

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-H-5851)

Complainant,

v.

Chit-Chat Inc.
d/b/a Scuttlebutts,

Respondent.

Docket No. T-17-6681

Decision No. TB3144

Date: October 1st 2018

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty (CMP) of \$2,236 against Respondent, Chit-Chat Inc. d/b/a Scuttlebutts, located at 590 Main Street, Acushnet, Massachusetts 02743, for four violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140, within a 24-month period. Specifically, CTP alleges that Scuttlebutts violated the Act by impermissibly selling cigarettes to minors and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. For the reasons discussed below, I find in favor of CTP and impose a \$2,236 CMP against Respondent.

I. BACKGROUND AND PROCEDURAL HISTORY

CTP began this matter by serving an administrative complaint (Complaint) seeking a \$2,236 CMP on Respondent, at 590 Main Street, Acushnet, Massachusetts 02743, and by

filing a copy of the Complaint with the Departmental Appeals Board. *See* DAB E-File Docket (Dkt.) Nos. 1-1b.

On October 24, 2017, Respondent, represented by its owner Gary Hathaway, timely answered CTP's Complaint. Dkt. No. 3. On November 2, 2017, I issued an Acknowledgement and Pre-Hearing Order that set deadlines for discovery and the parties' pre-hearing exchanges. Dkt. No. 4. Subsequently, parties filed separate motions for a protective order. Dkt. Nos. 7-9a and 13-13e. After outstanding discovery disputes were resolved, *see* Dkt. Nos. 14 and 16-19a, I modified the pre-hearing exchange deadlines, *see* Dkt. No. 20.

On March 29, 2018, CTP timely filed a pre-hearing brief, a list of proposed witnesses and exhibits, and 14 exhibits (CTP Exhibits (Exs.) 1-14) including the written direct testimony of two proposed witnesses, Senior Regulatory Counsel Laurie Sternberg and Inspector Pamela Pollock (CTP Exs. 3-4). Dkt. Nos. 21-21o. On April 27, 2018, after being granted an extension of time, *see* Dkt. Nos. 23-24, Respondent filed a pre-hearing brief, but submitted no exhibits and proposed no witnesses, *see* Dkt. No. 25.

On June 1, 2018, I held a pre-hearing conference in this case. *See* Dkt. Nos. 26-27. During the pre-hearing conference, we discussed the purpose and function of the hearing. *See* Dkt. No. 27, at 1. Respondent advised of its intent to cross-examine Inspector Pollock. *Id.*

On July 10, 2018, I held a hearing in this case. *See* Dkt. No. 28, July 10, 2018 Hearing Transcript (Hr'g Tr.). During the course of the hearing, I admitted into evidence CTP's exhibits 1 through 14 without objection. *See* Hr'g Tr. 14:3-21. Respondent cross-examined Inspector Pollock. *See* Hr'g Tr. 21:1-25:10. CTP's counsel, Anna K. Thompson, then conducted a re-direct examination of Inspector Pollock, *see* Hr'g Tr. 26:1-27:1, and Respondent conducted a re-cross examination, *see* Hr'g Tr. 27:9-32:11.

On July 19, 2018, I informed the parties that the Civil Remedies Division had received the transcript of the hearing, and set the deadline for the parties' simultaneous post-hearing brief submissions as August 20, 2018. Dkt. No. 29. On August 20, 2018, both parties timely filed post-hearing briefs. Dkt. Nos. 30-31. As the briefing period is over, I now render my decision.

II. ISSUES

- A. Whether Respondent sold cigarettes to a minor and failed to verify by means of photographic identification that the cigarette purchaser was of sufficient age, on August 23, 2017, in violation of 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i); and
- B. If so, whether the CMP amount of \$2,236 sought by CTP is appropriate.

III. ANALYSIS

In order to prevail, CTP must prove Respondent's liability by a preponderance of the evidence. 21 C.F.R. § 17.33(b). The U.S. Supreme Court has described the preponderance of the evidence standard as requiring that the trier-of-fact believe that the existence of a fact is more probable than not before finding in favor of the party that had the burden to persuade the judge of the fact's existence. *In re Winship*, 397 U.S. 358, 371-72 (1970); *Concrete Pipe and Prods. of Cal., Inc. v. Constr. Laborers*, 508 U.S. 602, 622 (1993).

