

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

Center for Tobacco Products,
Complainant

v.

Beach Steil Inc.
d/b/a 7-Eleven Store 32781,
Respondent.

Docket No. T-17-2221
FDA Docket No. FDA-2017-H-0835

Decision No. TB2866

Date: July 6, 2018

DECISION

Found:

- 1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1)¹ on February 1, 2016, and August 15, 2016, as charged in the complaint; and
- 2) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(2)(i) on August 15, 2016, as charged in the complaint; and
- 3) Respondent committed three (3) violations in a twenty-four (24) month period as set forth hereinabove; and
- 4) Respondent is hereby assessed a civil money penalty in the amount of \$275.

Glossary:

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

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

² See 5 C.F.R. § 930.204.

FDA	Food and Drug Administration
HHS	Dept. of Health and Human Services
OSC	Order to Show Cause
PO	Procedural Order
POS	UPS Proof of Service
Respondent	Beach Steil Inc. d/b/a 7-Eleven Store 32781
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 dated February 13, 2017, alleging that the FDA documented three (3) violations within a twenty-four (24) month period. CTP seeks a civil money penalty in the amount of \$550.

Beach Steil Inc., d/b/a 7-Eleven Store 32781 (Respondent) was served with process on February 23, 2017, and Respondent filed an answer on March 22, 2017. Respondent admitted that it owns 7-Eleven Store 32781, which sells tobacco products, and it acknowledged that the Compliance Check Inspections occurred. Answer ¶¶ 5-8. However, Respondent “denie[d] that the alleged violations giving rise to such actions

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).

ever took place,” and, alternatively, asserted several affirmative defenses. Answer at ¶¶ 6, 8.

I conducted a hearing on March 6, 2018. The parties filed post-hearing briefs on May 18, 2018.

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

III. BURDEN OF PROOF

As the petitioning party, CTP has the burden to prove, by a preponderance of the evidence, that Respondent is liable and that the proffered penalty is appropriate. 21 C.F.R. § 17.33.

IV. LAW

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

V. ISSUES

1. Did Respondent violate 21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i), as alleged in the complaint?
2. If so, is a civil money penalty in the amount of \$550 appropriate?

VI. ALLEGATIONS

A. Complainant’s recitation of facts

In its complaint, CTP alleged that Respondent owns an establishment doing business under the name 7-Eleven Store 32781, located at 6100 Daniels Parkway, Fort Myers, Florida 33912. CTP also alleged that Respondent’s establishment received

tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

CTP's complaint further alleged that on February 11, 2016, CTP issued a Warning Letter to Respondent, alleging that Respondent committed the following violation:

- a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a)(1). Specifically, a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes on February 1, 2016, at approximately 6:50 PM.

During a subsequent inspection of 7-Eleven Store 32781, an FDA-commissioned inspector documented the following violations:

- a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a)(1). Specifically, a person younger than 18 years of age was able to purchase a package of 305's Full Flavor King's cigarettes on August 15, 2016, at approximately 7:50 PM; and
- b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on August 15, 2016, at approximately 7:50 PM.

B. Respondent's recitation of facts

In its answer, Respondent admitted that it owns an establishment that does business under the name 7-Eleven Store 32781, and that it is located at 6100 Daniels Parkway, Fort Myers, Florida 33912. Answer at 2. Respondent also admitted that it receives tobacco products in interstate commerce, including 305's Full Flavor Kings cigarettes and Newport Box cigarettes, and holds them for sale. *Id.* Respondent further admitted that CTP issued the Notices of Compliance Check Inspection on February 3, 2016, and August 17, 2016, but it denied that all of the alleged violations occurred. *Id.* Respondent further offered twelve affirmative defenses in its answer. *Id.* at 3-4.

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 (CFR).

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. 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/UCM447310.pdf> [hereinafter *Guidance for Industry*], at 13-15. So, for instance, if a retailer sells a tobacco product on a particular occasion to a minor without checking for photographic identification, in violation of 21 C.F.R. §§ 1140.14(a)(1) and (a)(2)(i), this will count as two separate violations for purposes of computing the civil money penalty, unless it is the first time violations were observed at that particular establishment. This policy of counting violations has been determined by the HHS Departmental Appeals Board (Board) to be consistent with the language of the FDCA and its implementing regulations, see *CTP v. Orton Motor Company*, Departmental Appeals Board Decision number 2717 of June 30, 2016. The Board's decision was upheld on appeal. See *Orton Motor, Inc. d/b/a Orton's Bagley v. United States Department of Health and Human Services*, No. 16-1299, WL 1386141, (D.C. Cir. Mar. 20, 2018). In *Orton*, the court held that the FDCA permits multiple violations where multiple regulations were breached. *Id.*

at 14. The regulations authorize the FDA to impose penalties for each violation of the tobacco sale restrictions arising during a single inspection. *Id.* at 11.

