

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

Center for Tobacco Products,
Complainant

v.

UEL, Inc.
d/b/a Knight's Discount Liquor,
Respondent

FDA Docket No. FDA-2018-H-0077
CRD Docket No. T-18-827

Decision No. TB3502

Date: February 5, 2019

INITIAL DECISION

Found:

- 1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1)¹ as charged in the Complaint; and
- 2) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), and 1140.14(a)(2)(i) as charged in the prior Complaint; and
- 3) Respondent committed six (6) violations in a 48-month period as set forth hereinabove.
- 4) Respondent is hereby assessed a civil penalty in the amount of \$11,182.

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 as they currently appear.

Glossary:

ALJ	administrative law judge ²
CMP	civil money penalty
CTP/Complainant	Center for Tobacco Products
DJ	Default Judgment
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	UEL, Inc. d/b/a Knight's Discount 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 17.³

II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) filed a Complaint on January 11, 2018, alleging that FDA documented six (6) violations within a 48-month period.

² See 5 C.F.R. § 930.204.

³ 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).

There is a presumption UEL, Inc. d/b/a Knight's Discount Liquor (Respondent or Knight's Discount Liquor) was served with process on January 10, 2018, by United Parcel Service (UPS). Respondent filed an answer on February 13, 2018.⁴ On March 1, 2018, I issued a Pre-Hearing Order (PHO) setting a schedule for filings and procedures.

Pursuant to my PHO, CTP served Respondent's counsel with a Request for Production of Documents on March 12, 2018. On April 18, 2018, CTP filed Motions to Compel Discovery and Stay Deadlines averring that Respondent failed to comply with its request for production of documents. On May 10, 2018, I issued an Order giving Respondent until May 21, 2018, to comply with CTP's Request for Production of Documents. I warned Respondent that its "[f]ailure to [comply] may result in sanctions, including the issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty." My May 10, 2018 Order also stayed all deadlines pending resolution of the discovery issue. Respondent did not file a response to CTP's Motion to Compel or otherwise respond to CTP's request for production.

On May 25, 2018, CTP filed a Motion to Impose Sanctions against Respondent asserting that Respondent failed to respond to CTP's request for production of documents or comply with my May 10, 2018 Order. In its motion, CTP asked that I strike Respondent's Answer and issue a Default Judgment against Respondent as a sanction for

⁴ I note that the deadline for Respondent's submission of an answer was February 9, 2018. Respondent's counsel filed a Notice of Appearance and Answer on February 13, 2018. CTP did not object to the timeliness of Respondent's Answer.

failure to comply with my Orders. On June 6, 2018, counsel for Respondent filed a response to CTP's Motion to Impose Sanctions stating that, due to his unfamiliarity with the Departmental Appeals Board's electronic case filing system, he was unaware of CTP's April 18, 2018 Motion to Compel, or my May 10, 2018 Order. Counsel further advised that upon receipt of CTP's Motion to Impose Sanctions, steps were taken to comply with CTP's request for production of documents. On June 7, 2018, based on Respondent's response, I issued an Order denying CTP's Motion to Impose Sanctions and re-establishing the simultaneous pre-hearing exchange deadline.

On July 23, 2018, CTP filed its pre-hearing exchange, containing a brief (CTP Pre-Hearing Br.), a list of proposed witnesses and exhibits, and 16 exhibits (CTP Exhibits (Exs.) 1-16), and including the written direct testimony of two proposed witnesses (CTP Exs. 5 and 6). As of the deadline set in my June 7, 2018 Order, Respondent's pre-hearing exchange was not received in the Civil Remedies Division. Nor did Respondent file any objections to CTP's proposed exhibits.

On July 30, 2018, I issued an Order scheduling a hearing in this case for August 30, 2018. My Order also directed the parties to, among other things, advise within 15 days of the hearing of their respective intent to cross-examine the opposing party's witness. Subsequently, based on CTP counsel's unavailability and motion to reschedule the hearing, I issued an Order on August 9, 2018 rescheduling the hearing for September 13, 2018 at 1:00 PM Eastern Time.

