing regulations within a 24-month period. Complaint ¶ 1. In its pre- and post-hearing briefs, CTP continued to assert that a \$ 2,236 civil money penalty is appropriate. CTP Br. at 8-13; CTP Post-Hrg. Br. at 7-8.

It is Respondent's position that the proposed civil money penalty is unreasonable.
Answer; Nov. 28, 2017 filing.

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 three violations of selling tobacco products to minors, and one violation for failure to verify the photographic identification of a purchaser, totaling four violations of the tobacco regulations.

Respondent's repeated inability 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

Respondent has not presented any evidence that it does not have the ability to pay the \$2,236 civil money penalty sought by CTP.

C. History of Prior Violations

The current action is the second civil money penalty action brought against Respondent for violations of the Act and its implementing regulations. On January 13, 2017, CTP initiated the first civil money penalty action, CRD Docket Number T-17-1546, FDA Docket Number FDA- 2017-H- 0096, against Respondent. In the first action, Respondent violated the prohibition against selling tobacco products to persons younger

than 18 years of age, 21 C.F.R. § 1140.14(a)(1) in two separate inspections. CTP Ex. 2. Respondent settled the prior complaint with CTP for an undisclosed penalty amount and admitted that the violations occurred as described in the complaint. CTP Ex. 3.

Respondent's history of repeated noncompliance demonstrates its continued inability to comply with the federal tobacco regulations. This calls for a more severe penalty. The regulations escalate the civil money penalty to encourage repeat violators to clean up their acts.

D. Degree of Culpability

Respondent asserts that it trains its employees and requires them to check the birthdate of each customer seeking a tobacco product. Therefore, Respondent concludes, "the responsibility does not lie on me as the owner." Answer. Respondent further argues that the FDA should issue the complaint against the employee who violated the tobacco regulation, not the owner of the business. Answer; *see* Tr. 7-8.

Respondent's argument that the civil money penalty should be imposed against the store clerk and not the owner suggests a failure to appreciate the gravity of the violations, as well as a failure on Respondent's part to acknowledge the significant responsibility the law imposes upon it to avoid selling tobacco to minors. Its argument is also without merit; federal tobacco regulations specifically place the responsibility to uphold the law on the retailer. "Each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements under this part." 21 C.F.R. § 1140.10; *see also United States v. Dotterweich*, 320 U.S.

277, 281-285 (1943) (holding the only way in which a corporation can act is through the individuals who act on its behalf). The civil money penalty imposed in this matter is properly assessed against Respondent, not its employees.

I hold Respondent fully culpable for all four 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. *See* 21 C.F.R. § 17.33(c).

Respondent asserts that it “invested a large amount of money to make sure such a thing never happens at my store.” Answer. Respondent states that after the previous complaint, it trained its employees and invested in a scanning system, which requires each employee to check the birthdate of any customer purchasing a tobacco product. Answer; Nov. 28, 2017 filing.

However, Respondent has provided no evidence to support its assertions and they are due no weight. Moreover, even if Respondent submitted evidence of these claims, these measures were not sufficient to prevent its staff from selling a tobacco product to a minor for a third time and also failing to verify photographic identification for the first time.

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 \$ 2,236 is appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).

XIV. CONCLUSION

Respondent committed four violations in a 24-month period as set forth in the complaint. Respondent is liable for a civil money penalty of \$2,236. *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 has been 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 April 1, 2017, in that a person younger than 18 years of age was able to purchase a package of Marlboro Gold Pack 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 April 1, 2017, in that Respondent failed to verify the age of a person purchasing cigarettes by means of photographic identification containing the bearer's date of birth as set forth in the complaint;

- d. 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 April 10, 2016 and June 23, 2016, as stipulated in the settlement agreement of the prior civil money penalty action, CRD Docket Number T-17-1546, FDA Docket Number FDA-2017-H-0096;
- e. I find and conclude Respondent committed four violations of the regulations within a 24-month period; and
- f. I assess a monetary penalty in the amount of \$2,236, is appropriate.

_____/s/_____
Richard C. Goodwin
U.S. Administrative Law Judge