

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

Center for Tobacco Products,
Complainant

v.

Brown's Mill LLC
d/b/a Brown's Mill,
Respondent

FDA Docket No. FDA-2017-H-0300
CRD Docket No. T-17-1726

Decision No. TB 2292

Date: December 15, 2017

DECISION

Found:

- 1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. §§1140.14(a)/1140.14(a)(1) on July 9, 2016 and January 16, 2016 as charged in the Complaint; and
- 2) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. §1140.14(b)(1)¹ on January 16, 2016 as charged in the Complaint; and
- 3) Respondent committed two violations in a 12-month period as set forth hereinabove.
- 4) Respondent is hereby assessed a civil penalty in the amount of \$200.

Glossary:

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

¹ As of August 8, 2016, the citations to certain tobacco regulations have changed. *See* <https://federalregister.gov/a/2016-10685>.

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	Dept. of Health and Human Services
POS	UPS Proof of Service
SOP	Service of Process
Respondent	Brown's Mill LLC d/b/a Brown's Mill
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 February 3, 2017 alleging that FDA documented two violations within a 12-month period.

Brown's Mill LLC d/b/a Brown's Mill was served with process on February 1, 2017 by United Parcel Service. Respondent filed an Answer dated February 26, 2017 in which it denied the current allegations.

I conducted a hearing on September 19, 2017. Both parties elected not to file post-hearing briefs. The matter is now ready for decision. 21 C.F.R. § 17.33.

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).

III. BURDEN OF PROOF

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

IV. LAW

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

V. ISSUE

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

VI. ALLEGATIONS

A. Complainant's Recitation of Facts

CTP alleged that Respondent owned an establishment, doing business under the name Brown's Mill, located at 12029 North Mountaineer Highway, Arthurdale, West Virginia 26520. Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

CTP's Complaint alleged that on May 5, 2016, CTP issued a Warning Letter to Respondent, alleging that 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 Marlboro cigarettes on January 16, 2016, at approximately 9:33 AM;
- b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification in 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 on January 16, 2016, at approximately 9:33 AM.

Complainant further alleged that during an inspection of Brown's Mill conducted on July 9, 2016, an FDA-commissioned inspector documented the following violation:

- a. Selling tobacco products to a minor, in violation 21 C.F.R. § 1140.14(a)(1).
Specifically, a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes on July 9, 2016, at approximately 10:58 AM.

B. Respondent's Recitation of Facts

In its February 26, 2017 Answer, Respondent admitted to the alleged January 16, 2016 violations, but denied the July 9, 2016 violation. Respondent argued that the July 9, 2016 inspection was not handled properly by the FDA-commissioned inspector. Specifically, Respondent alleged that when the cashier asked for the minor's identification, the inspector intervened and asked the cashier the price of a pack of gum. Respondent claimed that this distraction caused the cashier to forget to check the identification, handed it back to the minor, and completed the sale. As a result of the actions of the inspector, Respondent claims entrapment as a defense and asks that the civil money penalty to be reduced and enforced against the store clerk.

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 387 a-1 directed FDA to re-issue, with some modifications, regulations previously passed in 1996. 21 U.S.C. § 387 a-1(a)(2012). These regulations were passed pursuant to section 387f(d), which authorizes FDA to promulgate regulations on the sale and distribution of tobacco products. 75 Fed. Reg. 13,225 (March 19, 2010), codified at 21 C.F.R. Part 1140 (2015); 21 U.S.C. § 387f(d)(1) (2012). Accordingly, 21 C.F.R. § 1140.1(b) provides that “failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.”

