

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

Center for Tobacco Products,
Complainant

v.

H and M of Sylvan Lake, Inc.
d/b/a Sylvan Fine Wine and Liquor,
Respondent.

Docket No. T-17-421
FDA Docket No. FDA-2015-H-4825

Decision No. TB1209

Date: May 4, 2017

DECISION

Found:

- 1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a) on September 17, 2015 as charged in the complaint; and
- 2) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a) on July 9, 2014 and March 6, 2015 and 21 C.F.R. § 1140.16(c) on February 7, 2014 as charged in the prior complaint; and
- 3) Respondent committed four (4) violations in a twenty-four (24) month period as set forth hereinabove.
- 4) Respondent is hereby assessed a civil penalty in the amount of \$2,000.

Glossary:

ALJ	administrative law judge ¹
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

¹ 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	H and M of Sylvan Lake, Inc. d/b/a Sylvan Fine Wine and Liquor
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 dated January 4, 2016 alleging that FDA documented four (4) violations within a twenty-four (24) month period.

H and M of Sylvan Lake, Inc. d/b/a Sylvan Fine Wine and Liquor was served with process on January 11, 2016 by United Parcel Service. Respondent filed an Answer dated February 18, 2016 in which it denied the current allegation.

I conducted a hearing on September 8, 2016.

The Civil Remedies Division – Tobacco Cases of the Departmental Appeals Board began managing civil money penalty actions against retailers of tobacco products on

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).

November 18, 2016. I retained jurisdiction and remained assigned to hear and decide this case.

The parties filed posthearing briefs on November 25, 2016 and on February 7, 2017.³

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

III. BURDEN OF PROOF

The Center for Tobacco Products (CTP/Complainant) 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).

V. ISSUES

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

If so, is a civil money penalty in the amount of \$2,000 appropriate?

VI. ALLEGATIONS

A. Complainant's Recitation of facts

³ Respondent filed its posthearing brief, due November 25, 2016, with the Civil Remedies Division – Tobacco Cases on February 7, 2017. Respondent certified that on November 25, 2016 it served its posthearing brief to Complainant at Complainant's address of record and to me at the office that previously managed these cases at the FDA. Complainant did not file an objection. Given Respondent's certification and the associated circumstances, I accept Respondent's posthearing brief as timely filed on February 7, 2017.

CTP alleged that Respondent owned an establishment, doing business under the name Sylvan Fine Wine and Liquor, located at 2310 Orchard Lake Road, Sylvan Lake, Michigan 48320. Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

Complainant further alleged during a two-part inspection of Sylvan Fine Wine and Liquor conducted on September 17 and 23, 2015, FDA-commissioned inspectors documented the following violation:

- a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a).
Specifically, a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes on September 17, 2015, at approximately 9:11 PM.

B. Respondent's recitation of facts

In its Answer, Respondent responded generally that it could neither admit nor deny the allegations because Respondent lacked sufficient knowledge or information to form a belief as to the truth of the allegation and left the Complainant to its proofs. Respondent denied that it sold a package of Newport Box 100s cigarettes to a person younger than 18 years of age on September 17, 2015, based on camera footage taken on the asserted date and at the approximate time. Respondent further contended that it only settled the first two complaints, admitting the violations as asserted, upon advice of counsel.

VII. PRIOR VIOLATIONS

On July 7, 2015, CTP initiated the most recent civil money penalty action, FDA Docket Number FDA-2015-H-2272, against Respondent for three (3) violations of 21 C.F.R. pt. 1140 within a twenty-four (24) month period. CTP alleged those violations to have occurred at Respondent's business establishment on February 7, 2014, July 9, 2014 and March 6, 2015 as follows:

- a. Sale to a minor (21 C.F.R. § 1140.14(a)) on March 6, 2015 and July 9, 2014; and
- b. Use of a self-service display in a non-exempt facility (21 C.F.R. § 1140.16(c)) on February 7, 2014.

The previous action concluded in settlement where Respondent “admit[ted] all of the allegations in the Complaint, [paid] the agreed upon penalty, and the Court clos[ed] the case.” Further, “Respondent expressly waived its right to contest such violations in subsequent actions.”

