

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

Center for Tobacco Products,
Complainant,

v.

Greek Village, Inc.,
Respondent.

FDA Docket No. FDA-2015-H-3711
CRD Docket No. T-17-370

Decision No. TB3098

Date: September 21, 2018

INITIAL DECISION

Found:

- 1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a), 1140.14(b)(1), and 1140.14(c) (2015)¹ as charged in the Complaint; and
- 2) Respondent committed four (4) violations in a 24-month period as set forth hereinabove.
- 3) Respondent is hereby assessed a civil penalty in the amount of \$2,000.

Glossary:

ALJ	administrative law judge ²
CMP	civil money penalty
CTP/Complainant	Center for Tobacco Products
DJ	Default Judgment

¹ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>. For the purpose of clarity, when referencing the violations alleged in the Complaint, I will refer to the regulations that were in effect during the conduct at issue in this case, as cited by CTP.

² See 5 C.F.R. § 930.204.

FDCA	Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9)
DN	UPS Delivery Notification
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
OSC	Order to Show Cause
POS	UPS Proof of Service
SOP	Service of Process
Respondent	Greek Village Inc.
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 17.³

II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) filed a Complaint on October 20, 2015, alleging that FDA documented four (4) violations within a 24-month period.

There is a presumption Greek Village Inc. (Respondent or Greek Village Inc.) was served with process on October 21, 2015, by United Parcel Service. Respondent filed an answer, which was received on March 15, 2016.

³ See also *Butz v. Economou*, 438 U.S. 478, 513 (1978); *Marshall v. Jerrico, Inc.*, 446 U.S. 238 (1980); *Fed. Maritime Com'n v. S.C. State Ports Auth.*, 535 U.S. 743, 744 (2002).

The Civil Remedies Division – Tobacco Cases of the Departmental Appeals Board began managing civil money penalty and No-Tobacco-Sale Order actions against retailers of tobacco products in 2016. I retained jurisdiction and remained assigned to hear and decide this case.

On January 13, 2017, I issued an Acknowledgment and Pre-Hearing Order (APHO) setting a schedule for filings and procedures.

CTP filed its Motion for Summary Decision and Memorandum in Support, along with a list of proposed witnesses and exhibits, on February 14, 2017. Subsequently, and prior to issuance of my Order on the pending motion, CTP submitted its Status Report and requested an extension of the pre-hearing deadlines set in the APHO. I issued an Order on April 4, 2017, granting CTP's request and extending CTP's and Respondent's pre-hearing exchange deadlines to May 4, 2017 and May 25, 2017, respectively. On April 28, 2017, I issued my Ruling Denying CTP's Motion for Summary Decision (Ruling), finding that "there is a dispute as to an issue of material fact in this case, which is whether Respondent violated the prohibition of use of vending machines for the sale of tobacco products in a non-exempt facility." Ruling at 1.

CTP filed its pre-hearing exchange, containing a brief (CTP Pre-Hearing Brief), a list of proposed witnesses and exhibits, and 37 exhibits (CTP Exhibits (Exs.) 1-37), and including the written direct testimony of three proposed witnesses (CTP Exs. 35-37). As of the deadline set in my APHO, neither Respondent's pre-hearing exchange submission nor any objection to CTP's proposed exhibits was received in the Civil Remedies Division.

I conducted a hearing on January 18, 2018. *See* Transcript (Tr.). The purpose of the hearing was to allow Respondent an opportunity to cross-examine CTP's witnesses – FDA Senior Regulatory Counsel Laurie Sternberg, and Inspectors Julie Lahtinen and Deanna Kishpaugh. During the hearing, Respondent made references to evidence and other documents that do not appear as part of the evidentiary record.

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), 1140.14(a)(2)(i), and 1140.14(a)(3) (2017).

V. ISSUES

Did Respondent violate 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a), 1140.14(b)(1), and 1140.14(c) (2015) 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

CTP alleged that Respondent owned an establishment, doing business under the name Greek Village, located at 301 Northwest Murray Boulevard, Portland, Oregon 97229. Respondent's establishment receives tobacco products in interstate commerce and holds them for sale after shipment in interstate commerce.