Under 21 U.S.C. § 331(k), “[t]he alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with

respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded” is a prohibited act under 21 U.S.C. § 331. Thus, when a Retailer such as Respondent misbrands a tobacco product by violating a requirement of 21 C.F.R. Part 1140, that misbranding in turn violates the FDCA, specifically 21 U.S.C. § 331(k). FDA may seek a civil money penalty from “any person who violates a requirement of this chapter which relates to tobacco products.” 21 U.S.C. § 333(f)(9)(A) (2012). Penalties are set by 21 U.S.C. § 333 note and 21 C.F.R. § 17.2. Under current FDA policy, the first time FDA finds violations of 21 C.F.R. Part 1140 at an establishment, FDA only counts one violation regardless of the number of specific regulatory requirements that were actually violated, but if FDA finds violations on subsequent occasions, it will count violations of specific regulatory requirements individually in computing any civil money penalty sought. This policy is set forth in detail, with examples to illustrate, at *U.S. Food & Drug Admin., Guidance for Industry and FDA Staff, Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers, Responses to Frequently Asked Questions (Revised) (2016), available at* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/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) and (b)(1), this will count as two separate violations for purposes of computing the civil money penalty,

unless it is the first time violations were observed at that particular establishment. This policy of counting violations has been determined by the HHS Departmental Appeals Board to be consistent with the language of the FDCA and its implementing regulations, *see CTP v. Orton Motor Company*, Departmental Appeals Board Decision number 2717 of June 30, 2016.

VIII. HEARING

A hearing was held on September 19, 2017 by telephone as set forth in my August 15, 2017 Order Rescheduling Telephone Hearing. In attendance at the hearing were:

Roselle Oberstein, Esquire, appeared on behalf of Complainant;

LaRae Biggins and Steve Biggins appeared pro se on behalf of Respondent; and

Witness Dayton Whitt testified on behalf of Complainant.

IX. SUMMARY OF TESTIMONY AND EVIDENCE

A. Complainant's case

Complainant submitted evidence and testimony in the form of written declarations and photographs. None of the evidence was marked for identification during the hearing. Respondent did not object to any of the evidence submitted into the record by Complainant.

i. Inspector Dayton Whitt

Witness Dayton Whitt, the FDA-commissioned Inspector who conducted the inspection of Respondent's establishment on January 16, 2016 testified on behalf of Complainant. Complainant provided Inspector Whitt's written direct testimony as CTP

Ex. 9.

In his declaration, Inspector Whitt stated that on January 16, 2016, at approximately 9:33 AM, he and Minor A conducted a UB compliance check inspection at Respondent's establishment, Brown's Mill, located at 12029 North Mountaineer Highway, Arthurdale, West Virginia 26520. CTP Ex. 9, at 3. Before the inspection, Inspector Whitt confirmed that Minor A was under the age of 18 and had photographic identification (ID) showing his/her actual date of birth. *Id.* Inspector Whitt also ensured that the minor did not have any tobacco products in his/her possession. *Id.* The Inspector testified that Exhibit 10 is a true and accurate redacted copy of Minor A's driver's license. *Id.* at 2.

According to his declaration, Inspector Whitt entered the establishment and took position where he could visibly observe the transaction between the store employee and Minor A. *Id.* at 3. Minor A then entered the store, went to the counter, and purchased a package of cigarettes from a store employee. *Id.* Inspector Whitt also observed that Minor A did not present any identification to the employee before or during the transaction. *Id.*

After purchasing the package of cigarettes, Minor A exited the store and Whitt followed shortly thereafter. *Id.* at 4. Upon entering the vehicle, Minor A immediately handed Inspector Whitt a package of Marlboro cigarettes. *Id.* Inspector Whitt processed the evidence according to procedure and completed a narrative report. *Id.*

On July 9, 2016, at approximately 10:58 AM, Inspector Whitt and Minor B conducted a follow-up compliance check inspection at Brown's Mill, located at 12029

North Mountaineer Highway, Arthurdale, West Virginia 26520. *Id.* at 4; Hearing Transcript (Tr.) at 7. Before the inspection, Inspector Whitt confirmed that Minor B was under the age of 18 and had ID showing his/her actual date of birth. CTP Ex. 9, at 4. Inspector Whitt also ensured that the minor did not have any tobacco products in his/her possession. *Id.* In his declaration, the Inspector testified that Exhibit 11 is a true and accurate redacted copy of Minor B's driver's license. *Id.* at 2.

