

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

Center for Tobacco Products,
Complainant

v.

Sinjil, Inc.
d/b/a Sunoco,
Respondent

FDA Docket No. FDA-2017-R-0223
CRD Docket No. T-17-1631

Decision No. TB2454

Date: February 14, 2018

DECISION

Found:

- 1) Respondent violated 21 U.S.C. § 387f(d), specifically 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(a)(2)(i) on February 13, 2016 as charged in the Complaint; and
- 2) Respondent violated 21 U.S.C. § 387f(d), specifically 21 C.F.R. § 1140.14(a)(1)¹ and 21 C.F.R. § 1140.14(a)(2)(i) as charged in prior complaints; and
- 3) Respondent committed six (6) repeated violations in a thirty-six (36) month period as set forth hereinabove.
- 4) Respondent is hereby assessed a two (2) day No-Sale-Tobacco Order (NTSO) and a civil money penalty in the amount of \$7,500.

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

Glossary:

ALJ	administrative law judge ²
CMP	Civil Money Penalty
CTP/Complainant	Center for Tobacco Products
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	Sinjil, Inc. d/b/a Sunoco
TCA	The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009)
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 17.³

II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) filed a Complaint dated January 17, 2017 alleging that FDA documented six (6) repeated violations within a thirty-six (36) month period.

² See 5 C.F.R. § 930.204.

³ See also *Butz v. Economou*, 438 U.S. 478 at 513, 98 S.Ct. 2894, 57 L.Ed.2d 895 (1978); *Marshall v. Jerrico, Inc.*, 446 U.S. 238 (1980); *Federal Maritime Com'n v. South Carolina State Ports Authority*, 535 U.S. 743, 744 (2002).

Sinjil, Inc. d/b/a Sunoco was served with process on January 18, 2017 by United Parcel Service. Respondent filed an Answer dated February 15, 2017 in which it could not confirm nor deny the current allegations and requested I dismiss the Complaint with prejudice.

I conducted a hearing on September 13, 2017. Both parties filed post-hearing briefs on December 8, 2017.

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

III. BURDEN OF PROOF

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

IV. LAW

21 U.S.C. § 387f(d), specifically 21 C.F.R. § 1140.14(a)(1) and § 1140.14(a)(2)(i).

V. ISSUES

Did Respondent violate 21 U.S.C. § 387f(d), specifically § 1140.14(a)(1) and § 1140.14 (a)(2)(i) as alleged in the complaint?

Is a thirty (30) day NTSO appropriate?

VI. ALLEGATIONS

A. Complainant's Recitation of Facts

Complainant alleged that Respondent owned an establishment, doing business under the name Sunoco, located at 21435 West 8 Mile Road, Detroit, Michigan 48219. Complainant further alleged during an inspection of Sunoco, conducted on February 13, 2016, 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 Newport Box 100s cigarettes on February 13, 2016 at approximately 12:37 PM.

- 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(a)(2)(i). Specifically, the minor's identification was not verified before the sale on February 13, 2016 at approximately 12:37 PM.

B. Respondent's Recitation of Facts

In its Answer and subsequent filings, Respondent could not confirm nor deny the allegations listed in the Complaint. Respondent argued that it did not receive proper service of the February 13, 2016 Notice of Compliance Check Inspection. Respondent also argued that Complainant did not demonstrate that the cigarettes in question were held in interstate commerce. Finally, Respondent argued that the imposition of an NTSO is reserved for the "most egregious" offenders. As such, Respondent asked for the Complaint to be dismissed or a lesser sanction be imposed.

VII. PRIOR VIOLATIONS

On June 10, 2014, CTP initiated its first Civil Money Penalty (CMP) action, CRD Docket Number C-14-1217, FDA Docket Number FDA-2014-H-0719, against

Respondent⁴ for three⁵ (3) violations of 21 C.F.R. pt. 1140 within a twenty-four (24) month period. CTP alleged Respondent sold cigarettes to a minor and failed to verify the age of a person purchasing cigarettes by means of photographic identification containing the bearer's date of birth on March 9, 2013 and November 2, 2013.