CTP's Complaint alleged that, on March 19, 2015, CTP issued a Warning Letter to Respondent alleging that Respondent committed the following violations:

- a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a) on January 30, 2015;
- 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(b)(1) on January 30, 2015; and
- c. Using a vending machine in a non-exempt facility, in violation of 21 C.F.R. § 1140.14(c), on January 30, 2015.

Because no opportunity for a hearing was provided before the Warning Letter was issued, Respondent had a right to challenge the allegations in the Warning Letter in the instant case. *See Orton Motor Co. d/b/a Orton's Bagley v. HHS*, 884 F.3d 1205 (D.C. Cir. 2018).

Subsequently, during a two-part inspection of Greek Village conducted on June 22, 2015 and June 29, 2015, an FDA-commissioned inspector documented the following violations:

- a. Selling cigarettes 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 Parliament cigarettes on June 22, 2015, at approximately 1:39 PM;
- 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(b)(1). Specifically, the minor's identification was not

verified before the sale, as detailed above, on June 22, 2015, at approximately 1:39 PM; and

- c. Using a vending machine in a non-exempt facility, in violation of 21 C.F.R. § 1140.14(c). Specifically, a minor was able to enter the establishment and purchase a tobacco product from a vending machine.

B. Respondent's recitation of facts

In its Answer, Respondent does not specifically deny the allegations pertaining to sale to a minor or failure to verify a purchaser's age. Instead, Respondent alleges:

We do not sell any cigarettes across the counter but instead from a vending machine which is allowed by law in a business serving only customers 21 years of age or older. The machine was next to the main entrance and a purchase could be made before a bartender could reasonably card someone. The machine was moved far from the door and next to the bar.

CRD E-File Docket Number 5 (Answer), at 1; *see also* CRD E-File Docket Number 17(a).

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 387a-1 directed FDA to re-issue, with some modifications, regulations previously passed in 1996. 21 U.S.C. § 387a-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 (2) 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).

VIII. HEARING

I conducted a hearing on January 18, 2018, by telephone.

Sonia W. Nath, Esquire, appeared on behalf of Complainant.

Irene Pavlatos appeared pro se on behalf of Respondent.

Witnesses Julie Lahtinen and Deanna Kishpaugh (FDA Inspectors), and Laurie Sternberg (Senior Regulatory Counsel, CTP, FDA) provided written direct testimony (CTP Exs. 35-37) on behalf of CTP, and were cross-examined by Respondent at hearing. Tr. at 16-18, 19-21, and 21-24.

IX. SUMMARY OF TESTIMONY AND EVIDENCE

A. Complainant's case

CTP submitted evidence and testimony in the form of written declarations and photographs. Complainant offered CTP Exs. 1-37, inclusive, which were marked for identification. Respondent did not object to CTP's exhibits. However, the exhibits were not formally admitted into the record at the hearing. I now admit CTP Exs. 1-37 into evidence.

1. Inspector Julie Lahtinen

Witness Julie Lahtinen, the FDA-commissioned Inspector who conducted the inspection at issue on January 30, 2015, testified on behalf of Complainant. Complainant provided Inspector Lahtinen's written direct testimony as CTP Ex. 35.

Inspector Lahtinen testified that on January 30, 2015, at approximately 3:29 PM, she and Minor OR-UP-15-04 (Minor 1) conducted an undercover buy (UB) compliance

check inspection at Respondent's establishment, Greek Village, located at 301 Northwest Murray Boulevard, #E, Portland, Oregon 97229. Before the inspection, Inspector Lahtinen confirmed that Minor 1 had his or her photographic identification (ID) and did not have any tobacco products in his or her possession. CTP Ex. 35, at 2-3.

According to her testimony, Inspector Lahtinen entered Respondent's establishment followed by Minor 1 approximately one minute later. The inspector testified that from her location of 15 feet, she observed Minor 1 purchase a package of Camel cigarettes from a vending machine at Respondent's establishment. The inspector testified that prior to the purchase, she observed that Minor 1 did not present identification to any employee. Minor 1 did not receive a receipt after the purchase. CTP Ex. 35, at 3.

Inspector Lahtinen testified that after both she and Minor 1 exited Respondent's establishment, approximately 2-3 minutes apart, they returned to the vehicle where immediately upon entering, Minor 1 handed the inspector the package of Camel cigarettes. Inspector Lahtinen labeled the cigarettes as evidence, photographed the evidence (CTP Exs. 3-10), and processed the evidence in accordance with standard procedures at the time of the inspection. CTP Ex. 35, at 3.