Inspector Whitt stated that he accompanied the minor into Respondent's establishment and positioned himself where he could visibly observe the transaction. CTP Ex. 9, at 5. Minor B then entered Brown's Mill, went to the counter, presented identification to the clerk, and purchased a package of cigarettes. *Id.* Inspector Whitt then stated once Minor B exited the store, met him at his car, and handed over a package of Marlboro cigarettes. *Id.* Inspector Whitt processed the evidence according to procedure and completed a narrative report. *Id.*

B. Respondent's case

As a part of its February 26, 2017 Answer, Respondent submitted a narrative of the July 9, 2016 inspection. CRD Docket (Dkt.) 3a, at 5. In addition, Respondent produced various documents in response to Complainants Request of Production of Documents. Among the documents produced to CTP by Respondent is a May 16, 2017 statement by Billi Jo Collins. Dkt. #19. None of Respondent's witnesses were crossed at the September 19, 2017 hearing.

i. Respondent's narrative

Respondent concedes the January 16, 2016 violations. However, Respondent

disputes the violation alleged on July 9, 2016. In this instance, Respondent's position is that Inspector Whitt acted unprofessionally during the July 9, 2016 inspection and that his actions caused the violation to occur on that date.

Respondent states that on July 9, 2016, Inspector Whitt entered Brown's Mill with Minor B. Dkt. #3a, at 5. Respondent claims that once the minor went to the cashier to buy the cigarettes, Inspector Whitt took a pack of gum off the shelf and asked the cashier how much the gum cost. *Id.*; *see also*, Tr. at 8-10. This caused the cashier to abandon the sale to Minor B and ask a co-worker to do a price check on the gum. Dkt #3a, at 5. After conducting the price check, the cashier returned to the transaction with Minor B and thought he had already checked the ID. *Id.* The cashier then completed the sale. *Id.* Respondent states that it verified its account of the transaction by checking the security tape from that day.⁴ *Id.* Respondent claims that but for Inspector Whitt's actions on July 9, 2016, the sale of cigarettes to a minor would never have occurred. *Id.*

In addition, Respondent also argues the civil money penalty should be assessed against the store clerk who committed the violations and not the store owners. Dkt. #3a, at 5; Dkt. #11. Specifically, Respondent states "[w]e have employees who are responsible to follow all policy and procedures . . . we cannot be at our place of business every minute" Dkt. #11, at 1. Respondent further argues "fining the employee . . . will be a better deterrent instead of the business owner." Dkt. #3a, at 5.

ii. Billi Jo Collins' statement

Respondent submitted the statement of Billi Jo Collins. Dkt. #19. Ms. Collins,

⁴ Respondent never submitted the tape into evidence.

manager of Brown's Mill, stated that she viewed the video of the July 9, 2016 transaction. *Id.* Ms. Collins stated that on the video, the cashier selling to the minor began entering the minor's ID into the system to check the birthdate. *Id.* At this point, Mr. Whitt is seen holding a pack of gum and interrupted the sale with the minor to ask the cashier for the price of the gum. *Id.* The cashier is then seen turning to a co-worker to assist with the price check. *Id.* Ms. Collins then stated that, after seeking assistance, the cashier came back and completed the sale to the minor. *Id.*

C. Credibility determination

I find and conclude the testimony and evidence of both parties is credible.

X. RULING ON ADMISSIBILITY OF EVIDENCE

Complainant submitted evidence and testimony in the form of written declarations and photographs. None of the evidence was marked for identification during the hearing. Respondent did not object to any of the evidence submitted into the record by Complainant.

Respondent offered evidence, in response to CTP's request for production of documents, in the form of nine exhibits on the DAB E-File system (Dkt. #s 12-19) on May 22, 2017. None of the evidence was marked for identification during the hearing. Complainant did not object to any of the evidence submitted by Respondent.

I am to rule on the admissibility of evidence in these proceedings. 21 C.F.R. § 17.39(a). While I am not bound by the Federal Rules of Evidence, I may apply the Rules when appropriate. 21 C.F.R. § 17.39(b). I am only required to exclude evidence that is not relevant or material to the issues before me. 21 C.F.R. § 17.39(c). I may

however exclude relevant evidence if I determine that its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence. 21 C.F.R. § 17.39(d).

I find that the evidence submitted by Complainant and Respondent is credible and relevant.