On September 7, 2018, I issued an Order noting Respondent's failure to advise of its intent to cross-examine CTP's witnesses, in accordance with my July 30, 2018 and

August 7, 2018 Orders scheduling a hearing. The September 7, 2018 Order gave Respondent until September 11, 2018 to inform the Civil Remedies Division of its intent to cross-examine CTP's witnesses. I further advised that failure to follow my directive would result in cancellation of the scheduled hearing and issuance of a decision on the record. On September 11, 2018, Respondent filed its notice of intent to cross-examine CTP's witness, FDA-commissioned Inspector Janet Reaves.

On September 12, 2018, CTP filed a Motion to Exclude Evidence Not Exchanged in Accordance with 21 C.F.R. § 17.25 and Administrative Law Judge Orders (Motion to Exclude). In its Motion to Exclude, CTP noted Respondent's reference to "video footage" in the Notice to Cross-Examine submitted on September 11, 2018 – two days before commencement of the scheduled hearing. CTP asserted:

Based on the representation made by Respondent's counsel in the Notice[,] . . . it appears that he intends to introduce security camera footage allegedly from December 14, 2017 at 1:43 P.M. into evidence at the hearing. It is unclear how Respondent's counsel intends to use such footage, but presumably he either intends to present it through his own witness or to use it to cross-examine Inspector Reaves. Accordingly, CTP seeks an order excluding Respondent from presenting any evidence, testimonial or documentary, including the security camera footage referenced in the Notice, at the hearing in this matter, due to Respondent's failure to timely exchange evidence as required under 21 C.F.R. § 17.25(a), the [PHO], and the June 7, 2018 Order.

Motion to Exclude at 3.

I conducted a hearing on September 13, 2018. *See* Transcript (Tr.). The purpose of the hearing was to allow Respondent an opportunity to cross-examine Inspector Janet Reaves only. During the hearing, Respondent made references to videotape footage that does 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) and 1140.14(a)(2)(i).

V. ISSUES

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

If so, is a civil money penalty in the amount of \$11,182 appropriate?

VI. ALLEGATIONS

A. Complainant's recitation of facts

CTP alleged that Respondent owned an establishment, doing business under the name Knight's Discount Liquor, located at 5139 Park Heights Avenue, Baltimore, Maryland 21215. Respondent's establishment receives tobacco products in interstate commerce and holds them for sale after shipment in interstate commerce.

During an inspection of Knight's Discount Liquor conducted on December 14, 2017, an FDA-commissioned inspector documented the following violation:

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

Specifically, a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes on December 14, 2017, at approximately 1:43 PM.

B. Respondent's recitation of facts

In its Answer, Respondent denies the allegations pertaining to sale to a minor or failure to verify a purchaser's age on December 14, 2017. Respondent also disputes the civil money penalty sought by CTP. Answer.

VII. PRIOR VIOLATIONS

On June 21, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-4862, FDA Docket Number FDA-2017-H-3752 (*see also*, CRD Docket Number T-17-2165, FDA Docket Number FDA-2017-H-0776), against Respondent for five violations⁵ of 21 C.F.R. pt. 1140. CTP alleged those violations to have occurred at Respondent's business establishment, 5139 Park Heights Avenue, Baltimore, Maryland 21215, on March 2, 2016, August 16, 2016, and May 5, 2017.

The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and paid the agreed upon monetary penalty in settlement on that claim. Further, "Respondent expressly waived its right to contest such

⁵ An FDA-commissioned inspector documented one violation on March 2, 2016, two on August 16, 2016, and two on May 5, 2017.

violations in subsequent actions.”

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 September 13, 2018, by telephone.

Claudia Ahiabor, Esquire, appeared on behalf of Complainant.

Peter Prevas, Esquire, appeared on behalf of Respondent.

Witness Janet Reaves (an FDA Inspector), and Laurie Sternberg (Senior Regulatory Counsel, CTP, FDA) provided written direct testimony (CTP Exs. 5 and 6) on behalf of CTP, and Inspector Reaves was cross-examined by Respondent at the hearing. Tr. at 9-15, 23-25.

X. 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. 1-16, inclusive, which were marked for

identification. Respondent did not object to CTP's exhibits. Therefore, I admitted CTP Exs. 1-16 into evidence. Tr. at 25-26.

Inspector Janet Reaves

Witness Janet Reaves, the FDA-commissioned Inspector who conducted the inspection at issue on December 14, 2017, testified on behalf of Complainant.

Complainant provided Inspector Reave's written direct testimony as CTP Ex. 6.