VIII. HEARING

A hearing was held on March 6, 2018, by telephone. Michael D. Helbing, Esquire, appeared on behalf of Complainant, and Alaina B. Karsten, Esquire, appeared on behalf of Respondent.

IX. SUMMARY OF TESTIMONY AND EVIDENCE

i. Complainant's case

Complainant submitted CTP Exhibits 1-37, which included photos, witness testimony, and two videos.⁴ Respondent did not object to the admission of any of Complainant's exhibits. I admit Complainant's Exhibits 1 through 37, inclusive. Complainant also presented Witnesses, Eric Galloway and Daryl Sherley, for cross-examination during the hearing on March 6, 2018.

a. Inspector Eric Galloway

Complainant provided the written direct testimony of Witness Eric Galloway, the FDA-commissioned Inspector who conducted the inspection of Respondent's establishment on February 1, 2016, as CTP Ex. 5. During the hearing, Respondent's counsel cross-examined Mr. Galloway.

⁴ These videos were submitted to CTP by Respondent during discovery and document the February 1, 2016 investigation of Respondent's establishment. *See* CTP Ex. 37. Pursuant to my Order dated October 27, 2017, Exhibit 37 has been sealed and marked "Confidential – No Disclosure," so as to protect the identity of the minor.

During Respondent's cross-examination, Mr. Galloway testified regarding the events of the February 1, 2016 Compliance Check Inspection. He stated that prior to the inspection that day, he verified the identity of the minor who accompanied him on the inspection by looking at the date of birth printed on the minor's driver's license. Hearing Transcript (Tr.) at 9. On cross-examination, Mr. Galloway testified that the minor's driver's license was issued by the state of Florida and confirmed that the minor was under the age of 18 at the time of the inspection. *Id.* He could not recall whether the minor's identification was in the minor's hand or in his wallet at the time of verification. *Id.* Mr. Galloway stated that he did not pat the minor down or otherwise verify that the minor did not have an alternative form of identification which could have been used to purchase tobacco products during the investigation. *Id.* at 9-10. He further testified that prior to the inspection on February 1, 2016, he verified that the minor did not have any tobacco products in his possession. *Id.* at 14.

When asked to describe the events of the February 1, 2016 Compliance Check Inspection, Mr. Galloway testified that he arrived at Respondent's business establishment to begin the inspection at approximately 6:50 PM. Tr. at 11. He stated that he parked at a gas pump and waited in his car while the minor went into the store. *Id.* at 15. Mr. Galloway stated that he could see the sales counter and observed the transaction from the exterior window of his vehicle, which was parked approximately 100 feet away. *Id.* at 15-16. Mr. Galloway testified that after the transaction was complete, the minor returned to his vehicle, and he then drove across the street to the hospital parking lot to take

photographs of the purchased merchandise and log the evidence of the transaction. *Id.* at 22-23; *see* CTP Exhibits (Exs.) 9-18.

b. Inspector Daryl Sherley

Complainant provided the written direct testimony of Inspector Daryl Sherley, the FDA-commissioned Inspector who conducted the inspection of Respondent's establishment on August 15, 2016, as CTP Ex. 21. During the March 6, 2018 hearing, Respondent cross-examined Witness Daryl Sherley.

Mr. Sherley testified that prior to the inspection of Respondent's business establishment on August 15, 2016, he verified that the minor had photographic identification showing the minor's actual date of birth by examining his state-issued driver's license. Tr. at 30-31. He recalled that the identification was inside of the minor's wallet at the time of verification. *Id.* He stated that he did not confirm whether the minor had any other forms of identification in the minor's possession, as he had no reason to suspect that the minor had any other form of identification. *Id.* at 32.