XI. ANALYSIS OF EVIDENCE AND TESTIMONY

A. Complainant's case

Pursuant to 21 C.F.R. 17.33(b), in order to prevail, Complainant must prove Respondent's liability and appropriateness of the penalty under the applicable statute by a preponderance of the evidence.

I must determine whether the allegations in the Complaint are true, and if so, whether Respondent's actions identified in the Complaint violated the law. 21 C.F.R. §17.45(b)(1).

B. Respondent's case

Pursuant to 21 C.F.R. § 17.33(c), Respondent must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

It is Respondent's position that Inspector Whitt caused a distraction during the July 9, 2016 inspection that led to the cashier selling the cigarettes to a minor.

Respondent asserts that after viewing the video surveillance from the day of the transaction, it observed Inspector Whitt take a pack of gum off the shelf and ask the cashier how much the gum cost. Dkt. 3a, at 5; Tr. at 8-10. This caused the cashier to

abandon the sale to the minor and ask a co-worker to do a price check on the gum. Dkt #3a, at 5. After conducting the price check, the cashier returned to the minor and thought he had already checked the ID. *Id.*

Respondent did not produce the video surveillance into evidence. However, Respondent did submit testimony from Billi Jo Collins. Dkt. #19. Ms. Collins testified that on the video, Mr. Whitt is seen holding a pack of gum and interrupted the sale with the minor to ask the cashier for the price of the gum. *Id.* The cashier is then seen turning to a co-worker to assist with the price check. *Id.* Ms. Collins then testified that after seeking assistance, the cashier came back and completed the sale to the minor. *Id.*

Therefore, Respondent concludes that the sale was a product of entrapment by Inspector Whitt. Respondent also concludes that due to the actions of Inspector Whitt, the fine should be reduced and assessed to the store clerk responsible for the July 9, 2016 sale.

C. Analysis

- i. I find and conclude that Complainant has shown by a preponderance of the evidence that Respondent violated 21 U.S.C. §331, specifically 21 C.F.R. § 1140.14(a)(1) when it impermissibly sold cigarettes to a minor on January 16, 2016.

On January 16, 2016, Inspector Whitt and Minor A, the confidential state-contracted minor, conducted a UB compliance check inspection of Respondent's establishment at approximately 9:33 AM. CTP Ex. 9, at 3. Before the inspection, Inspector Whitt confirmed that Minor A was under the age of 18 and had ID showing

his/her actual date of birth. *Id.* Inspector Whitt also ensured that the minor did not have any tobacco products in his/her possession. *Id.*

Inspector Whitt entered the establishment and took position where he could visibly observe the transaction between the store employee and Minor A. *Id.* at 3. The inspector maintained a view of the minor, the sales counter, and the transaction. Inspector Whitt observed the minor purchase the package of cigarettes from the sales clerk. *Id.* The inspector also observed that Minor A did not present any identification to the employee before or during the transaction. *Id.* The inspector then followed the Minor to his vehicle where the minor immediately tendered the package of cigarettes to him. *Id.* Upon receiving the cigarettes, Inspector Whitt processed the evidence according to procedure and completed a narrative report. *Id.*

I find Inspector Whitt's testimony about the January 16, 2016 inspection credible and unbiased. I find that it, in conjunction with the corroborating documentary evidence (*e.g.*, the contemporaneous report) and the physical evidence (*e.g.*, the photographs of the Marlboro cigarettes purchased on that date), Complainant has satisfied its burden of proving that Respondent violated section 1140.14(a)(1) on January 16, 2016, at approximately 9:33 AM by a preponderance of the evidence.

- ii. I find and conclude that Complainant has shown by a preponderance of the evidence that Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(2)(i) when, on January 16, 2016, it failed to verify, by means of a photo identification containing the purchaser's date of birth, that no cigarette purchaser is younger than 18 years of age.