A. Violations

CTP determined to impose a CMP against Respondent pursuant to the authority conferred by the Act and implementing regulations at Part 21 of the Code of Federal Regulations. The Act prohibits the misbranding of tobacco products while they are held for sale after shipment in interstate commerce. 21 U.S.C. § 331(k). FDA and its agency, CTP, may seek CMPs from any person who violates the Act's requirements as they relate to the sale of tobacco products. 21 U.S.C. § 331(f)(9). The sale of cigarettes to an individual who is under the age of 18 and the failure to verify the photographic identification of an individual who is not over the age of 26 are violations of implementing regulations. 21 C.F.R. § 1140.14(a)(1) and (a)(2).

In its Complaint, CTP alleges that Respondent Scuttlebutts committed four violations of the Act and its implementing regulations within a 24-month period. Dkt. No. 1 ¶ 1. Specifically, CTP alleges that on August 23, 2017, Respondent sold cigarettes to a minor and failed to verify the photographic identification of the minor, and previously admitted to two¹ violations of regulations found at 21 C.F.R. pt. 1140. *Id.* ¶¶ 7, 9-10. In settling the prior complaint, Respondent not only admitted the violations occurred, but also waived the right to contest the violations in the future and stated that it understood that the admitted violations may be counted in determining the total number of violations for future enforcement actions. *Id.* ¶ 10; *see also* Dkt. No. 21, at 2-3 and CTP Ex. 2. Accordingly, the only issue before me is whether Respondent sold cigarettes to a minor and failed to verify the photographic identification of the minor, on August 23, 2017, in violation of 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i), as alleged in the Complaint.

CTP's case against Respondent rests on the testimony of Ms. Sternberg and Inspector Pollock, supported by corroborating evidence. *See* CTP Exs. 3-4. Ms. Sternberg testified that the Marlboro cigarettes purchased during the August 23, 2017 inspection were

¹ Two violations were documented on May 3, 2016 (sale to a minor and failure to verify date of birth), and one on December 27, 2016 (sale to a minor). Dkt. No. 1 ¶ 9. In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and subsequent violation as a separate individual violation.

manufactured or processed for commercial distribution at facilities in Virginia. CTP Ex. 3 ¶¶ 7-8. The manufacturer of Marlboro cigarettes does not have production facilities in Massachusetts, where the cigarettes were purchased. *Id.* ¶ 9. Respondent did not challenge Ms. Sternberg's testimony and did not dispute that Respondent held Marlboro cigarettes for sale at its business establishment on August 23, 2017. *See* Dkt. No. 27, at 1; *see also* Hr'g Tr. 15:11-16; Dkt. No. 25, at 3. Accordingly, I find that Respondent's establishment received Marlboro cigarettes in interstate commerce and held them for sale on August 23, 2017, after shipment in interstate commerce.

Inspector Pollock is an FDA-commissioned officer for the state of Massachusetts whose duties include performance of undercover buy (UB) inspections to determine a retailer's compliance with the age and photo identification requirements relating to the sale of tobacco products. CTP Ex. 4 ¶¶ 2-3. The UB inspections are conducted with trained minors by providing "direct field oversight of the minors to ensure that they follow FDA inspection protocol." *Id.* ¶¶ 4, 6.

Inspector Pollock testified that on August 23, 2017, she conducted such an inspection of Respondent's establishment, located at 590 Main Street, Acushnet, Massachusetts 02743. CTP Ex. 4 ¶ 7. Minor A accompanied Inspector Pollock on prior UB inspections and accompanied her on the August 23, 2017 inspection. *Id.* Minor A, whose date of birth is April 29, 2000, was 17 years old at the time of the August 23, 2017 inspection. *See* CTP Ex. 5. Minors in the tobacco program are trained not to carry photographic identification with them during an inspection, and are instructed to tell the truth if they are asked about their age or whether they have identification. CTP Ex. 4 ¶ 6.

Before the inspection, Inspector Pollock verbally confirmed that Minor A was under the age of 18, that Minor A did not possess any photographic identification showing his/her actual date of birth, and that Minor A did not have any tobacco products in his/her possession. CTP Ex. 4 ¶ 8; *see also* Hr'g Tr. 26:2-5. Minor A carried only his/her phone and the cash provided by Inspector Pollock to purchase the tobacco products. CTP Ex. 4 ¶ 8.