Mr. Sherley testified that the inspection on August 15, 2018, began at approximately 7:50 PM, when he parked his vehicle in the parking lot of Respondent's business establishment, exited his vehicle, and accompanied the minor into the store. *Id.* at 33; CTP Ex. 21 at 3. He testified that when he conducts inspections, he generally stands approximately 10 to 15 feet from the counter so that he is able to see the store clerk, the minor, the counter, and the point of sale system. Tr. at 35. During the inspection on August 15, 2018, Mr. Sherley testified that he observed the minor asking

for and purchasing a package of cigarettes and that the clerk did not verify the minor's identification. *Id.* at 37. Mr. Sherley testified that after the inspection, both he and the minor returned to his vehicle, where he documented the evidence and took pictures of the cigarettes purchased by the minor. *Id.* at 40-41; *see* CTP Exs. 25-32.

ii. Respondent's case

Respondent submitted eleven exhibits marked 1, 2, and A through J,⁵ which included witness testimony, a store policy manual, and evidence of previous store-sponsored compliance check inspection results. Complainant did not object to any of Respondent's exhibits. I admit Respondent's Exhibits 1, 2, and A through J, inclusive. Respondent also presented Witness Amanda Steil for cross-examination during the March 6, 2018 hearing.

a. Amanda Steil

Witness Amanda Steil, Respondent's owner, submitted written testimony as Respondent's Ex. 1, and CTP cross-examined Ms. Steil during the hearing.

Ms. Steil testified that in order to complete a transaction for the sale of tobacco, the point of sale system used by her store requires that either the purchaser's identification be scanned or that the store clerk manually enter the purchaser's date of birth from the purchaser's identification. Respondent's (Resp.) Ex. 1 at 2. She stated that the point of sale system will not complete a tobacco sale unless the identification of the purchaser is verified in one of these two ways. *Id.* She further testified that her store

⁵ Respondent purposefully omitted an Exhibit I.

participates in the Bars Program, wherein she pays a fee and 7-Eleven sends out anonymous investigators to conduct age restrictive sales in order to ensure that the store is complying with applicable laws. *Id.* at 5; Tr. at 46.

b. Frank Macon

Respondent also offered the written testimony of Witness Frank Macon, Respondent's employee, as Respondent's Exhibit 2. Mr. Macon testified that he was working as an employee at Respondent's store during the time of the inspection on August 15, 2016. Resp. Ex. 2 at 1. Mr. Macon stated that after he was hired as an employee, he took a computer based training course regarding tobacco sales, wherein he learned, among other things, how to check for a purchaser's identification and how to determine whether the identification presented is fraudulent. *Id.* He further stated that Ms. Steil constantly reminded him of the store's policies on tobacco restrictions, and that "without exception," he required a person who appeared younger than the age of 30 to present an identification card prior to purchasing a tobacco product. *Id.* at 2. Mr. Macon maintained that he always used the store's point of sale system in order to ring up tobacco product purchases, and he stated that the system would not allow him to complete a tobacco sale unless the purchaser scanned his or her identification or he manually entered the purchaser's date of birth into the system. *Id.* He stated that after Ms. Steil notified him of the August 15, 2016 investigation, he began asking "any and all customers for identification if they wanted to purchase cigarettes." *Id.*

iii. Credibility Determinations

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

X. ANALYSIS OF EVIDENCE AND TESTIMONY

a. Complainant's case

Complainant offered and I admitted into evidence Exhibits 1 through 37, inclusive. Pursuant to 21 C.F.R. § 17.33(b), in order to prevail, CTP must prove Respondent's liability and the appropriateness of the penalty under the applicable statute by a preponderance of the evidence.

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

b. Respondent's case

Respondent offered and I admitted into evidence Exhibits 1, 2, and A through J, inclusive. Pursuant to 21 C.F.R. § 17.33(c), Respondent must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

c. Analysis

- i. I find and conclude that CTP has shown by a preponderance of the evidence that Respondent violated 21 C.F.R. § 1140.14(a)(1) when it impermissibly sold cigarettes to a minor on February 1, 2016, at approximately 6:50 PM.

On February 1, 2016, Inspector Galloway and the confidential state-contracted minor conducted an undercover buy compliance check inspection of Respondent's establishment at approximately 6:50 PM. CTP Ex. 7 at 1. Prior to beginning the day's inspections, Inspector Galloway confirmed that the minor possessed a driver's license issued by the State of Florida bearing his correct date of birth and that the minor did not possess any tobacco products on his person before the inspection. *Id.*; *see also* CTP Ex. 6 at 1.