According to Inspector Lahtinen, she recorded the inspection shortly thereafter in the FDA's Tobacco Inspection Management System (TIMS) (CTP Ex. 11) and created a contemporaneous Narrative Report (CTP Ex. 12). Inspector Lahtinen also testified that CTP Exs. 2 through 10 were true and accurate copies of photographs taken during the inspection. CTP Ex. 35, at 3.

On cross-examination, Inspector Lahtinen testified that on entering Respondents's establishment, she saw "21 and over" signage posted. However, because "[i]t's not anything that we have to check for," that observation was omitted from the Narrative Report for the January 30, 2015 inspection. Tr. at 16. At the hearing, Inspector Lahtinen also stated that for approximately 30 seconds, Minor 1 was physically in view of the bartender on duty during the relevant period. *Id.* at 17-18.

2. Inspector Deanna Kishpaugh

Witness Deanna Kishpaugh, the FDA-commissioned Inspector who conducted the inspection at issue on June 22, 2015, testified on behalf of Complainant. Complainant provided Inspector Kishpaugh's written direct testimony as CTP Ex. 36.

Inspector Kishpaugh testified that on June 22, 2015, at approximately 1:39 PM, she and Minor OR-UP-15-17 (Minor 2) conducted a follow-up UB compliance check inspection at Respondent's establishment, Greek Village, located at 301 Northwest Murray Boulevard, #E, Portland, Oregon 97229. Before the inspection, Inspector Kishpaugh confirmed that Minor 2 had his photographic ID and did not have any tobacco products in his or her possession. CTP Ex. 36, at 2.

According to her testimony, Inspector Kishpaugh entered Respondent's establishment followed by Minor 2 approximately one minute later. The inspector testified that from her location of 10-15 feet, she observed Minor 2 purchase a package of cigarettes from a vending machine at Respondent's establishment. The inspector testified that prior to the purchase, she observed that Minor 2 did not present identification to any employee. Minor 2 did not receive a receipt after the purchase. CTP Ex. 36, at 3.

Inspector Kishpaugh testified that after both she and Minor 2 exited Respondent's establishment, approximately 2-3 minutes apart, they returned to the vehicle where immediately upon entering, the Minor handed the inspector the package of cigarettes. Inspector Kishpaugh testified that she moved her vehicle to a different location prior to processing the evidence. Inspector Lahtinen noted at that time the cigarettes purchased by Minor 2 was a package of Parliament cigarettes. Inspector Lahtinen labeled the cigarettes as evidence, photographed the evidence (CTP Exs. 21-28), and processed the evidence in accordance with standard procedures at the time of the inspection. CTP Ex. 36, at 3.

According to Inspector Kishpaugh, she recorded the inspection shortly thereafter in the FDA's TIMS (CTP Ex. 29) and created a contemporaneous Narrative Report (CTP Ex. 30). Inspector Kishpaugh also testified that CTP Exs. 20-28, inclusive, were true and accurate copies of photographs taken during the inspection. *Id.*

On cross-examination, in response to Respondent's question of whether a receipt would have been provided for a vending machine purchase, Inspector Kishpaugh testified "Out of a vending machine I would say probably not." Tr. at 20-21.

3. Senior Regulatory Counsel 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. 37.

Ms. Sternberg testified that Camel brand cigarettes, the tobacco product purchased during the January 30, 2015 inspection, are manufactured at facilities in North Carolina.

CTP Ex. 37, at 2-3. The manufacturer of Camel brand cigarettes does not have any production facilities in Oregon, where the tobacco product at issue was purchased. *Id.* at 3.

Ms. Sternberg also testified that Parliament brand cigarettes, the tobacco product purchased during the June 22, 2015 inspection, are manufactured at facilities in Virginia.

CTP Ex. 37, at 3. The manufacturer of Parliament brand cigarettes does not have any production facilities in Oregon, where the tobacco product at issue was purchased. *Id.*

Further, at the hearing, Ms. Sternberg testified that paragraph 13 of her written declaration, among other things, attested “that the attached Warning Letter and Notice of Compliance Check Inspection sent to Greek Village Inc., and these documents accompanying United Parcel Service (“UPS”) delivery notifications for this case” are true and accurate copies. Tr. at 24; *see also*, CTP Ex. 37, at 3.

