

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

Center for Tobacco Products,
Complainant,

v.

Coronis Market, LLC
d/b/a Coronis Market,

Respondent.

Docket No. T-18-1815
FDA Docket No. FDA-2018-R-1353

Decision No. TB3978

Date: June 21, 2019

DECISION

Found:

- 1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) on November 26, 2017, as charged in the complaint; and
- 2) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(a)(2)(i) as charged in the prior complaints; and
- 3) Respondent committed five repeated violations in a 36-month period as set forth hereinabove.
- 4) Respondent is hereby assessed a 30-day No Sale Tobacco Order (NTSO).

Glossary:

ALJ
CTP/Complainant
FDCA

administrative law judge¹
Center for Tobacco Products
Federal Food, Drug, and Cosmetic Act
(21 U.S.C.A. Chap. 9)

¹ 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	Coronis Market, LLC d/b/a Coronis Market
TCA	The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009)(TCA)
TR	Transcript

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 17.²

II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) filed a Complaint dated April 2, 2018, alleging that FDA documented five repeated violations within a 36-month period.

Coronis Market, LLC d/b/a Coronis Market was served with process on April 4, 2018, by United Parcel Service. Respondent filed an Answer on May 3, 2018, in which it denied the current allegations and argued that the 30-day NTSO is inappropriate.

² 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).

I conducted a hearing on January 16, 2019.

CTP filed its post-hearing brief on March 25, 2019. Respondent also filed its post-hearing brief on March 25, 2019.

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

III. BURDEN OF PROOF

The Center for Tobacco Products (CTP/Complainant) 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).³

V. ISSUES

Whether Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) as alleged in the complaint; and

Whether a consecutive 30-day NTSO is appropriate?

VI. ALLEGATIONS

A. Complainant's Recitation of facts

CTP alleged that Respondent owned an establishment, doing business under the name Coronis Market, located at 81 Sunapee Street, Newport, New Hampshire 03773. Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

³ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

Complainant further alleged that during an inspection of Coronis Market conducted on November 26, 2017, an FDA-commissioned inspector documented 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 Marlboro 100's cigarettes on November 26, 2017, at approximately 11:08 AM.

B. Respondent's recitation of facts

In its Answer, Respondent, through counsel, denied the violations as alleged. Respondent contends that it has no knowledge of selling cigarettes or smokeless tobacco to a minor on November 26, 2017. Answer at 2. In its defense, Respondent argues that it employs high school students at its establishment and provides them with the proper training to ensure minors are not purchasing tobacco products. Unfortunately, hiring local high school students results in high turnover, but Respondent dedicates his time to train and ensure employees verify identification and refrain from selling tobacco products to under age customers. Specifically, Respondent places a calendar on the counter by the cash register with the dates for the employees to confirm patrons are old enough to buy the products. Answer at 3. Respondent contends that on this particular date, the owner reviewed the video tape after receiving notice of the initial allegation, which illustrates the cashier requesting identification and reviewing the calendar before selling the tobacco product. Respondent further contends that the 30-day NTSO penalty is inappropriate

because it is a small local market that depends on the sale of tobacco products as a major source of its business. Answer at 3.

VII. PRIOR VIOLATIONS

On July 21, 2016, CTP initiated the first civil monetary penalty (CMP), CRD Docket Number T-16-1184, FDA Docket Number FDA-2016-H-1900, against Respondent for three⁴ violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred at Respondent's business establishment on May 7, 2015,⁵ and January 4, 2016, as follows:

- a. Sale to a minor (21 C.F.R. § 1140.14(a)(1)) on May 7, 2015, and January 4, 2016; and
- b. Failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth (21 C.F.R. § 1140.14(a)(2)(i)) on May 7, 2015, and January 4, 2016.