Although Respondent now asserts that it only settled the prior complaints upon the advice of counsel, Respondent availed itself to the benefits of settlement. Respondent conceded the violations asserted in the prior complaints. Those cases were closed and became administratively final thirty days thereafter. Respondent's opportunity to challenge the prior complaints has expired.

I find and conclude Respondent committed three (3) violations of 21 U.S.C. § 331, specifically two (2) violations of 21 C.F.R. § 1140.14(a)(1) and one (1) violation of 21 C.F.R. § 1140.16(c) based on the conduct as set forth in the prior complaint (FDA-2015-H-2272).

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. 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) and (b)(1), 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 CTP v. Orton Motor Company*, Departmental Appeals Board Decision number 2717 of June 30, 2016.

IX. HEARING

Hearing was held on September 8, 2016 by telephone as set forth in my June 2, 2016 Order of the Court.

Joshua A. Davenport, Esquire, appeared on behalf of Complainant.

Christina R. Abro, Esquire, and Joslin Monahan, Esquire, appeared on behalf of Respondent.

Witnesses Justin Bishop and Laurie Sternberg testified on behalf of CTP.

Witnesses Valerie Abro and Merna Shathaia testified on behalf of Respondent.

X. 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 objected to all of CTP Exhibits generally. *See* Respondent's Motion in Limine; Respondent's Post Trial Brief. However, Respondent expressed that it did not object to CTP Ex. 4, a photograph of Respondent's signage, during the hearing. Transcript (Tr.) at 14-15. I received CTP Exhibits 1-21 into evidence subject to the objection of Respondent. Tr. at 14-19, 52-59, 60-61.

i. Inspector Justin Bishop

Witness Justin Bishop, the FDA-commissioned Inspector who conducted the inspection of Respondent's establishment on September 17, 2015 testified on behalf of Complainant. Complainant provided Inspector Bishop's written direct testimony as CTP Ex. 19.

Inspector Bishop testified that on September 17, 2015, at approximately 9:11 PM, he and the minor conducted the follow-up compliance inspection at Respondent's establishment, Sylvan Fine Wine and Liquor, located at 2310 Orchard Lake Road, Sylvan Lake, Michigan 48320. Before the inspection, Inspector Bishop physically examined the minor's photographic identification (ID) and prior to entering the establishment Inspector Bishop ensured that that the minor had her ID and did not have any tobacco products in her possession. CTP Ex. 19 at 2; Tr. at 35-37, 43. Inspector Bishop testified that the minor is a female with brown hair and was of average height and weight. He did not

recall what the minor was wearing. Inspector Bishop identified the minor as African-American. Tr. at 29-30. Inspector Bishop testified that CTP's Ex. 1 is a true and accurate redacted copy of the minor's identification card and confirmed that the minor was under the age of 18 when she participated in the inspection in this case. CTP Ex. 19 at 2; Tr. at 41-44.

According to his testimony, Inspector Bishop accompanied the minor into Respondent's establishment and took a position a few feet from her, staying within direct eyesight and earshot of the minor. CTP Ex. 19 at 3. The inspector explained that his observable location, which is "not obstructed from eyes and ears," is essentially protocol because "observation is what is key and paramount." Tr. at 49. From his location, he had a "clear unobstructed view of the sales counter and [the minor]." CTP Ex. 19 at 3. Inspector Bishop observed the minor give an ID to the clerk and the clerk return the ID back to the minor. The inspector testified that he witnessed the exchange of money and the clerk provide the minor with a package of cigarettes. CTP Ex. 19 at 3; Tr. at 48-49. The employee did not provide the minor with a receipt and it is not practice for the minor to request one. CTP Ex. 15 at 1.

The minor exited the establishment and the inspector followed several seconds later. Both returned to the vehicle where immediately upon entering, the minor handed the inspector the package of Newport cigarettes. Inspector Bishop processed the evidence according to procedure and completed a narrative report. CTP Ex. 19 at 3; *see* CTP Exs. 14-15.

Inspector Bishop also testified that CTP Exhibits 1 and 4 through 15, inclusive, were true and accurate copies. CTP Ex. 19 at 2-3.