The inspector testified that he had a clear, unobstructed view of the service counter from the exterior window of his vehicle, which was parked approximately 100 feet away at a gas pump. CTP Ex. 7 at 1; Tr. at 15-16. He further stated that the minor showed the clerk his photo identification and purchased a package of Newport Box cigarettes. CTP Ex. 7 at 1; Tr. at 16. Video evidence submitted by CTP also confirms these events. CTP Ex. 37. I find Inspector Galloway's testimony to be credible and unbiased. I find that, in conjunction with the corroborating documentary evidence (e.g. the contemporaneous report) and physical evidence (e.g. the photographs of the Newport Box cigarettes purchased on that date), CTP has satisfied its burden of proving that

Respondent violated 21 C.F.R. §1140.14(a)(1) on February 1, 2016, at 6:50 PM, by a preponderance of the evidence.

- ii. Respondent did not offer sufficient evidence to rebut the evidence of noncompliance on February 1, 2016, presented by CTP.

In its post-hearing brief, Respondent maintained that the evidence CTP presented does not establish that the February 1, 2016 violation occurred. Respondent pointed out that Inspector Galloway did not have a specific recollection of the sale, and he never confirmed whether the minor carried a secondary, false identification which could have been used during the transaction. Resp. Post-Hearing Br. at 2. Respondent also argues that the video evidence submitted by CTP as Exhibit 37 is evidence that the February 1, 2016 violation did not occur. Resp. Informal Brief (Br.) at 3.

With respect to Respondent's first argument, the fact that Inspector Galloway did not have a specific recollection of the February 1, 2016 sale during his cross examination during the hearing on March 6, 2018, is of no consequence. Inspector Galloway's contemporaneous records made at the time of the February 1, 2016 transaction are the most persuasive evidence of the events that took place that day. At the time of the hearing, two years had passed since the February 1, 2016 inspection, and Inspector Galloway testified that he conducted many inspections before and since. Thus, it is unsurprising that he was unable to recall the exact details of the inspection.

Moreover, Inspector Galloway testified that he had worked with the minor on several previous occasions. Respondent did not submit any affirmative evidence showing

that the minor had or could have had a secondary, fake identification which was used during the February 1, 2016 investigation. CTP also filed a photocopy of the minor's state-issued driver's license, showing he was under the age of 18 at the time of the investigation. CTP Ex. 6 at 1. The mere speculation that the minor could have been carrying a secondary, false identification card is not sufficient to rebut CTP's evidence.

Respondent also pointed to video evidence of the February 1, 2016 transaction at its store and argues that the video supports its argument that the violation on that date did not occur. *See* CTP Ex. 37. The relevant portion of the video footage shows the minor attempting to purchase cigarettes at the sales counter of Respondent's establishment. The minor hands the store clerk his photo identification, the store clerk types in a date of birth into the point of sale system, and the minor pays for the cigarettes and exits the store. Respondent argues that the video presents a "gaping hole" in CTP's evidence, because the point of sale system used in Respondent's store will not allow a tobacco sale to be completed unless the photographic identification of the purchaser is either scanned or the purchaser's date of birth is manually entered into the point of sale system. Respondent maintains that the clerk followed proper protocol, because the video shows that the clerk verified the identification of the purchaser prior to the sale and entered a date of birth into the point of sale system. Because the tobacco sale went forward after the clerk entered the purchaser's date of birth, Respondent argues that the sale was lawful because the minor's identification demonstrated that he was over the age of eighteen.

I find that the video evidence of the February 1, 2016 transaction is insufficient to rebut CTP's evidence of noncompliance for several reasons. First, Inspector Galloway testified that he verified that the minor carried a Florida driver's license bearing his correct date of birth prior to the sale. Respondent did not present any evidence, aside from mere speculation, that the minor was carrying a second, fake identification. Second, although the video shows that the store clerk asked for the minor's identification prior to the sale on February 1, 2016, the footage does not show the date of birth that Respondent's sales clerk actually entered into the point of sale system. Respondent thus assumes not only that the minor was over 18, but also that the clerk entered the minor's correct date of birth into the point of sale system and that the system did not malfunction. However, Respondent did not file any evidence showing the actual date of birth that the clerk entered into the system. Respondent's clerk could have typed in the minor's incorrect date of birth, thus allowing the sale to move forward despite the point of sale system's precaution. Moreover, Respondent did not provide any evidence that the system was working correctly on the date of the sale and that it did not malfunction to inadvertently allow the sale.