The previous action concluded in settlement where Respondent admitted all of the allegations in the Complaint and paid the agreed-upon penalty. In acknowledging that

⁴ All violations observed during the initial failed inspection are counted as a single violation, and each separate violation observed during subsequent failed inspections count as a discrete violation. *Orton Motor, Inc., d/b/a Orton's Bagley v. U.S. Dep't of Health & Human Serv.*, 884 F.3d 1205 (D.C. Cir. 2018).

⁵ The May 7, 2015 violations are original violations. Respondent's five repeated violations of regulations for the purpose of the most recent Complaint are those that occurred within the specified 36-month period after the May 7, 2015 original violations.

the alleged violations occurred, Respondent expressly waived its right to contest such violations in subsequent actions.

On March 28, 2017, CTP initiated its second CMP action, CRD Docket Number T-17-2977, FDA Docket Number FDA-2017-H-1677, against Respondent for at least five violations of 21 C.F.R. pt. 1140 within a 36-month period. CTP alleged those violations to have occurred at Respondent's business establishment on May 7, 2015, January 6, 2016, and October 15, 2016, as follows:

- a. Sale to a minor (21 C.F.R. § 1140.14(a)(1)) on October 15, 2016;
and
- b. Failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth (21 C.F.R. § 1140.14(a)(2)(i)) on October 15, 2016.

The previous action concluded in settlement where Respondent admitted all of the allegations in the Complaint and paid the agreed-upon penalty. In acknowledging that the alleged violations occurred, Respondent expressly waived its right to contest such violations in subsequent actions.

I find and conclude Respondent committed five violations of 21 U.S.C. § 331 based on the conduct as set forth in the prior complaints (CRD Docket Number T-16-1184, FDA-2016-H-1900; CRD Docket Number T-17-2977, FDA-2017-H-1677).

VIII. FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

The “relevant statute” in this case is actually a combination of statutes and regulations: The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111 31, 123 Stat. 1776 (2009) (TCA), amended the Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9) (FDCA) and created a new subchapter of that Act that dealt exclusively with tobacco products, (21 U.S.C. §§ 387-387u), and it also modified other parts of the FDCA explicitly to include tobacco products among the regulated products whose misbranding can give rise to civil, and in some cases criminal, liability. The 2009 amendments to the FDCA contained within the TCA also charged the Secretary of Health and Human Services with, among other things, creating regulations to govern tobacco sales. The Secretary’s regulations on tobacco products appear in Part 1140 of title 21, Code of Federal Regulations.

Under the FDCA, “[a] tobacco product shall be deemed to be misbranded if, in the case of any tobacco product sold or offered for sale in any State, it is sold or distributed in violation of regulations prescribed under section 387f(d).” 21 U.S.C. § 387c(a)(7)(B) (2012). Section 387 a-1 directed FDA to re-issue, with some modifications, regulations previously passed in 1996. 21 U.S.C. § 387 a-1(a)(2012). These regulations were passed pursuant to section 387f(d), which authorizes FDA to promulgate regulations on the sale and distribution of tobacco products. 75 Fed. Reg. 13,225 (March 19, 2010), codified at 21 C.F.R. 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) (2015)*, available at

<http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/U>

[CM447310.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) 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 Orton Motor, Inc., d/b/a Orton's Bagley v. U.S. Dep't of Health & Human Serv.*, 884 F.3d 1205 (D.C. Cir. 2018).

IX. HEARING

The hearing in this matter was held on January 16, 2019, by telephone as set forth in my December 7, 2018 Order of the Court.

Bruce R. Jasper, Esquire, appeared on behalf of Respondent.

Michele Svonkin, Esquire, appeared on behalf of Complainant.

Witness Nicholas Cutting testified on behalf of Complainant by way of a sworn affidavit and live testimony at the hearing.

Witness Brian Coronis testified on behalf of Respondent by way of a sworn affidavit.