On cross-examination, Inspector Bishop testified that he and the minor are paid the same amount regardless of whether they find a violation and that there is not an incentive program or pay structure differential based on such a finding. Tr. at 28, 46.

ii. Ms. Laurie Sternberg

Witness Laurie Sternberg, Senior Regulatory Counsel, Office of Compliance and Enforcement, CTP, FDA, testified on behalf of CTP. CTP offered Ms. Sternberg's written direct testimony as CTP Ex. 20.

Ms. Sternberg testified that Newport brand cigarettes, the tobacco product purchased during the September 17, 2015 inspection, are manufactured at facilities in North Carolina and Virginia and then sold in interstate commerce. CTP Ex. 20 at 2-3; *see* CTP Ex. 18; *see also* CTP Exs. 5-12. The manufacturer of Newport brand cigarettes does not have any production facilities in Michigan, where the tobacco product at issue was purchased. CTP Ex. 20 at 3. Ms. Sternberg testified that she was not present in Michigan during the inspection. Tr. at 58.

Ms. Sternberg also testified that CTP Exhibits 2, 3, 16, 17, and 21 are true and accurate copies. CTP Ex. 20 at 3-5.

B. Respondent's case

Respondent submitted three exhibits marked as R. Exhibits A, B and C.

Respondent's Exhibit A is video surveillance footage. CTP did not object to any of Respondent's exhibits. Tr. at 64. I admit Respondent's Exhibits A through C, inclusive.

It is Respondent's position that it did not sell a tobacco product to a minor on September 17, 2015.

i. Ms. Valerie Abro

Ms. Valerie Abro, Respondent's manager and owner, testified on behalf of Respondent. Ms. V. Abro testified that Respondent had a number of surveillance cameras in the establishment. Tr. at 71. Ms. V. Abro testified that she was able to retrieve the camera footage from September 17, 2015 at 9:11 PM "exactly." Tr. at 72. She testified that she viewed the surveillance video from the whole day. Tr. at 73. The witness testified that, based on her review of the surveillance footage taken anytime on September 17, 2015, no patrons presented identification that appeared vertical rather than horizontal. Tr. at 73-74.

Ms. V. Abro also testified as to Respondent's policy manual containing rules and regulations. Tr. at 75. She testified regarding the employee-training program that included an extensive orientation prior to beginning work; a follow-up training every six months that incorporated role-play and quizzes; and an annual review of the policy manual that was followed by an exam. The training program covered FDA rules on cigarettes and smokeless tobacco and associated penalties. The program also included

training on how to examine photographs, watermarks, state seals, and other characteristics on the ID. Tr. at 75-76.

Ms. V. Abro further testified that Merna Shathaia, the cashier on duty during the September 17, 2015 inspection, was employed by Respondent for seven years, had completed the training, and signed off on it. Tr. at 77. She explained that Respondent had not had an issue with Ms. Shathaia selling tobacco products to minors. Tr. at 77.

Ms. V. Abro testified that it is Respondent's policy was to check everyone's ID if they look under the age of 27. Tr. at 76.

Ms. V. Abro testified that when she viewed the surveillance footage, she clearly saw a female, handing the ID to Ms. Shathaia, who held and examined the ID, in a horizontal position. Tr. at 80. The witness opined that it does not make sense to hold a vertical ID in a horizontal position, and therefore the ID itself was horizontal, and she concluded that the individual was over 21 years of age. Tr. at 80.

Ms. V. Abro testified that Hazim Abro is the owner of Respondent's establishment.

ii. Ms. Merna Shathaia

Ms. Merna Shathaia, the cashier on duty during the September 17, 2015 inspection, also testified on behalf of Respondent. Ms. Shathaia testified that she was not on duty on the dates and times of the prior violations. Tr. at 90. Ms. Shathaia testified that she has worked for Respondent as a clerk and cashier for seven years where she routinely sold alcohol and tobacco products. Tr. at 91. She testified that she knows the

majority of Respondent's customers by name and that she will ask for ID from anyone who looks suspicious or under the age of 27. Tr. at 88.

She specifically testified that she did not sell tobacco products to a minor on September 17 at 9:11 PM. Tr. at 91. She testified that she was not presented with a vertical identification card *at all* on the day in question. Tr. at 91. Ms. Shathaia testified that she personally reviewed the video footage from the entire day of September 17, 2015 and did not see any patron present a vertical identification on that date.