On January 16, 2016, Inspector Whitt and Minor A, the confidential state-contracted minor, conducted a UB compliance check inspection of Respondent's establishment at approximately 9:33 AM. CTP Ex. 9, at 3. Before the inspection, Inspector Whitt confirmed that Minor A was under the age of 18 and had ID showing his/her actual date of birth. *Id.* Inspector Whitt also ensured that the minor did not have any tobacco products in his/her possession. *Id.*

Inspector Whitt entered the establishment and took position where he could visibly observe the transaction between the store employee and Minor A. *Id.* at 3. The inspector maintained a view of the minor, the sales counter, and the transaction. Inspector Whitt observed the minor purchase the package of cigarettes from the sales clerk. *Id.* The inspector also observed that Minor A did not present any identification to the employee before or during the transaction. *Id.* The inspector then followed the Minor to his vehicle where the minor immediately tendered the package of cigarettes to him. *Id.* Upon receiving the cigarettes, Inspector Whitt processed the evidence according to procedure and completed a narrative report. *Id.*

I find Inspector Whitt's testimony regarding the January 16, 2016 inspection to be credible and unbiased. I find that it, in conjunction with the corroborating documentary evidence (*e.g.*, the contemporaneous narrative report) and the physical evidence (*e.g.*, the photographs of the Marlboro cigarettes purchased on that date), Complainant has satisfied its burden of proving that Respondent violated § 1140.14(a)(2)(i) on January 16, 2016, at approximately 9:33 AM by a preponderance of the evidence.

- iii. I find and conclude that Complainant 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 July 9, 2016.

On July 9, 2016, Inspector Whitt and Minor B, the confidential state-contracted minor, conducted a follow-up compliance check inspection at Brown's Mill at approximately 10:48 AM. CTP Ex. 9, at 4; Tr. at 7. Before the inspection, Inspector Whitt confirmed that Minor B was under the age of 18 and had ID showing his/her actual date of birth. CTP Exh 9, at 4. Inspector Whitt also ensured that the minor did not have any tobacco products in his/her possession. *Id.*

Inspector Whitt entered the establishment and took position where he could visibly observe the transaction between the store employee and Minor B. *Id.* at 5. The inspector maintained a view of the minor, the sales counter, and the transaction. Minor B then entered Brown's Mill, went to the counter, presented identification to the clerk, and purchased a package of cigarettes. *Id.* Inspector Whitt then stated Minor B exited the store, met him at his car, and handed over a package of Marlboro cigarettes. *Id.* Inspector Whitt processed the evidence according to procedure and completed a narrative report. *Id.*

I find Inspector Whitt's testimony about the July 9, 2016 inspection credible and unbiased. I find that it, in conjunction with the corroborating documentary evidence (*e.g.*, the contemporaneous narrative report) and the physical evidence (*e.g.*, the photographs of the Marlboro cigarettes purchased on that date), Complainant has satisfied its burden of proving that Respondent violated § 1140.14(a)(1) on July 9, 2016, at

approximately 10:48 AM by a preponderance of the evidence.

- iv. Respondent offered no affirmative proof to rebut the evidence of noncompliance presented by Complainant.

Respondent argues that Inspector Whitt acted improperly during the transaction on July 9, 2016 by asking the store clerk for a price check on a package of gum during the transaction with Minor B. Dkt. #3a, at 5. In addition, Respondent asks that I consider the defense of entrapment as a justification for the violation. *Id.*

In support of its assertions, Respondent submitted testimony from its manager, Billi Jo Collins. Ms. Collins stated that she personally reviewed the video footage from the day of July 9, 2016. According to Ms. Collins, she observed Inspector Whitt take a pack of gum off the shelf and ask the cashier how much the gum cost. Dkt. #19; Tr. at 8-10. This caused the cashier to abandon the sale to the minor and ask a co-worker to do a price check on the gum. Dkt. #19. After conducting the price check, the cashier returned to the minor and thought he had already checked the ID. *Id.*

I do not find Ms. Collin's testimony convincing. Given that Respondent did not submit the video surveillance footage, which it claims to have viewed and stated would be produced, Ms. Collins' position is self-serving and unsupported.⁵ On the other hand, the testimony of Inspector Whitt is supported by evidence in the record.

Furthermore, Respondent describes the CTP inspection as entrapment by the FDA.