X. SUMMARY OF TESTIMONY AND EVIDENCE

A. Complainant's case

Complainant submitted evidence and testimony in form of a written declaration and photographs. Complainant offered CTP Exhibits 1 through 14, inclusive, the exhibits were marked for identification. Respondent did not object to the exhibits. I admit Complainant's Exhibits 1 through 14, inclusive.

i. Inspector Nicholas Cutting

Witness Nicholas Cutting, the FDA-commissioned Inspector who conducted the inspection of Respondent's establishment on November 26, 2017, testified on behalf of Complainant. Complainant provided Inspector Cutting's written direct testimony as CTP Ex. 5.

Inspector Cutting testified that on November 26, 2017, at approximately 11:08 AM, he and the minor conducted the follow-up compliance inspection at Respondent's establishment Coronis Market, located at 81 Sunapee Street, Newport, New Hampshire 03773. Before the inspection, Inspector Cutting confirmed the minor possessed his true and accurate photographic identification (ID), and prior to entering the establishment, Inspector Cutting confirmed that the minor did not have any tobacco products in his possession. CTP Ex. 5 at 2.

According to his testimony, Inspector Cutting parked his car near Coronis Market, where he had an obstructed view of the sales counter and the minor. CTP Ex. 5 at 2-3. The minor reported to Inspector Cutting that the minor had provided his ID and was able

to purchase Marlboro 100's cigarettes. CTP Ex. 5 at 3. The minor also reported that the employee did not provide the minor with a receipt after the purchase. CTP Ex. 5 at 3.

The minor exited the establishment and returned to Inspector Cutting's vehicle. Immediately upon entering the vehicle, the minor handed the Inspector the package of Marlboro 100's cigarettes. Inspector Cutting processed the evidence according to procedure and completed a narrative report. CTP Ex. 5 at 3.

B. Respondent's case

Respondent submitted six exhibits marked as Resp. Exs. 1-6. In addition to the exhibits, Respondent submitted a proposed witness list and testimony. On December 28, 2018, CTP moved to exclude the direct testimony of Respondent's proposed witnesses, pursuant to 21 C.F.R. § 17.37(b). On January 8, 2019, I ordered Respondent to refile its witness testimony in accordance with 21 C.F.R. § 17.37(b), no later than January 11, 2019. On January 11, 2019, Respondent refiled Brian Coronis' Declaration, R. Declaration (Decl.). I admit R. Decl. and R. Exs. 1-6, inclusive.

i. Mr. Brian Coronis

Mr. Brian Coronis, Respondent's owner, testified on behalf of Respondent. Mr. Coronis testified that he employs various part-time persons, including high school students. R. Decl. at 1. He testified that he has trained all employees, which includes reviewing the We Card pamphlets with employees and providing a We Card calendar so that employees can verify the age of tobacco product purchasers. Id. at 1-2; R. Ex. 1 at 2. Mr. Coronis further testified that employees are required to sign contracts to confirm that

they understand and abide by the regulations pertaining to tobacco products. He also stated that the store refrains from carrying “vape products” because of its known popularity amongst teenagers. R. Decl. at 1-2.

In the instant case, Mr. Coronis testified that he reviewed the video footage relating to the November 26, 2017 incident. Id at 2. According to Mr. Coronis, the video footage revealed that the cashier on duty received the ID from the customer and verified the birthdate using the calendar before selling the cigarettes to the customer. Id. The footage does not display the ID used nor is the video accessible. Id. Due to the lapse of time between the alleged offense and the service of the complaint, the video has been taped over. Answer at 5.

C. Credibility determinations

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

XI. RULING ON ADMISSIBILITY OF EVIDENCE

Complainant offered and I received into evidence Exhibits 1 through 14, inclusive. Respondent offered and I received into evidence Exhibits 1 through 6, inclusive. There were no further objections to the exhibits other than previously discussed.

I am not bound by the Federal Rules of Evidence in these proceedings. 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).

XII. ANALYSIS OF EVIDENCE AND TESTIMONY

A. Complainant's case

Complainant offered and I received into evidence Exhibits 1 through 14, 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).