Ms. Shathaia also testified that video footage not saved within about 30 days is recorded over. Tr. at 92.

C. Credibility determinations

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

XI. RULING ON ADMISSIBILITY OF EVIDENCE

Complainant offered and I received into evidence Exhibits 1 through 21, inclusive, subject to the objection of Respondent. Respondent filed a Motion in Limine to Exclude Age and Date of Birth of Decoy, inter alia, and objected generally to CTP's exhibits and associated testimony. Respondent renewed its objection during the hearing and in Respondent's Post Trial Brief.

On August 5, 2016, Complainant filed a motion for a protective order against discovery. On August 24, 2016, I issued my Ruling on Request for Protective Order in which I granted Complainant's motion insofar as Complainant was not required to disclose the identity of the minor buyer. In my Ruling, I explained that because the

Complainant asserted that it would not call the minor as a witness during the hearing, the information sought regarding the minor became irrelevant.

On September 2, 2016, Respondent filed a Motion in Limine to Exclude Age and Date of Birth of Decoy seeking to exclude all evidence of and references to the identity, age, and date of birth of the minor participant. Based on the Federal Rules of Evidence, Respondent argues that without offering the minor as a witness, CTP's testimony and evidence is inadmissible hearsay and lacking foundation. Respondent's Motion in Limine ¶¶ 6-9, 11. Respondent further asserts that the impact of my August 24, 2016 Ruling not requiring CTP to disclose the identity of the minor is to deprive it of its property without due process.

I am not bound by the Federal Rules of Evidence in these proceedings. 21 C.F.R. § 17.39(b). I am only required to exclude evidence that is not relevant or material to the issues before me. 21 C.F.R. § 17.39(c). I may however exclude relevant evidence if I determine that its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence. 21 C.F.R. § 17.39(d).

I find that the probative value of CTP Exhibits 1-21 is not substantially outweighed by the danger of unfair prejudice or confusion of the issues. I find that CTP Exhibits 1-21 are relevant and reliable. I deny Respondent's motion and admit CTP Exhibits 1-21, inclusive. 21 C.F.R. § 17.39.

XII. 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 A through C, 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.

It is Respondent's position that it did not sell a tobacco product to a minor on September 17, 2015. Instead, Respondent argues that the undercover purchaser it refers to as a "decoy" was not a minor. Respondent's Post Trial Brief at 6. Citing Michigan Public Acts 553 and 554 of 2002, Respondent asserts that Michigan State identifications are oriented horizontally (landscape) for individuals 21 years of age and older, whereas, Michigan State identifications are oriented vertically (portrait) for individuals under the age of 21. Respondent asserts that no patron presented a vertically oriented identification

on September 17, 2015. Respondent produced video surveillance from the evening of September 17, 2015 identified as Respondent's Exhibit A.

Based on the video surveillance, Respondent asserts that both the "decoy" and the sales person looked at the ID card horizontally. Respondent surmises that by viewing the ID in a horizontal orientation indicates that the ID itself was oriented as such, and thus that on September 17, 2015 the "decoy" presented Respondent an ID formatted for individuals over the age of 21. Therefore, Respondent concludes that the "decoy" was over the age of 21 on September 17, 2015 and accordingly, that Respondent did not sell a tobacco product to a minor. Respondent's Post Trial Brief at 6.

C. Analysis

- i. I find and conclude that the confidential state-contracted individual, or "decoy," was a minor during the inspection on September 17, 2015.

Inspector Bishop is an FDA-commissioned officer who performs undercover buy inspections to determine a retailer's compliance with the age and photo identification requirements relating to the sale of tobacco products. Inspector Bishop conducts inspections in conjunction with confidential state-contracted minors to ensure retailer compliance with these requirements. He provides direct field oversight of the minors to ensure that they follow FDA inspection protocol.

Inspector Bishop testified that he physically examined the state-issued photographic identification of the confidential state-contracted individual in accordance with protocol. He described the confidential state-contracted individual as an African-

American female, with brown hair and of average height and weight. Tr. at 29-30.