⁵ Respondent stated in its February 26, 2017 Answer that it maintained video surveillance from July 9, 2016. *See* Dkt. #3a, at 5. Respondent then stated in its May 22, 2017 Answers to Document Requests that the video footage "has been misplaced." *See* Dkt. #11, at 1. Further, Respondent informed me in its pre-hearing exchange, filed on July 5, 2017, that it had not been able to locate the footage. *See* Dkt. #23.

Respondent has not cited any case law or other authority supporting the proposition that entrapment is available as a defense.

Entrapment is a defense seen in criminal proceedings based on the theory that “[g]overnment agents may not originate a criminal design, implant in an innocent person’s mind the disposition to commit a criminal act, and then induce commission of the crime so that the Government may prosecute.” *Jacobson v. United States*, 503 U.S. 540, 548 (1992). “According to federal jurisprudence, the defense of entrapment is apparently non-available in the federal civil litigations and is limited only to criminal actions.” *Rodriguez v. United States*, 534 F.Supp 370, 373 (D.P.R. 1982).⁶

The Departmental Appeals Board (Board) has twice indicated that a defense of entrapment does not appear to be available in a federal enforcement action for the sale of tobacco products to minors. *J. Peaceful L.C. v. Town Market*, DAB No. A-16-105, at 11-13 (2016); *TOH Inc. d/b/a Ridgeville Serv. Ctr.*, DAB No. 2668, at 14-15 (2015). While the Board has not definitively resolved the issue, in both cases the Board determined it need not determine whether entrapment is available, as the Respondents had “not described, much less proven ... [the government] engaged in trickery or dishonesty to induce the illegal sales” and had “not proven the elements of such a defense.” *Id.*

The same conclusion is warranted here. Respondent has failed to prove the elements of a defense of entrapment even assuming entrapment was available as a

⁶ The entrapment defense was developed, in part, to protect defendants in criminal proceedings. *Rodriguez*, 534 F.Supp. at 373-374. Administrative hearings, however, are supervisory proceedings. They are regulatory in nature. *See generally United States v. Morton Salt*, 338 U.S. 632 (1950).

defense. Complainant has not initiated any criminal complaint against Respondent, nor has it accused Respondent of engaging in any criminal act. Furthermore, Respondent has not presented any evidence into the record that indicates that the government induced it into performing any criminal act. There is no evidence to support Respondent's claim that the government engaged in any sort of trickery or dishonesty to induce the illegal sale.

Respondent has not proven a valid defense of entrapment, nor has it presented any other affirmative defense. Therefore, 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 may be liable to pay a civil monetary penalty. 21 U.S.C. §§ 331, 333.

I find and conclude that the evidence presented, by a preponderance of the evidence standard, supports a finding Respondent violated 21 U.S.C. § 331. Specifically, Respondent violated 21 C.F.R. § 1140.14(a)(1), in that persons younger than 18 years of age were able to purchase package of Marlboro cigarettes on January 16, 2016 and July 9, 2016, as set forth in the Complaint.

I find and conclude that the evidence presented, 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 January 16, 2016 in that Respondent violated the requirement that retailers verify, by means of photo identification containing a

purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age.

The conduct, as set forth, on January 16, 2016 and July 9, 2016 counts as two (2) 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 two (2) violations of FDA policy in a 12- 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 the Complaint, Complainant sought to impose the maximum penalty amount, \$275, against Respondent for two (2) violations of the Act and its implementing regulations within a twelve (12) month period. Complaint ¶ 1. At the hearing, Complainant continued to assert that a \$275 civil money penalty is appropriate. Tr. at 14.

Respondent admits liability to the initial inspection on January 16, 2016, but argues that the civil money penalty is too high due to the improper actions of Inspector Whitt. Dkt. #3a, at 3, 5. In addition, Respondent asserts that the civil money penalty should be assessed against the store clerks who committed the violations and not the store owner. *Id.*

As discussed, I found that Complainant met its burden by a preponderance of the evidence and concluded that Respondent committed two (2) violations of the Act and its

implementing regulations within a 12-month period. When determining the amount of a civil money penalty, I am required to take into account “the nature, circumstance, 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, Circumstance, Extent and Gravity of the Violations.