B. Respondent’s case

Respondent did not submit written direct testimony or documentary evidence in accordance with my APHO dated January 13, 2017, and subsequent Order Granting Motion for Extension dated April 4, 2017.

It is Respondent’s position that: 1) no tobacco product was sold to a minor since the purchase was from a legal vending machine which is not a living being and therefore cannot be considered an employee; and 2) the vending machine at issue is allowed under Oregon state law in a business serving only customers 21 years or older. CRD E-File Docket Numbers 17a, at 1 and 39, at 2.

X. PRELIMINARY MATTER - RULING ON MOTION TO EXCLUDE

On January 11, 2018, CTP filed a Motion to Exclude Evidence Not Exchanged in Accordance with 21 C.F.R. §§ 17.25 and 17.37(b) (Motion to Exclude). CTP argued that it:

ha[d] no idea whether Respondent will attempt to offer testimony to support its bold denials or any potential defenses to the allegations stated in CTP's [C]omplaint . . . CTP respectfully requests that the ALJ not condone any attempt by Respondent to "surprise" CTP with witnesses and exhibits at the hearing. Allowing such evidence would deny CTP appropriate notice and adequate time to prepare.

See CRD E-File Docket Number 30, at 4.

At the telephone hearing convened on January 18, 2018, Respondent made references to evidence and other documents that were purportedly exchanged between Respondent and CTP during the course of these proceedings, but do not appear in the record. *See* Tr. at 27-29. At the conclusion of cross-examination, I continued the hearing without prejudice and directed CTP to file a Status Update regarding the documents purportedly submitted by Respondent during the course of the pre-hearing process. *See* CRD E-File Docket Number 31 (Order Continuing Hearing dated January 26, 2018); *see also* Tr. at 29-30.

On February 6, 2018, the Civil Remedies Division received a submission from Respondent, presumably sent after the January 18, 2018 hearing, which consisted of a letter dated January 18, 2018, exhibits purported to have been submitted previously to CTP, and various correspondence exchanged between CTP and Respondent. *See* CRD E-File Docket Numbers 32-32g.

CTP filed a response to Respondent's submission on February 23, 2018. In its response, CTP acknowledged receipt of Respondent's post-hearing submission. Among other things, CTP also sought a ruling on the outstanding Motion to Exclude. *See* CRD E-File Docket Number 34, at 3.

On May 2, 2018, I issued an Order giving Respondent until May 16, 2018 to submit a response to CTP's Motion to Exclude, and to advise this Court of whether the documentation filed as an attachment to its January 18, 2018 letter "represents the totality of the documentary evidence purportedly submitted to CTP earlier in these proceedings." CRD E-File Docket Number 35, at 2. To date, Respondent's response has not been received by this office.

The regulations grant me the authority to "receive, rule on, exclude, or limit evidence." 21 C.F.R. § 17.19(b)(11). I also have the authority to "[w]aive, suspend, or modify any rule in this part if the presiding officer determines that no party will be prejudiced, the ends of justice will be served, and the action is in accordance with law" 21 C.F.R. § 17.19(b)(17).

In its February 23, 2018 Status Report, CTP stated:

At the January 18, 2018 hearing, Respondent referenced "exhibits" that it allegedly provided in "May." CTP did not receive such documents in a pre-hearing exchange, nor were any such exhibits on file with the DAB, in accordance with the ALJ's January 13 and April 4, 2017 orders. CTP noted at the hearing that it did receive letters from Respondent in response to its Motion to Compel discovery, which CTP cited and addressed in its Motion for Summary Decision, filed on February 13, 2017 (Dkt. 20 at 7). These letters appear on the DAB docket as Entries 17a & 17b.

CRD E-File Docket Number 34, at 2.

With regard to Respondent's January 18, 2018 letter with attachments, CTP further states:

Without waiving the objections raised in th[e] Motion [to Exclude], CTP notes that nothing provided by Respondent, which was docketed on February 6, 2018, . . . refutes the evidence presented by CTP that on January 30, 2015, and June 22, 2015, Greek Village violated the tobacco regulations and therefore misbranded tobacco products when it sold cigarettes to minors through a vending machine without verifying the minor's photographic identification .