Inspector Bishop identified CTP Ex. 1 as a true and correct redacted copy of the confidential state-contracted individual's identification. Inspector Bishop testified that the date of birth, weight, sex, height, and eye color shown on the identification, submitted as CTP Ex. 1, is the same information that he had observed on the minor's identification when he physically inspected it on September 17, 2015 and that it accurately reflected that of the confidential participant. Tr. at 41. Inspector Bishop confirmed that the confidential state-contracted individual had an accurate state-issued ID and was under the age of 18 at when she participated in this inspection. I find that Inspector Bishop testified credibly.

In addition to the inspector's credible testimony as to the age of the individual, the very nature of the confidential state-contracted individual's employment is valuable. Confidential state-contracted individuals are employed for the specific purpose of ascertaining whether retailers sell tobacco products to minors. Accordingly, I conclude that the state-contracted participant, or "decoy," was a minor at the time of the inspection.

- 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) when it impermissibly sold cigarettes to a minor on September 17, 2015 at 9:11 PM.

On September 17, 2015, Inspector Bishop and the confidential state-contracted minor conducted a follow-up undercover compliance check inspection of Respondent's establishment at approximately 9:11 PM. CTP Ex. 19 at 2. Inspector Bishop confirmed

through verbal confirmation and observation that the minor did not possess any tobacco products on her person before entering the establishment. Tr. at 35-36, 46-47.

The inspector followed the minor into Respondent's establishment and took a position a few feet away, within "direct eyesight and earshot of the minor." CTP Ex. 19 at 3. Inspector Bishop maintained an unobstructed view of the minor, the sales counter, and the transaction. Inspector Bishop observed the minor purchase a package of cigarettes from Respondent's sales clerk. The inspector followed the minor out of the store several second later and the two returned to his vehicle. When they entered the vehicle, the minor immediately tendered the package of cigarettes to Inspector Bishop. Inspector Bishop labeled the cigarettes as evidence, documented the physical evidence (CTP Exs. 4-13) and contemporaneously recorded the transaction (CTP Exs. 14, 15, 19). I find Inspector Bishop'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) on September 17, 2015 at 9:11 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 CTP relies on the hearsay evidence of Inspector Bishop that it contradicts with the "non-hearsay" testimony of Ms. Shathaia, which is supported by the surveillance video submitted as Respondent's Exhibit A.

The surveillance video submitted as Respondent's Exhibit A does not refute the evidence of noncompliance submitted by CTP. The video is a total of 28 seconds long. It shows a female patron, with brown hair, who appears Caucasian, at a sales counter. It shows a female clerk with long dark hair assisting the customer. The video shows the female patron hand the clerk what appears to be an identification card, it shows the clerk looking at the card and then returning it to the patron. It shows an exchange of money, the female patron picking up what appears to be a package of cigarettes, and the customer walking away from the sales counter.

I explained during the hearing that if I admit Respondent's video, I will let the video speak for itself; however, it does not support Respondent's claims. First, although Inspector Bishop described the minor-participant as African-American, the patron in the video appears Caucasian. Respondent does not address the obvious discrepancy between the observed race of the minor as described by Inspector Bishop and that of the individual shown in the video.

Second, the video contains the date marking of "2015-09-15" (September 15, 2015), and the time marking of "20:42," or 8:42 PM. However, the inspection was conducted on September 17, 2015 at 9:11 PM, and *not* September 15, 2015 at 8:42 PM. The video appears to represent a transaction two days and 29 minutes prior to the inspection at issue.

Respondent's manager and co-owner explicitly testified that it saved all of the footage from September 17, 2015 and unequivocally testified that Respondent retained

and reviewed the surveillance footage from 9:11 PM. Yet, Respondent submitted surveillance video indicating an entirely different date and time.

Respondent does not explain or address either discrepancy - the race of the minor or the date and time of the footage - and I do not believe there is an explanation. The video speaks for itself and reflects footage from a much earlier transaction. I find and conclude that the surveillance video at Respondent's Exhibit A is not sufficient to rebut the testimonial and documentary evidence of a violation.

Additionally, Respondent's witness Ms. Shathaia testified that she was not presented with a vertical identification card at all on the day in question. Tr. at 91. Ms. Shathaia testified that she personally reviewed the video footage from the entire day of September 17, 2015 and did not see any patron present a vertical identification on that date.