I find that, based on the testimonial and documentary evidence, (CTP Exs. 5-10, T. 8, 14-15), CTP has fulfilled its burden in that Respondent violated the regulations on November 26, 2017. 21 C.F.R. § 1140.14(a)(1). Respondent has prior violations that are administratively final. Accordingly, I find that Respondent has repeatedly violated the regulations five times within a 36-month period.

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 the violation on November 26, 2017, did not occur as alleged. Mr. Coronis contends that he is very mindful of the seriousness of violating

the law by selling tobacco products to underage customers. R. Decl. at 2. During the hearing and in its post-hearing brief, Respondent's counsel attacks the validity of the allegation that the minor purchased the Marlboro 100's cigarettes from Respondent's store. Respondent implies that there is a possibility that the cigarettes were not purchased from Respondent's store because Inspector Cutting did not physically accompany the minor in the store and physically pat down the minor to ensure that he did not already possess the Marlboro 100's cigarettes on his person before entering the Respondent's establishment. R. Post-Hearing Br. at 3-4; T. 11-13. Respondent also argues that the minor could have used another ID to purchase the cigarettes. Id.

C. Analysis

- i. I find and conclude that Respondent committed five repeated violations in a 36-month period

Although Respondent contends that it did not violate the regulations by selling cigarettes to a minor on November 26, 2017, Respondent's speculations are without merit as Respondent fails to provide evidence to corroborate its theories or to overcome the allegation that it sold a package of Marlboro 100's cigarettes to a minor on the date in question. Respondent did not provide evidence to rebut Inspector Cutting's testimony, which I find credible. Therefore, I find that Respondent's additional repeated violation of selling cigarettes to a minor on November 26, 2017, amounts to five total repeated violations of the tobacco regulations within a 36-month period.

XIII. LIABILITY

When a retailer such as Respondent is found to have “misbranded” a tobacco product in interstate commerce, it may be subject to an NTSO for a period. 21 U.S.C. § 333(f)(8). Under 21 U.S.C. § 333(f)(8), a No-Tobacco-Sale Order is permissible for five repeated violations of the regulations found at 21 C.F.R. pt. 1140. The maximum period of time for the first No-Tobacco-Sale Order received by a retailer is 30 consecutive calendar days. See Pub. L. 111–31, div. A, title I, § 103(q)(1)(A), June 22, 2009, 123 Stat. 1838, 1839; Food & Drug Admin., Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers at 5-6, available at <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM252955.pdf> (last updated Dec. 15, 2016); Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with Order at 3-4, available at <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf> (last updated August 2015). While the CTP guidance documents are not binding, as a matter of law, I consider them to be persuasive when interpreting the statutory factors that must be considered in determining the length of an NTSO.

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), in that a person younger than 18 years of age was able to purchase a package of Marlboro 100s cigarettes on November 26, 2017, at approximately 11:08 AM as set forth in the complaint.

The conduct set forth above on November 26, 2017, counts as an additional repeated violation under FDA policy for purposes of computing the penalty in this matter. *See Guidance for Industry*, at 13-15. Respondent previously admitted to prior repeated violations of FDA policy in the relevant timeframe. Accordingly, I find and conclude that Respondent is liable for five repeated violations of FDA policy in a 36-month period.

XIV. PENALTY

There being liability under the relevant statute, I must now determine the appropriate penalty to impose. Pursuant to 21 U.S.C. § 333(f)(5)(B), an NTSO may be imposed against Respondent for repeated violations of the regulations promulgated under section 906(d) of the Act. In its Complaint, CTP sought the maximum period of a 30-day NTSO against Respondent for five repeated violations of the Act and its implementing regulations within a 36-month period. In its Post-Hearing Brief, CTP continued to assert that a 30-day NTSO is appropriate. Complainant's Post Hearing Brief at 2-3.

Respondent objects to the 30-day NTSO and instead requests that a three-day NTSO be imposed as well as a \$250 fine. Respondent's Post Hearing Brief at 6.