Id. at 3.

Based on the foregoing, I find it appropriate to accept and consider Respondent's filing, to serve the ends of justice, and because no party will be prejudiced by so doing. Accordingly, I deny CTP's Motion to Exclude. Respondent's correspondence with seven attachments, docketed on February 6, 2018, are included into the evidentiary record and will be considered in deciding this case.

XI. ANALYSIS OF EVIDENCE AND TESTIMONY

A. Complainant's case

Complainant offered and I have admitted into evidence CTP Exs. 1-37.

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.

Respondent has offered an affirmative defense to rebut the allegations in the Complaint. It is Respondent's position that the vending machine at issue was allowed under Oregon state law in a business serving only customers 21 years of age or older and, therefore there were no violations committed. CRD E-File Docket Number 5, at 1.

C. Analysis

1. 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 January 30, 2015 and June 22, 2015.

a. **January 30, 2015 Violation**

On January 30, 2015, at approximately 3:29 PM, Inspector Lahtinen conducted a UB compliance check inspection of Respondent's establishment with a confidential state-contracted minor (Minor 1). Inspector Lahtinen confirmed that Minor 1 did not possess any tobacco products in his or her possession before entering the establishment. CTP Ex. 35, at 3.

The inspector followed Minor 1 into Respondent's establishment and took a position "approximately 15 feet from the minor." *Id.* Inspector Lahtinen observed Minor 1 purchase a package of cigarettes from a vending machine in Respondent's establishment. Inspector Lahtinen observed that Minor 1 did not provide identification to any employee of Respondent's establishment. The inspector followed Minor 1 out of the

establishment and the two returned to the vehicle. When they entered the vehicle, Minor 1 immediately handed the package of cigarettes to Inspector Lahtinen. Inspector Lahtinen observed that the package of cigarettes were Camel cigarettes. *Id.* Inspector Lahtinen labeled the cigarettes as evidence, documented the physical evidence (CTP Exs. 2-10), and contemporaneously recorded the transaction (CTP Exs. 11-12). *Id.*

Inspector Lahtinen's testimony is additionally supported by physical evidence. CTP submitted a redacted copy of the undercover minor's state photo identification (redacted), listing the date of birth as February 26, 1998, meaning Minor 1 was 16 years old during the January 30, 2015 inspection. CTP Ex. 1; *see also* CTP Ex. 35, at 2. CTP also submitted copies of the photographs that Inspector Lahtinen took of the package of Camel cigarettes. CTP Exs. 3-10; *see also* CTP Ex. 35, at 3.

I find Inspector Lahtinen's 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) on January 30, 2015, at approximately 3:29 PM, by a preponderance of the evidence.

b. June 22, 2015 Violation

On June 22, 2015, at approximately 1:39 PM, Inspector Kishpaugh conducted a follow-up UB compliance check inspection of Respondent's establishment with a confidential state-contracted minor (Minor 2). Inspector Kishpaugh confirmed that Minor 2 did not possess any tobacco products in his or her possession before entering the establishment. CTP Ex. 36, at 2.

The inspector followed Minor 2 into Respondent's establishment and took a position "10-15 feet from [Minor 2]." *Id.* at 3. Inspector Kishpaugh observed Minor 2 purchase a package of cigarettes from a vending machine in Respondent's establishment. Inspector Kishpaugh observed that Minor 2 did not provide identification to any employee of Respondent's establishment. The inspector followed Minor 2 out of the establishment and the two returned to the vehicle. When they entered the vehicle, Minor 2 immediately gave the package of cigarettes to Inspector Kishpaugh. Prior to processing the evidence, Inspector Kishpaugh moved her vehicle to a different location. Inspector Kishpaugh observed that the package of cigarettes were Parliament cigarettes. *Id.* Inspector Kishpaugh labeled the cigarettes as evidence, documented the physical evidence (CTP Exs. 20-28) and contemporaneously recorded the transaction (CTP Exs. 29-30). *Id.*

Inspector Kishpaugh's testimony is additionally supported by physical evidence. CTP submitted a redacted copy of the undercover minor's state photo identification (redacted), listing the date of birth as November 26, 1997, meaning Minor 2 was 17 years old during the June 22, 2015 inspection. CTP Ex. 19; *see also* CTP Ex. 36, at 2. CTP also submitted copies of the photographs that Inspector Kishpaugh took of the package of Parliament cigarettes. CTP Exs. 21-28; *see also* CTP Ex. 36, at 3.