Inspector Reaves testified that on December 14, 2017, at approximately 1:43 PM, she and a confidential state-contracted minor (Minor A) conducted an undercover buy (UB) compliance check inspection at Respondent's establishment, Knight's Discount Liquor, located at 5139 Park Heights Avenue, Baltimore, Maryland 21215. Before the inspection, Inspector Reaves confirmed that Minor A had his or her photographic identification (CTP Ex. 9) and did not have any tobacco products in his or her possession. CTP Ex. 6, at 2-3.

According to her testimony, Inspector Reaves entered Respondent's establishment after Minor A. The inspector testified that from her unobstructed location in the establishment, she observed Minor A purchase a package of cigarettes "directly from an employee" at Respondent's establishment. The inspector testified that Minor A did not receive a receipt after the purchase. CTP Ex. 6, at 3.

Inspector Reaves testified that after both she and Minor A separately exited Respondent's establishment, they returned to the vehicle where immediately upon entering, Minor A handed the inspector the package of Newport Box cigarettes. Inspector Reaves labeled the cigarettes as evidence, photographed the evidence (CTP

Exs. 10, 11), and processed the evidence in accordance with standard procedures at the time of the inspection. CTP Ex. 6, at 3.

According to Inspector Reaves, she recorded the inspection shortly thereafter in the FDA's Tobacco Inspection Management System (TIMS) (CTP Ex. 8) and created a contemporaneous Narrative Report (CTP Ex. 7). Inspector Reaves also testified that CTP Exs. 7-8 and 10-11 were true and accurate copies. CTP Ex. 6, at 3.

On cross-examination, Inspector Reaves testified that on entering Respondent's establishment at approximately 1:43 PM on December 14, 2017, she observed Minor A purchase a package of Newport Box cigarettes. Inspector Reaves also testified that at no time on the date of inspection did she purchase a package of cigarettes from Respondent's establishment. Tr. at 10. Inspector Reaves further testified that the time of inspection was 1:43 PM. *Id.* at 11, 13. At the hearing, Inspector Reaves also mentioned that Minor A was a "male," and that she did not recall what either she or Minor A wore on the day of inspection. *Id.* at 10, 11-12.

B. Respondent's case

Respondent did not submit written direct testimony or documentary evidence in accordance with my PHO dated March 1, 2018, and subsequent Order dated June 7, 2018.

It is Respondent's position that, based on review of videotape footage from Respondent's establishment on December 14, 2017 at 1:43 PM: 1) no tobacco product was sold to a minor; and therefore, 2) the CMP of \$11,182 sought by CTP is

inappropriate since no violation occurred on December 14, 2017. CRD E-File Docket Number 6, at 2-3 (R's Post Br.).

XI. PRELIMINARY MATTER – RULING ON MOTION TO EXCLUDE

On September 12, 2018, CTP filed a Motion to Exclude Evidence Not Exchanged in Accordance with 21 C.F.R. § 17.25 (Motion to Exclude) and the Administrative Law Judge's Orders. CTP argued:

[T]he ALJ ordered Complainant and Respondent to file their pre-hearing exchanges by July 23, 2018 The contents of the pre-hearing exchange were described in the [PHO]; specifically, paragraph 4(b) of the [PHO] required that each party's pre-hearing exchange consist of, among other things, a list of all proposed exhibits and witnesses and a copy of each proposed exhibit, including the written direct testimony of any proposed witness.

* * *

Respondent did not submit a pre-hearing exchange by the July 23, 2018 deadline

[O]n September 11, 2018 – two days before the scheduled hearing in this case – Respondent's counsel filed a "Notice of Intent to Cross-Examine Janet Reaves (FDA Commissioned Inspector) in which he states the following:

"Respondent intends to cross examine [CTP] witness, Janet Reaves A review of the security camera

footage for the premises on December 14, 2017 at 1:43 P.M. reveals one African American female entering the premises A copy of the security camera footage was provided to counsel for [CTP] for review”

Based on representation made by Respondent’s counsel in the Notice[,] . . . it appears that he intends to introduce security camera footage allegedly from December 14, 2017 at 1:43 P.M. into evidence at the hearing. It is unclear how Respondent’s counsel intends to use such footage, but presumably he either intends to present it through its own witness or to use it to cross-examine Inspector Reaves. Accordingly, CTP seeks an order excluding Respondent from presenting any evidence, testimonial or documentary, including security camera footage referenced in the Notice at the hearing in this matter due to Respondent’s failure to timely exchange of evidence as required under 21 C.F.R. § 17.25(a) and the June 7, 2018 order.