As discussed, I found that CTP met its burden by a preponderance of the evidence and concluded that Respondent committed five repeated violations of the Act and its implementing regulations within a 36-month period. When determining the appropriate penalty, I am required to take into account "the nature, circumstances, extent and gravity of the violations and, with respect to the violator, ability to pay, effect on ability to

continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.” 21 U.S.C. § 333(f)(5)(B).

A. The Nature, Circumstances, Extent and Gravity of the Violations

I have found that Respondent specifically committed three repeated violations of selling tobacco products to minors, and two repeated violations for failure to ID, totaling five repeated violations of the tobacco regulations. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the penalty should be set accordingly.

B. Respondent’s Ability to Pay And Effect on Ability to do Business

In its Answer, Respondent’s owner, Mr. Coronis, argued that the business is a small family local market that depends on the sale of tobacco as a major source of its business. Answer at 3. However, Respondent failed to submit evidence to support his argument that enforcing a 30-day NTSO would result in a financial hardship for the business. Therefore, I do not find that enforcing the proposed penalty would result in a financial burden.

C. History of Prior Violations

The current action is the third action brought against Respondent for violations of the Act and its implementing regulations. On July 21, 2016, CTP initiated the first civil money penalty action, CRD Docket Number C-16-1184, FDA Docket Number FDA-2016-H-1900, against Respondent. In the first action, Respondent violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), and failed to verify the age of a person purchasing tobacco

products by means of photographic identification, 21 C.F.R. § 1140.14(a)(2)(i). The original violations occurred on May 7, 2015, and the repeated violations on January 4, 2016. Respondent settled the prior complaint with CTP for an undisclosed penalty amount and admitted that the violations occurred as described in the complaint. Complaint at 4.

On March 28, 2017, CTP initiated the second civil money penalty action, CRD Docket Number C-17-2977, FDA Docket Number FDA-2017-H-1677, against Respondent. Complaint at 5. In the second action, Respondent again violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), and failed to verify the age of a person purchasing tobacco products by means of photographic identification, 21 C.F.R. § 1140.14(a)(2)(i). The repeated violations occurred on October 15, 2016. Respondent settled the second prior complaint with CTP for an undisclosed penalty amount and admitted that the repeated violations occurred as described in the complaint. Complaint at 5.

Respondent's history of noncompliance demonstrates its continued inability to comply with the federal tobacco regulations. This calls for a severe penalty.

D. Degree of Culpability

Based on my finding that Respondent committed the most recent violation in the current complaint, I hold it fully culpable for five repeated 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 provided evidence of its training program.

R. Ex. 1. Respondent also submitted that it displayed We Card signs throughout the store, provided a calendar to assist store cashiers with age verification, provided incentives for employees who alert management of potential underage tobacco sales, and refrained from selling “vape products in [the] store knowing they are popular with teens.”

R. Exs. 2-5, R. Decl. at 2. While I acknowledge Respondent’s efforts to prevent tobacco sales to minors, the preventative measures are minimal and Respondent has not proven that these steps were taken in response to the most recent violation as it is my belief these actions were implemented after the first two infractions.

F. Penalty

Based on the foregoing reasoning, I conclude the 30-day NTSO is appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(8).

XV. CONCLUSION

Respondent committed five repeated violations in a 36-month period as set forth in the Complaint. Therefore, I find Respondent is liable for a 30-day NTSO. *See* 21 C.F.R. § 17.2.

WHEREFORE, evidence having read and considered it be and is hereby ORDERED as follows:

- a. I find Respondent 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 November 26, 2017, in that a person younger than 18 years of age was able to purchase a package of Marlboro 100s 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)(1) on May 7, 2015, January 4, 2016, and October 15, 2016, and 21 C.F.R. § 1140.14(a)(2)(i) on those same dates, as stipulated in the settlement agreement of the most recent action, CRD Docket Number T-17-2977, FDA Docket Number FDA-2017-H-1677; and
- d. I find and conclude Respondent committed five repeated violations of the regulations within a 36-month period; and
- e. I affirm the 30-day No Sale Tobacco Order.

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