Inspector Pollock testified that she parked her car near Respondent's establishment and remained in the vehicle during the inspection, because she felt her presence would compromise the undercover nature of the inspection. CTP Ex. 4 ¶ 9; *see also* Hr'g Tr. 21:2-7; *accord* Hr'g Tr. 24:22-25:7 (confirming Inspector Pollock had no safety concerns with respect to entering the store). Inspector Pollock had an unobstructed view of Minor A exiting the vehicle, entering Respondent's establishment, exiting the establishment minutes later, and immediately returning to the vehicle. CTP Ex. 4 ¶¶ 9-10; *see also* Hr'g Tr. 24:7-19, 26:6-9. Inspector Pollock testified that upon entering the vehicle, Minor A handed her a package of cigarettes and the change from the purchase. CTP Ex. 4 ¶ 10; *see also* Hr'g Tr. 26:10-14. Inspector Pollock observed that the package of cigarettes were Marlboro cigarettes. CTP Ex. 4 ¶ 10.

Inspector Pollock testified that Minor A reported to her that during the inspection, Minor A was able to purchase a package of cigarettes from an employee at Respondent's establishment. CTP Ex. 4 ¶ 11. Minor A also reported to Inspector Pollock that prior to the purchase, the employee did not ask for Minor A's identification, Minor A did not present any identification to the employee, and the employee did not provide Minor A with a receipt after the purchase. *Id.*; *see also* Hr'g Tr. 26:15-21.

Inspector Pollock labeled the cigarettes as evidence, photographed all of the panels of the package, and processed the evidence in accordance with standard procedures. CTP Ex. 4 ¶ 11. Shortly after the inspection, Inspector Pollock recorded the inspection in the FDA's Tobacco Inspection Management System (TIMS) and created a Narrative Report. *Id.* ¶ 12. CTP corroborated Inspector Pollock's testimony by offering as evidence photographs that Inspector Pollock made of the cigarettes that Minor A purchased on the date in question. CTP Exs. 8-9. CTP also submitted the TIMS form and Narrative Report created by Inspector Pollock shortly after the inspection. CTP Exs. 6-7.

On cross-examination, Inspector Pollock testified that because she was not present inside the store, she does not know what was said between the cashier and Minor A during the inspection. Hr'g Tr. 22:1-10. Inspector Pollock also testified, in response to a question posed by Respondent, that it was possible that the cashier asked Minor A for an identification, and, despite that no identification was provided, the cashier proceeded with the sale. Hr'g Tr. 31:22-32:7.

Respondent filed an answer, informal brief, and post-hearing brief. *See* Dkt. Nos. 3, 25, and 31. In its filings, Respondent argues that the inspection notice was untimely, and, as a result, Respondent had no opportunity to review security camera tapes or interview the cashier close to the time of the inspection. Dkt. No. 3 ¶¶ 1, 3 and Defenses 1, 4. Respondent posits that the inspection notice was received six days after the inspection, at which point the camera data was overwritten and the cashier had no recollection of the sale. Dkt. No. 25, at 3; *see also* Dkt. No. 31, at 1-2.

There is, however, no requirement to notify Respondent of alleged violations at the time of the inspection. Instead, the Family Smoking Prevention and Tobacco Control Act (TCA) Pub. L. No. 111-31, 123 Stat. 1776 (2009), requires "timely and effective notice by certified or registered mail or personal delivery to the retailer of each alleged violation at a particular retail outlet prior to conducting a follow-up compliance check" and notice of "all previous violations at the outlet" prior to charging a person with a violation. TCA § 103(q)(1)(B), (D).

Based on the evidence of record, CTP issued a Compliance Check Inspection Notice (Notice) to Respondent, stating that an inspection was conducted on August 23, 2017, and that during the inspection, a minor was able to enter the establishment and purchase

cigarettes in a package. CTP Ex. 10. The Notice also stated that “[o]ther potential violations of federal tobacco laws may have also been reported” and that violations “may result in a Warning Letter, a Civil Money Penalty or No-Tobacco-Sale Order.” *Id.* The UPS Delivery Notification shows that the Notice was shipped on August 25, 2017, and delivered to Respondent’s address of 590 Main Street, Acushnet, Massachusetts 02743, on August 29, 2017, six days after the inspection. CTP Ex. 11.