I do not find Ms. Shathaia's testimony convincing. Given that Respondent did not submit the surveillance footage, which it preserved, Ms. Shathaia's position is self-serving and unsupported. On the other hand, the testimony of Inspector Bishop 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.

XIII. 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), in that a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes on September 17, 2015, at approximately 9:11 PM as set forth in the complaint.

The conduct set forth above on September 17, 2015 counts as one (1) *additional* violation under FDA policy for purposes of computing the civil money penalty. *See Guidance for Industry*, at 13-15. Respondent previously admitted to three (3) violations of FDA policy in the relevant timeframe. Accordingly, I find and conclude that Respondent is liable for four (4) violations of FDA policy in a twenty-four (24) month period.

XIV. 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, \$2,000, against Respondent for four (4) violations of the Act and its

implementing regulations within a twenty-four (24) month period. Complaint ¶¶ 1-2. In its posthearing brief, CTP continued to assert that a \$2,000 civil money penalty is appropriate. Complainant's Closing Argument at 2, 7-8.

Respondent denies any obligation to pay a civil money penalty arguing that CTP has not met its burden of proof. Respondent's Post Trial Brief at 16.

As discussed, I found that CTP met its burden by a preponderance of the evidence and concluded that Respondent committed four (4) 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 three (3) violations of selling tobacco products to minors, and one (1) violation for the use of a self-service display in a non-exempt facility, totaling four (4) violations 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

Respondent has not presented any evidence that it does not have the ability to pay the \$2,000 civil money penalty sought by CTP.

C. History of Prior Violations

The current action is the third civil money penalty action brought against Respondent for violations of the Act and its implementing regulations. On January 5, 2015, CTP initiated the first civil money penalty action, CRD Docket Number C-15-793, FDA Docket Number FDA-2014-H-2299, 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), and violated the prohibition against using a self-service display in a non-exempt facility, 21 C.F.R. § 1140.16(c). 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. 2 at 8-9.

On July 7, 2015, CTP initiated the second civil money penalty action, CRD Docket Number C-15-3045, FDA Docket Number FDA-2015-H-2272, against Respondent. CTP Ex. 2 at 1, 6. In the second action, Respondent again violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a). CTP Ex. 2 at 6-8. Respondent settled the second prior complaint with CTP for an undisclosed penalty amount and admitted that the violations occurred as described in the complaint. CTP Ex. 3.

Respondent argues that it only conceded the prior violations on the advice of counsel. However, this argument is without merit. As explained, the prior actions are administratively final and Respondent is not permitted to challenge them now. Respondent's history of noncompliance demonstrates its continued inability to comply with the federal tobacco regulations. This calls for a more severe penalty. As CTP notes,

the regulations escalate the civil money penalty “to encourage repeat violators to clean up their acts.” Complainant’s Closing Arguments at 8, citing *Orton Motor*, DAB No. 2717 at 17.

D. Degree of Culpability

Respondent admitted to three (3) prior violations. Based on my finding that Respondent committed the most recent violation in the current complaint, I hold it fully culpable for all four (4) 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 provided evidence of its training program. Tr. at 76-77; Respondent Ex. C. I am impressed by Respondent’s training that includes quizzes, role-playing, and regulation review. However, Respondent has taken no subsequent or remedial measures to ensure compliance with the law. 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. It is not enough for Respondent to card a potential minor; Respondent must also not sell them tobacco products.

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 \$2,000 to be appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).

XV. CONCLUSION

Respondent committed four (4) violations in a twenty-four (24) month period as set forth in the complaint.

Respondent is liable for a civil money penalty of \$2,000. *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) on September 17, 2015, in that a person younger than 18 years of age was able to purchase a package of Newport Box 100s 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) on July 9, 2014 and March 6, 2015, and 21 C.F.R. § 1140.16(c) on February 7, 2014 as stipulated in the settlement agreement of the most recent civil money penalty action, CRD Docket Number C-15-3045, FDA Docket Number FDA-2015-H-2272; and
- d. I find and conclude Respondent committed four (4) violations of the regulations within a twenty-four (24) month period; and
- e. I assess a monetary penalty in the amount of \$2,000.

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