- iii. I find and conclude that CTP has shown by a preponderance of the evidence that Respondent violated 21 C.F.R. §§1140.14(a)(1) and 1140.14(a)(2)(i) when it impermissibly sold cigarettes to a minor and failed to verify the minor's age by means of photographic identification on August 15, 2016, at approximately 7:50 PM.

On August 15, 2016, Inspector Sherley and the confidential state-contracted minor conducted a follow-up undercover buy compliance check inspection of Respondent's establishment at approximately 7:50 PM. CTP Ex. 21 at 2. Prior to the sale that evening, Inspector Sherley confirmed that the minor carried a state issued photographic identification and that the minor did not possess any tobacco products. *Id.* at 2; CTP Ex. 22 at 1.

The inspector accompanied the minor into Respondent's establishment and observed the minor purchase a package of 305's Full Flavor Kings cigarettes. CTP Ex. 21 at 3. The store clerk did not verify the minor's identification. *Id.* After the sale, the minor and Inspector Sherley exited the store and returned to Inspector Sherley's vehicle, whereupon the minor immediately gave the package of cigarettes to Inspector Sherley. *Id.* I find Inspector Sherley's testimony to be credible and unbiased. I find that his testimony, in conjunction with the corroborating documentary evidence (e.g. the contemporaneous report) and physical evidence (e.g. the photographs of the 305's Full Flavor Kings cigarettes purchase on that date), CTP has satisfied its burden of proving that Respondent violated 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i) on August 15, 2016, at 7:50 PM by a preponderance of the evidence.

- iv. Respondent did not offer affirmative proof to rebut the evidence of noncompliance on August 15, 2016, presented by CTP.

Similar to its response to the February 1, 2016 violations, Respondent first maintains that the August 15, 2016 violation did not occur. Respondent makes three essential points in its argument that CTP did not meet its preponderant burden. First,

Respondent offers the written direct testimony of Frank Macon, a former employee of Respondent who was working at Respondent's store on August 15, 2016, during the time of the sale. Second, Respondent argues that CTP did not meet its burden of proving the violation occurred, because Inspector Sherley did not have a specific recollection of the violation and did not confirm whether the minor had a second, fake identification in his possession. Third, Respondent argues that CTP has no affirmative proof that the sales clerk did not ask the minor to provide identification prior to the sale, because the minor did not submit a report summarizing the transaction, and CTP thus relies only on Inspector Sherley's observations, which it states are insufficient to satisfy preponderant evidence.

With regard to Respondent's first point, Mr. Macon testified that the violation could not have occurred without a valid photographic identification showing that a purchaser was over the age of 18, as Respondent's point of sale system will not permit the sale of tobacco products unless the purchaser's identification is scanned or the date of birth is otherwise manually entered into the system. However, Respondent did not provide any evidence of what date of birth was actually entered into the point of sale system during the August 15, 2016 inspection. Without this evidence, Respondent's argument does not overcome the preponderant evidence put forth by CTP, as set forth in the contemporaneous records. For example, Respondent's store clerk could have entered a different date of birth into the system so that the sale could go forward, or the system could have malfunctioned. Thus, although I find Witness Frank Macon's testimony to be

credible, I find CTP's evidence, especially the contemporaneous records and photographs, to be more persuasive.

I similarly find the other arguments put forth by Respondent to be unpersuasive. As discussed above, Inspector Sherley, like Inspector Galloway, has completed many investigations as part of his contract with CTP. That he could not specifically recall the investigation conducted at Respondent's establishment on August 15, 2016, at the hearing nearly 19 months later is of no consequence, because he documented the investigation in the contemporaneously created records. *See* CTP Ex. 23. Moreover, Inspector Sherley testified that he did not verify whether the minor had a second, false identification on his person because the inspector had no reason to believe that he did. Respondent did not file any affirmative evidence to suggest that the minor could have or did actually possess a secondary, false identification.