Motion to Exclude at 1-3.

At the outset of the telephone hearing convened on September 13, 2018, CTP’s pending Motion to Exclude was addressed. Tr. at 6-8. Respondent stated that the videotape footage was provided to CTP on a thumb drive as part of its June 6, 2018 discovery submission. *Id.* at 7. CTP confirmed receipt of the thumb drive. CTP contended that its objections “are based on the fact that the video was not submitted as part of the record for us to raise objections to it on the record with regards to its legitimacy and authenticity.” *Id.* At the hearing, I preliminarily denied CTP’s Motion to

Exclude, but afforded CTP an opportunity to renew its Motion to Exclude in its post-hearing brief, and Respondent an opportunity to file a response. *Id.* at 8, 25.

On November 19, 2018, CTP filed its Post-Hearing Brief (CTP Post Br.). In its submission, CTP renewed its Motion to Exclude from evidence the purported December 14, 2017, videotape footage, “and any testimony about the videotape being considered.” CTP Post Br. at 4-5. CTP objected “because the videotape was not properly exchanged and it was not authenticated by Respondent.” CTP Post Br. at 5.

On November 19, 2018, Respondent submitted its post-hearing brief (R’s Post Br.). CRD E-File Docket Number 26. In its post-hearing brief, Respondent relies heavily on the content of the videotape footage to rebut Inspector Reaves’ testimony, and to support its assertion that no violation occurred on December 14, 2017, as alleged in CTP’s Complaint. *Id.*

On March 1, 2018 and June 7, 2018, I issued Orders which established deadlines for the submission of pre-hearing exchanges which included, among other things, proposed exhibits, witness and exhibit list, and written direct testimony of any proposed witnesses. *See* CRD E-File Docket Numbers 6, 14. As previously discussed, Respondent provided CTP with a copy of the videotape footage. However, Respondent did not submit this footage as part of its pre-hearing exchange, or at any point thereafter. At no point during these proceedings did Respondent offer this purported evidence for my consideration.

Accordingly, I grant CTP's Motion to Exclude and any testimony or argument made based on the content of the videotape footage will not be considered in deciding this case.

XII. ANALYSIS OF EVIDENCE AND TESTIMONY

A. Complainant's case

Complainant offered and I have admitted into evidence CTP Exs. 1-16.

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

Respondent did not offer any evidence for inclusion into the record. Pursuant to 21 C.F.R. § 17.33(c), Respondent must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

C. Analysis

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)(1) when it impermissibly sold cigarettes to a minor on December 14, 2017 at approximately 1:43 PM.

On December 14, 2017, Inspector Reaves conducted a UB compliance check inspection of Respondent's establishment with a confidential state-contracted minor. Inspector Reaves confirmed that Minor A did not possess any tobacco products in his or her possession before entering the establishment. CTP Ex. 6, at 3.

The inspector entered into Respondent's establishment with Minor A and took a position where she "had a clear, unobstructed view of the sales counter and Minor A." *Id.* Inspector Reaves observed Minor A purchase a package of cigarettes from an employee in Respondent's establishment. Inspector Reaves observed that Minor A did not get a receipt from the employee for the purchase. After Inspector Reaves and Minor A separately exited Respondent's establishment, they returned to the vehicle. When they entered the vehicle, Minor A immediately tendered the package of cigarettes to Inspector Reaves. Inspector Reaves observed that the package of cigarettes were Newport Box cigarettes. *Id.* Inspector Reaves labeled the cigarettes as evidence, documented the physical evidence (CTP Exs. 10, 11) and contemporaneously recorded the transaction (CTP Exs. 7, 8). *Id.*

Inspector Reaves' testimony is additionally supported by physical evidence. CTP submitted a redacted copy of the undercover minor's state photo identification, listing the date of birth as September 20, 2000, showing that Minor A was 17 years old during the December 14, 2017, inspection. CTP Ex. 9. CTP also submitted copies of the photographs that Inspector Reaves took of the package of Newport Box cigarettes. CTP Exs. 10, 11.

I find Inspector Reaves' 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 December 14, 2017, at approximately 1:43 PM by a preponderance of the evidence.