I find Inspector Kishpaugh's 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) on June 22, 2015, at approximately 1:39 PM, by a preponderance of the evidence.

2. I find and conclude that CTP has shown by a preponderance of the evidence that Respondent violated 21 C.F.R. § 1140.14(b)(1) 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 January 30, 2015, and June 22, 2015.

a. January 30, 2015 Violation

On January 30, 2015, at approximately 3:29 PM, Inspector Lahtinen conducted a UB compliance check inspection of Respondent's establishment with Minor 1. Prior to the inspection, Inspector Lahtinen confirmed that Minor 1 had his or her photographic identification in the minor's possession. CTP Ex. 35, at 2-3. During the inspection, Inspector Lahtinen observed that no employee of Respondent's establishment, specifically Respondent's bartender, asked to see Minor 1's identification. Yet, the inspector also observed Minor 1 purchasing a package of cigarettes from a vending machine while being within physical view of Respondent's bartender. CTP Ex. 35, at 3; *see also* Tr. at 17-18.

I find Inspector Lahtinen's 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(b)(1) on January 30, 2015, at approximately 3:29 PM by a preponderance of the evidence.

b. June 22, 2015 Violation

On June 22, 2015, at approximately 1:39 PM, Inspector Kishpaugh conducted a follow-up UB compliance check inspection of Respondent's establishment with Minor 2. Prior to the inspection, Inspector Kishpaugh confirmed that Minor 2 had his or her photographic identification in the minor's possession. CTP Ex. 36, at 2. During the inspection, Inspector Kishpaugh observed that no employee of Respondent's establishment asked to see Minor 2's identification. Yet, the inspector also observed Minor 2 purchase a package of cigarettes from a vending machine. CTP Ex. 36, at 3.

I find Inspector Kishpaugh's 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(b)(1) on June 22, 2015, at approximately 1:39 PM, by a preponderance of the evidence.

3. I find and conclude that CTP has shown by a preponderance of the evidence that Respondent violated 21 C.F.R. § 1140.14(c) when it used a vending machine in a non-exempt facility on January 30, 2015, and June 22, 2015.

On January 30, 2015 and June 22, 2015, Inspectors Lahtinen and Kishpaugh, respectively, observed a customer-accessible vending machine containing cigarettes. The Inspectors also documented that on the respective dates at issue, a person younger than 18 years of age was able to enter Respondent's establishment and purchase cigarettes from the vending machine. *See* CTP Ex. 35, at 3; CTP Ex. 36, at 3.

I find the testimony of Inspectors Lahtinen and Kishpaugh to be credible and unbiased. I find that it is sufficient to satisfy CTP's burden of proving that Respondent violated 21 C.F.R. § 1140.14(c) on January 30, 2015 and June 22, 2015, by a preponderance of the evidence.

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

Respondent argues that the vending machine from which the undercover minors purchased cigarettes on January 30, 2015 and June 22, 2015 was on the premises legally; therefore, it has not committed the violations alleged by CTP in its Complaint. CRD E-File Docket Number 5, at 1; *see also* CRD E-File Docket Number 39, at 2 (R. Post Brief). Respondent contends that, as an establishment that serves only customers 21 and over, it is allowed by law to possess a vending machine on the premises for the purpose of selling tobacco products. *Id.*; *see also* CTP Ex. 17, at 1. Further, Respondent asserts that, under federal tobacco regulations, it is an "exempt" facility.⁴ Respondent relies on the posting of "warning" signs throughout the establishment to support its "exempt" status for its use of a vending machine to sell tobacco products. *See* CRD E-File Docket Number 5, at 4 and 7.

I find these arguments to be without merit. First and foremost, Respondent was charged with violations of federal tobacco law; not Oregon state law. *See* CRD E-File

⁴ The regulation at 21 C.F.R. § 1140.16(c) provides an exemption for use of vending machines in certain types of facilities. Specifically, the regulation allows use of vending machines "that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at anytime." 21 C.F.R. § 1140.16(c)(2)(ii).