I further find that CTP presented preponderant proof that the sales clerk did not verify the minor's identification prior to the August 15, 2016 sale. Consistent with his written testimony and the contemporaneously created records, Inspector Sherley testified that he observed the entire transaction while standing approximately 10 to 15 feet from the sales counter. The inspector stated that while he had a clear view of the minor, the clerk, and the sales counter, he did not observe the minor present his identification to the store clerk. CTP Ex. 21 at 3. The minors involved in CTP's investigations are trained to follow directives from store clerks, such as showing identification or stating their age, if prompted to do so. CTP Ex. 5 at 2. I thus find that it was reasonable for Inspector

Sherley to conclude that the store clerk did not request identification prior to the sale because he did not observe the minor present identification to the clerk.⁶

XI. LIABILITY

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

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), on February 1, 2016, and August 15, 2016, in that a person younger than 18 years of age was able to purchase cigarettes as set forth in the complaint.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(2)(i), on August 15, 2016, in that Respondent failed to verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age.

⁶ I further note that in its Answer, Respondent put forward a number of other arguments, many of which were unsupported by the evidence. Respondent argued that CTP used improper and deceitful investigatory methods, that the purchases were made in good faith based upon a purchaser’s verbal representation, that the narratives were written by biased individuals, and that proper notice was not provided so that Respondent could preserve evidence. Answer at 3-4. Respondent also argued that CTP’s investigation was deceitful, that it constitutes entrapment, and that the unclean hands doctrine should apply. Because Respondent did not file any evidence or case law supporting these cursory statements, I find them unpersuasive and do not address them here.

The conduct set forth above on February 1, 2016, and August 15, 2016, counts as three (3) violations under FDA policy for purposes of computing the civil money penalty. *See Guidance for Industry*, at 13-15.

XII. PENALTY

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

Since I found that CTP met its burden by a preponderance of the evidence and concluded that Respondent committed three (3) violations of the Act and its implementing regulations within a twenty-four (24) month period, the next step is to determine the amount of the civil money penalty. When making that determination, 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 violation

I have found that Respondent specifically committed two (2) violations of selling tobacco products to minors, and one (1) violation for failure to verify, by means of photo identification containing a purchaser's date of birth, that no tobacco product purchasers

are younger than 18 years of age, totaling three (3) violations 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 argues that a violation of the federal tobacco regulations would jeopardize its franchise agreement and could have a significant impact on its ability to do business. Resp. Informal Br. at 7. Although a finding of liability could jeopardize Respondent's franchise agreement, I find and conclude that Respondent has not proven how mitigation of the penalty would extricate Respondent from a breach of its franchise agreement.

c. History of prior violations

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

d. Degree of culpability

I find Respondent committed three (3) violations as alleged in the complaint, and I hold it fully culpable for all three (3) violations in 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's establishment uses a point of sale system which requires employees to solicit identification prior to the sale of any tobacco product. Resp. Informal Br. at 4. In order to complete a tobacco sale transaction, the system

requires that the clerk either scan the identification of the purchaser or manually input his or her date of birth. *Id.* Upon hire, Respondent also requires all of its employees to enroll in and pass a training regarding tobacco sales, and employees are frequently reminded of both the laws restricting tobacco sales to minors and the store's policy to request identification from anyone who appears under the age of thirty. *Id.* Respondent also voluntarily participates in a 7-Eleven program known as "Bars," wherein Respondent pays a yearly fee and the company sends undercover investigators to its participating stores to attempt to purchase tobacco products. *Id.* at 4-5. Although Respondent frequently passes the Bars inspections, when it does not, it takes immediate action to counsel the employee on how to prevent future violations. *Id.* at 5; *see also* Resp. Exs. 1 and H.

For these reasons, I find and conclude that the penalty should be mitigated by half, or \$275.

f. Penalty

Based on the foregoing reasoning, I conclude a reduced penalty amount of \$275 to be appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).

XIII. CONCLUSION

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

Respondent is liable for a civil money penalty of \$275. *See* 21 C.F.R. § 17.2.

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

ORDERED as follows:

- a. I find Respondent was served with process herein and is subject to this forum.
- b. I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. §1140.14(a)(1) on February 1, 2016, and August 15, 2016, in that a person younger than 18 years of age was able to purchase cigarettes as set forth in the complaint.
- c. I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 C.F.R. §1140.14(a)(2)(i) on August 15, 2016, in that Respondent failed to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age.
- d. I find and conclude Respondent committed three (3) violations of the regulations within a twenty-four (24) month period; and
- e. I assess a civil money penalty in the amount of \$275.

/s/

Richard C. Goodwin
U.S. Administrative Law Judge