As discussed above, the evidence shows that CTP sent Respondent the Notice on August 25, 2017, and Respondent received the Notice on August 29, 2017; which I find to be sufficiently timely. Respondent contends that its security camera overwrites the video tape every 4-5 days and thus Respondent was unable to review the sale footage. Respondent, however, provided no evidence that receiving the Notice on the sixth day rather than the fourth or fifth day prevented the necessary review as asserted. Even if I accept Respondent’s allegations as true, given Respondent’s history of past violations, Respondent had notice of the significance in preserving evidence and ample opportunity to change how it preserves its security camera tapes prior to the current violations. Indeed, on June 5, 2017, CTP filed a complaint in the prior CMP action, CRD Docket Number T-17-4495, FDA Docket Number FDA-2017-H-3353, alleging that Respondent unlawfully sold tobacco products to minors and unlawfully failed to verify a purchaser’s date of birth before the sale. *See* CTP Ex. 1. On July 5, 2017, Respondent signed an Acknowledgment Form, acknowledging that the violations occurred and waiving the ability to contest the violations in the future. *See* CTP Ex. 2. It is reasonable that within the next seven weeks, Respondent would have been sensitive to the potential for inspections and the need to preserve evidence in response to such inspections.

While Respondent concedes that based on the Notice and Inspector Pollock’s report, the inspection “most likely ... took place,” Dkt. No. 25, at 4, Respondent argues that CTP failed to provide a receipt indicating an exact time and proof of purchase of the product. Dkt. No. 3 ¶ 2 and Defense 2. Certainly, a receipt would be dispositive proof that the transaction occurred, but Inspector Pollock’s observations² and the physical evidence that was obtained on August 23, 2017, are, in and of themselves, adequate to prove CTP’s case. The absence of receipt does not derogate from that evidence.

I find Inspector Pollock’s testimony to be credible and corroborated by photographic proof that Respondent sold Marlboro cigarettes to Minor A on August 23, 2017, in violation of 21 C.F.R. § 1140.14(a)(1). Inspector Pollock’s testimony establishes that Minor A had no cigarettes in his/her possession before entering the store and had cigarettes upon leaving the establishment. Consequently, the only reasonable inference that I can draw from the evidence is that Minor A purchased cigarettes in the store. Minor A’s statement to Inspector Pollock further confirms that during the inspection,

² While it is undisputed that Inspector Pollock did not directly witness the alleged transactions on August 23, 2017, the regulations do not require such a direct eyewitness.

Minor A was able to purchase a package of cigarettes from an employee at Respondent's establishment.

It is also reasonable to infer that a store employee failed to check the minor's identification on August 23, 2017, in violation of 21 C.F.R. § 1140.14(a)(2)(i). It is undisputed that Minor A was 17 years old at the time of the inspection on August 23, 2017. Minor A reported to Inspector Pollock that Respondent's employee did not request to see his/her identification prior to purchasing the cigarettes on August 23, 2017. Indeed, it would have been impossible to verify Minor A's identification and age. Consistent with Massachusetts training procedures for undercover buys of tobacco products, Inspector Pollock confirmed that Minor A did not possess any photographic identification when he/she entered the establishment on August 23, 2017. Respondent's argument that Inspector Pollock agreed that it was possible for the cashier to ask for an identification from Minor A, and proceed with the sale without Minor A providing an identification, further supports that the cashier failed to verify the photographic identification of Minor A.

Respondent offered no evidence to rebut Inspector Pollock's testimony. Instead, Respondent argues that minor's recollection of what occurred in its establishment is unreliable hearsay. Dkt. No. 25, at 5. I agree that Minor A's accounts that he/she gave to Inspector Pollock of his/her experiences inside Respondent's establishment are hearsay. However, under 21 C.F.R. Part 17, the Administrative Law Judge determines the admissibility of evidence and has discretion to apply the Federal Rules of Evidence when deemed appropriate. Indeed, the Federal Rules of Evidence are not controlling in an administrative hearing, and I am not bound by the Federal Rules of Evidence in these proceedings. 21 C.F.R. § 17.39(b); *see also Deli-icious Catering, Inc. d/b/a Convenient Food Mart*, DAB No. 2812, 2017 WL 7734834, at *10-11 & n.10 (H.H.S. Aug. 21, 2017) (noting that hearsay is not inadmissible in tobacco civil money penalty administrative proceedings). Still further, even without relying on the Minor A's accounts, CTP sufficiently established its case based entirely on what Inspector Pollock observed personally, coupled with the corroborating evidence obtained on August 23, 2017. Inspector Pollock's testimony is that she observed Minor A enter Respondent's establishment with cash and without his/her identification or cigarettes and subsequently emerge from the store with a package of Marlboro cigarettes and the change from the purchase. That testimony, plus the corroborating evidence, leads to the only reasonable inference that Minor A purchased cigarettes at Respondent's establishment. Still further, given the unrefuted evidence that Minor A had no photographic identification at the time of the cigarette purchase, it is impossible that Respondent could have verified the age of Minor A by means of photographic identification.