Docket Number 1; *see also Western Spirits, Inc. d/b/a T-Joe's Steakhouse and Saloon (Western Spirits, Inc.)*, Departmental Appeals Board (DAB) Decision No. 2844, 2018 WL 1056521, at 4 (Jan. 16, 2018). As correctly argued by CTP, Respondent's compliance with state law does not obviate its responsibility to adhere to applicable federal law and regulations.

Further, Respondent's assertion that the posting of "warning" signs in the establishment supports its exempt status is also unpersuasive. An appellate panel of the DAB, in an unrelated case, considered similar arguments raised by the respondent. The Board concluded that where a minor is present in an establishment and able to access a vending machine, in spite of the posting of signs warning of prohibited use of vending machines by anyone under the age of 18, that establishment does not qualify as an "exempt" facility in accordance with the regulations. *Western Spirits, Inc.*, 2018 WL 1056521, at 4-6.

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 January 30, 2015 and June 22, 2015, Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R.

§ 1140.14(a), in that persons younger than 18 years of age were able to purchase, respectively, a package of Camel and Parliament cigarettes.

I find and conclude that the evidence presented supports a finding that on January 30, 2015 and June 22, 2015, Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. §1140.14(b)(1), 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.

Further, I find and conclude that the evidence presented supports a finding that on January 30, 2015 and June 22, 2015, Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. §1140.14(c), in that it used a vending machine in a non-exempt facility.

The conduct set forth above on January 30, 2015 and June 22, 2015 counts as four (4) violations under FDA policy for purposes of computing the civil money penalty. *See Guidance for Industry*, at 13-14. Accordingly, I find and conclude that Respondent is liable for four (4) 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, \$2,000, against Respondent for four (4) violations of the TCA and its implementing regulations within a 24-month period. Complaint ¶ 1. In its pre- and post-

hearing briefs, CTP continued to assert that a \$2,000 civil money penalty is appropriate. CTP Pre-Hearing Brief at 13-18; CTP Post-Hearing Brief at 9.

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 24-month period.

In essence, Respondent denies any obligation to pay a civil money penalty arguing that “we are not guilty of breaking any laws.” R. Post-Hearing Brief at 2.

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 two (2) violations of selling tobacco products to minors, two (2) violations of failing to verify the photographic identification of a purchaser, and two (2) violations of using a vending machine in a non-exempt facility, totaling six (6) violations of the tobacco regulations. However, Respondent is only being held liable for four (4) of those violations. *See Guidance for Industry*, at 13-14. 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 \$2,000 civil money penalty sought by CTP.

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. As noted above, Respondent has, at least four (4) times, violated the prohibition against selling cigarettes to persons younger than 18 years of age, failing to verify that the cigarette purchasers were of sufficient age, and using a vending machine in a non-exempt facility. 21 C.F.R. § 1140.14(a), 1140.14(b)(1), and 1140.14(c).

D. Degree of Culpability

Based on my finding that Respondent committed the four (4) violations in the Complaint, I hold it fully culpable for four (4) violations of the TCA 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 “[t]he machine was next to the main entrance and a purchase could be made before a bartender could reasonably card someone. The machine was moved far from the door and next to the bar.” CRD E-File Docket Number 5, at 1. Respondent also contends that after the January 30, 2015 violation, “I will post a notice on the machine stating that it is against the law for anyone under the age of 18yrs to

purchase cigarettes.” CTP Ex. 17, at 2. However, this in itself is not a mitigating factor. Respondent has not provided any evidence of implementation of new policies for its employees.

The purpose of the TCA is 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 are 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 \$2,000 is appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).

XIV. CONCLUSION

Respondent committed four (4) violations in a 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 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) on January 30, 2015 and June 22, 2015, 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(b)(1) on January 30, 2015 and June 22, 2015, 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(c) on January 30, 2015 and June 22, 2015, in that Respondent used a vending machine in a non-exempt facility as set forth in the Complaint;
- e. I find and conclude Respondent committed four (4) violations of the regulations within a 24-month period; and
- f. I assess a monetary penalty in the amount of \$2,000 is appropriate.

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