I have found that Respondent specifically committed two (2) violations of selling cigarettes to minors, and one (1) violation of failing to verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the civil money penalty amount should be set accordingly.

B. Respondent’s Ability to Pay and Effect on Ability to Do Business.

Respondent has not presented any evidence that it does not have the ability to pay the \$275 civil money penalty sought by Complainant.

C. History of Prior Violations.

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

D. Degree of Culpability

Respondent is responsible for paying the penalty, and not Respondent’s employee involved in the July 9, 2016 inspection. Federal tobacco regulations specifically place the responsibility to uphold the law on the retailer. “Each manufacturer, distributor, and

retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements under this part.” 21 C.F.R. § 1140.10. In addition, it is well-settled that as a general principle of law, the only way in which a corporation can act is through the individuals who act on its behalf. *See United States v. Park*, 421 U.S. 658 (1975); *United States v. Dotterweich*, 320 U.S. 277, 281-285 (1943).

The civil money penalty sought is meant to deter retailers from selling highly addictive and extremely harmful products to minors and retailers should take every measure to ensure these violations do not occur. Respondent’s repeated sale of tobacco products to a minors and failure to verify the age of tobacco products purchasers, in violation of law, creates the risk of serious harm.

Based on my finding that Respondent committed the violations in the current Complaint, I hold it fully culpable for two (2) violations of the Act and its implementing regulations.

E. Additional Mitigating Factors

Mitigation is an affirmative defense for which Respondent bears the burden of proof. 21 C.F.R. § 17.33(c). Respondent has not provided any evidence of a training program given to employees to prevent the sale of tobacco products to minors. However, Respondent has submitted Employee Rules and Regulations, signed by the cashiers working on January 16, 2016 and July 9, 2016. Dkt. #s12, 15. The Rules and Regulations require employees to “check valid ID’s when selling. . . tobacco products” The Rules and Regulations also indicate that employment will be terminated if

employees are found to have sold tobacco products to minors. *Id.* at 1, 2.

Respondent indicated that it terminated the employment of the cashier responsible for the January 16, 2016 sale. Dkt. #11, at 2. However, Respondent has not indicated that it terminated the employment of the cashier responsible for the July 9, 2016 sale. Instead, Respondent submitted an Employee Warning form, indicating that the cashier “was in the wrong” and “stressed to [the cashier] to ID his customers and minors are not to be sold tobacco or alcohol products.” Dkt. #18. Respondent has not presented any evidence demonstrating that it has taken any subsequent or remedial measure to comply with the law.

The purpose of the TCA to prevent unlawful sales of tobacco products to minors. Tobacco is a highly addictive and dangerous product. The reason that sales of tobacco products to minors is unlawful is that consumption of these products at an early age can lead to a lifetime of addiction, to illness, and ultimately to premature death. Sales of tobacco products to minors are unlawful because younger individuals often lack the maturity and judgment to make informed decisions about whether to consume such inherently dangerous and addictive products. Selling tobacco products to these individuals puts them at risk for all of the adverse consequences that addiction can cause. It is not enough for Respondent to card a potential minor; Respondent must also not sell tobacco products to minors.

Although there is no evidence of any subsequent remedial measures and only a self-serving testimony of its manager regarding the July 9, 2016 sale, Respondent did demonstrate its zero-tolerance policy by firing the cashier responsible for the January 16,

2016 sale and reprimanded the cashier from the July 9, 2016 sale.

I find and conclude that there is reason to consider mitigation of the penalty herein.

F. Penalty

Based on the foregoing reasoning, I conclude a reduced penalty amount of \$200 to be appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).

XVI. CONCLUSION

Respondent committed two (2) violations in a twelve (12) month period as set forth in the Complaint.

Respondent is liable for a civil money penalty of \$200. *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 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 January 16, 2016 and July 9, 2016, in that a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes as set forth in the Complaint.
- c. I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(2)(i) on January 16, 2016, in that Respondent violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age as set forth in the Complaint.

- d. I find and conclude Respondent committed two (2) violations of the regulations within a 12-month period.
- e. I assess a monetary penalty in the amount of \$200.

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