Respondent questions the appropriateness of counting multiple violations during a single inspection. Dkt. No. 3 ¶ 8 and Defense 7. Respondent argues it cannot be held liable for failure to verify identification because minors are trained not to carry identification

during undercover inspections in Massachusetts. Dkt. No. 25, at 2-3; *see also* Dkt. No. 31, at 2. While Respondent's assertion is factually consistent with Inspector Pollock's declaration that minors in the tobacco program are trained not to carry photographic identification with them during an UB inspection, Respondent's argument is legally incorrect. Indeed, CTP's method of counting violations was recently upheld by the District of Columbia Circuit. *See Orton Motor, Inc. v. U.S. Dep't of Health & Human Servs.*, 884 F.3d 1205 (D.C. Cr. 2018) (concluding that FDA's methodology of counting violations is proper).

Under 21 C.F.R. § 1140.14(a)(2)(i), "[e]ach retailer must verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age." Section 1140.14(a)(2)(ii) further provides that "[n]o such verification is required for any person over the age of 26." The plain language of the regulation contemplates that the first step for each retailer to follow is to ask for an identification and the second step is to verify the purchaser's date of birth by examining the photographic identification. A failure to provide an identification should result in no sale because no verification is possible without a photographic identification.

The effective enforcement of minimum age restriction is the most important element in reducing youth access to tobacco products. For this reason, age verification is required through an examination of a valid government-issued photographic identification card showing a photograph and at least the minimum age established by applicable law for the purchase of a tobacco product. This exchange between a retailer and a consumer ought to prevent the sale of tobacco products to individuals who have not attained the minimum age established by applicable law for the purchase of such products.

The fact that minors in Massachusetts are trained not to carry photographic identification with them during an inspection only supports my finding that Respondent failed to verify that a person purchasing the product is younger than 18 years of age. In this case, Inspector Pollock's affidavit attests that Minor A had no identification in his/her possession, but was able to purchase a package of cigarettes. Accordingly, the Inspector's affidavit provides a sufficient basis for finding that the age of Minor A was not and could not have been verified by means of photographic identification, in violation of section 1140.14(a)(2).

Respondent further argues that a sale to a minor only constitutes a violation of 21 C.F.R. § 1140.14(a)(1) and the same sale cannot be a violation of section 1140.14(a)(2). Dkt. No. 25, at 2-3. Respondent avers that when a minor carries no identification, verification is not possible, and thus there can only be a violation of section 1140.14(a)(1). *Id.* Respondent's argument is inconsistent with the applicable case law. Indeed, in *Orton Motor*, the District of Columbia Circuit stated that "[g]enerally speaking, a retailer who sells a tobacco product to a minor, in violation of 21 C.F.R. § 1140.14(a)(1), likely only would do so without checking identification first, in violation of 21 C.F.R.

§ 1140.14(a)(2).” *Id.* at 1212. The Court further indicated that the sale and verification each has independent significance explaining that “the requirement that a retailer verify age applies with respect to prospective tobacco purchasers up to 26 years old, while the sales restriction relates only to would-be purchasers under the age of 18.” *Id.* Accordingly, Respondent in this case first committed a violation of section 1140.14(a)(2) when it failed to verify the purchaser’s age, and then, since the minor was permitted to purchase a package of cigarettes, Respondent committed a violation of section 1140.14(a)(1).

The testimonies of both Ms. Sternberg and Inspector Pollock, supported by corroborating evidence, is sufficient to establish that it is more likely than not that on August 23, 2017, Respondent unlawfully sold cigarettes to Minor A, in violation of 21 C.F.R. § 1140.14(a)(1), and failed to verify the photographic identification of Minor A, in violation of 21 C.F.R. § 1140.14(a)(2)(i). 21 C.F.R. § 17.33(b). Further, Respondent failed to establish any affirmative defense by a preponderance of the evidence. 21 C.F.R. § 17.33(c).

Accordingly, I find that the facts as outlined above establish Respondent’s liability for four violations of the Act.

B. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Scuttlebutts is liable for a CMP not to exceed the amounts listed in FDA’s CMP regulations at 21 C.F.R. § 17.2. In its Complaint, CTP sought to impose the penalty amount of \$2,236 against Respondent for four violations of the Act and its implementing regulations within a 24-month period. Dkt. No. 1 ¶ 1. In its pre- and post-hearing briefs, CTP continued to assert that a \$2,236 CMP is appropriate. Dkt. No. 21, at 10-15; Dkt. No. 30, at 1, 6.