2. Respondent offered no affirmative proof to rebut the evidence of noncompliance on December 14, 2017, presented by CTP.

In its post-hearing brief, Respondent maintains that the evidence presented by CTP does not establish that the December 14, 2017, violation occurred. Respondent references purported videotape footage of the December 14, 2017, inspection and notes Inspector Reaves' hearing testimony; stating that neither she nor Minor A were observed in Respondent's videotape footage. R's Post Br. at 2-3.

Respondent failed to submit the purported footage or any evidence whatsoever in support of its position. This videotape footage is not part of the record of this case, has not been authenticated, and I have ruled I will not consider Respondent's arguments based on the content of the purported footage. However, even if I were to consider Respondent's arguments regarding the videotape footage and Inspector Reaves' review of the footage, these arguments would not sufficiently rebut Inspector Reaves' sworn testimony and related documentation regarding the December 14, 2017 inspection or otherwise alter my decision.

Respondent has not provided any evidence to rebut the documentation submitted by CTP or the testimony of Inspector Reaves. Therefore, 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 evidence presented supports a finding that on March 2, 2016, August 16, 2016, May 5, 2017, and December 14, 2017, Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), in that persons younger than 18 years of age were able to purchase cigarettes or smokeless tobacco.

I find and conclude that the evidence presented supports a finding that on August 16, 2016, and May 5, 2017, 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 or smokeless tobacco purchasers are younger than 18 years of age.

The conduct set forth above on March 2, 2016, August 16, 2016, May 5, 2017, and December 14, 2017 counts as six (6) 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 six (6) violations of FDA policy in a 48-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, \$11,182, against Respondent for six (6) violations of the Act and its implementing regulations within a 48-month period. Complaint ¶ 1. In its pre- and post-hearing briefs, CTP continued to assert that an \$11,182 civil money penalty is appropriate. CTP Informal Brief at 8-11 (CRD E-File Docket Number 15); CTP Post Br. at 5-7 (CRD E-File Docket Number 25).

As discussed, I found that CTP met its burden by a preponderance of the evidence and concluded that Respondent committed six (6) violations of the Act and its implementing regulations within a 48-month period.

In essence, Respondent denies any obligation to pay a civil money penalty arguing:

. . . the alleged sale of cigarettes to a minor either did not occur at all, at worst, or the CTP has not met its burden of proof by a preponderance of evidence at best. Therefore, no civil money penalties or other sanctions should be imposed against the Respondent.

R's Post Br. at 4.

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 four (4) violations of selling cigarettes or smokeless tobacco to minors, and two (2) violations of failing to verify the photographic identification of a purchaser, totaling six (6) 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 \$11,182 civil money penalty sought by CTP.

C. History of Prior Violations

It is undisputed that Respondent is a repeated violator of FDA’s tobacco regulations prohibiting the sale of tobacco products to minors. Respondent has been the subject of two (2) prior CMP actions. Specifically, Respondent has, three (3) times, violated the prohibition against selling cigarettes or smokeless tobacco to persons younger than 18 years of age, and two (2) times, failed to verify that the cigarette or smokeless tobacco purchasers were of sufficient age. 21 C.F.R. § 1140.14(a)(1), 1140.14(a)(2)(i).

D. Degree of Culpability

Based on my finding that Respondent committed the six (6) violations alleged in the Complaint, I hold it fully culpable for its 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). I do not find any mitigating factors. Respondent has not provided any evidence or witnesses to refute the evidence submitted by CTP proving the sale of cigarettes to Minor A by one of its employees on December 14, 2017, at approximately 1:43 PM.

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 \$11,182 is appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).

XV. CONCLUSION

Respondent committed six (6) violations in a 48-month period as set forth in the Complaint. Respondent is liable for a civil money penalty of \$11,182. *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 March 2, 2016, August 16, 2016, May 5, 2017, and December 14, 2017, in that a person younger than 18 years of age was able to purchase cigarettes or smokeless tobacco 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 August 16, 2016, and May 5, 2017, in that Respondent failed to verify the age of a person purchasing cigarettes or smokeless tobacco by means of photographic identification containing the bearer's date of birth as set forth in the Complaint;
- d. I find and conclude Respondent committed six (6) violations of the regulations within a 48-month period; and
- e. I assess a monetary penalty in the amount of \$11,182, is appropriate.

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