Respondent’s position is that the CMP is unfair and should be reduced to \$559 because Respondent should only be liable for three violations instead of four. *See* Dkt. No. 25, at 5. In its response to CTP’s Request for Production of Documents, Respondent certified that it has the ability to pay the \$2,236 CMP, but asked for a payment plan to pay. Dkt. No. 17.

I have found that CTP met its burden by a preponderance of the evidence and concluded that Respondent committed four violations of the Act and its implementing regulations within a 24-month period. Accordingly, I now turn to whether a \$2,236 CMP is appropriate. When determining the amount of a CMP, 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).

1. Nature, Circumstances, Extent and Gravity of the Violations

I find that Respondent committed a total of four violations of selling tobacco products to minors, and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the CMP amount should be set accordingly.

2. Respondent's Ability to Pay and Effect on Ability to do Business

Respondent has not argued that it does not have the ability to pay the \$2,236 CMP sought by CTP. In fact, the opposite is true. As noted above, Respondent previously certified that it has the ability to pay the \$2,236 CMP. Dkt. No. 17. Respondent has not presented any evidence that the penalty will affect the Respondent's ability to continue to do business.

3. History of Prior Violations

The current action is the second CMP action brought against Respondent since June 5, 2017 for violations of the Act and its implementing regulations. In the first CMP action, CRD Docket Number T-17-4495, FDA Docket Number FDA-2017-H-3353, Respondent twice violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), and violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(a)(2)(i).³ See CTP Ex. 1. Respondent settled the prior complaint with CTP for an undisclosed penalty amount on July 5, 2017. See CTP Ex. 2. Yet, seven weeks later, on August 23, 2017, Respondent once again sold cigarettes to a minor and failed to verify the identification of a purchaser of a tobacco product.

Respondent disputes the prior settlement acknowledged any violation. Dkt. No. 3 ¶ 4. Respondent, however, has already admitted that the prior violations occurred, paid a penalty, and waived its right to contest such violations in subsequent actions. CTP Ex. 2. The prior violations are administratively final, and Respondent cannot contest them here.

³ Respondent is only being held liable for two of prior violations. See *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)*, at 13-14, available at <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf> (2016); see also *Orton Motor, Inc. v. U.S. Dep't of Health & Human Servs.*, 884 F.3d 1205 (D.C. Cr. 2018).

I agree with CTP that “[t]hese repeated violations show an unwillingness or inability to sell tobacco products in accordance with federal tobacco regulations.” Dkt. No. 21, at 13. While Respondent has already paid a CMP for its previous violations, its continued inability to comply with the federal tobacco regulations calls for a more severe penalty.

4. Degree of Culpability

Respondent alleges that “[d]eciding whether to card someone or not is an individual decision and therefore the penalty should lie with the individual.” Dkt. No. 3 ¶ 7 and Defenses 3, 5. As a retailer, however, Respondent is liable for its employees’ violations of the Act and responsible for the CMP sought by CTP. I find that Respondent committed the four violations as alleged in the Complaint, and I hold it fully culpable for all four violations of the Act and its implementing regulations.

5. Additional Mitigating Factors

Mitigation is an affirmative defense for which Respondent bears the burden of proof. Respondent must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence. 21 C.F.R. § 17.33(c). Respondent asserts that it “just purchased a[n] ID scanner for \$900 ... so that reading the license incorrectly is eliminated.” Dkt. No. 3, at 3. Respondent also alleges that it added an ID checking machine, ordered ID checking calendars, and “is adding newer video technology.” Dkt. No. 25, at 5. Respondent also avers that Respondent’s other store has had no violations and the store in question was clean for five years before the first inspection. *Id.* However, Respondent’s mere assertions are not enough. Although Respondent’s alleged attempts to deter tobacco sales to minors are commendable, Respondent failed to provide any evidence of the remedial measures it has taken or evidence to show when Respondent took such measures. Moreover, this is Respondent’s second CMP action, and Respondent has had ample opportunity to correct its violations and come into compliance.

Thus, I find and conclude there is no basis in the record before me to find mitigating factors that would allow me to reduce the penalty requested by CTP, which I find proportional and appropriate in this case.

IV. PENALTY

Based on the foregoing reasoning, I find the penalty amount of \$2,236 to be reasonable and appropriate under 21 U.S.C. §§ 303(f)(5)(B) and 333(f)(9).