The first CMP action concluded with an Initial Decision and Default Judgment entered by an Administrative Law Judge, finding Respondent liable for the alleged violations.⁶

On April 6, 2015, CTP initiated a second CMP action, CRD Docket Number C-15-1875, FDA Docket Number FDA-2015-H-1044, against Respondent for five (5) violations of 21 C.F.R. pt. 1140 within a thirty-six (36) month period. CTP alleged Respondent sold cigarettes to a minor and failed to verify the age of a person purchasing cigarettes by means of photographic identification containing the bearer's date of birth on December 5, 2014.

The second CMP action concluded when Respondent "admitted all the allegations in the Complaint and paid the agreed upon penalty." Further, "Respondent expressly waived its right to contest such violations in subsequent actions."

⁴ In the June 10, 2014 action, Respondent was identified as Raed Iwais / Rafat Iwies d/b/a Sunoco. CTP alleged that licensing evidence showed that Sinjil, Inc. owns the establishment and does business as Sunoco. Respondent has not contested this issue.

⁵ Two original violations occurred on March 9, 2013 and two repeated violations on November 2, 2013. In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all repeated violations as separate individual violations.

⁶ Respondent subsequently paid the civil money penalty and admitted the allegations in the June 2014 CMP Complaint occurred. CTP Ex. 4.

I find and conclude that Respondent committed five (5) violations of 21 U.S.C. § 331, specifically two (2) original violations,⁷ two (2) repeated violations of 21 C.F.R. § 1140.14(a)(1) and two (2) repeated violations of 21 C.F.R. § 1140.14(a)(2)(i) based on the conduct as set forth in the prior complaint.

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

⁷ The original violations are not included in the counting for the current action.

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/UCM447310.pdf> [hereinafter *Guidance for Industry*], at 13-15. So, for instance, if a retailer sells a tobacco product on a particular occasion to a minor without checking for photographic identification, in violation of 21 C.F.R. §§ 1140.14(a) 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.

NTSOs are authorized at 21 U.S.C. § 333(f)(8). The section allows for the imposition of an NTSO against a person who has committed “repeated violations” of restrictions on the sale of tobacco products. The term “repeated violations” is defined to mean “at least 5 violations of particular requirements over a 36-month period at a particular retail outlet” *See* FDA Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers: Guidance for Industry (December 2016) at 3,5-6, available at

[https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm447308.](https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm447308)

[htm](#). The Act also provides that “[p]rior to the entry of a no-sale order under this

paragraph, a person shall be entitled to a hearing” 21 U.S.C. § 333(f)(8).

CTP developed policy guidelines that establish maximum NTSO durations. For a first NTSO, CTP recommends a maximum duration of 30 calendar days. *See* Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with an Order: Guidance for Tobacco Retailers (August 2015) at 4, *available at* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf>.

VIII. HEARING

A hearing was held on September 13, 2017 by telephone as set forth in my August 14, 2017 Order Scheduling Telephone Hearing.

Samantha Hong, Esquire, appeared on behalf of Complainant.

Sam M. Fakhri, Esquire, appeared on behalf of Respondent.

Witness Justin Bishop testified on behalf of Complainant.

Witness Rafat Iwies testified on behalf of Respondent.

IX. SUMMARY OF TESTIMONY AND EVIDENCE

A. Complainant's case

Complainant submitted evidence and testimony in the form of written declarations and photographs. Complainant offered CTP Exhibits 1 through 23, inclusive.

Respondent did not object to the exhibits. I admit Complainant's Exhibits 1 through 23, inclusive.

i. Inspector Justin Bishop

Witness Justin Bishop, the FDA-commissioned inspector who conducted the

inspection of Respondent's establishment on February 13, 2016, testified on behalf of Complainant. Complainant provided Inspector Bishop's direct testimony as CTP Ex. 21 in the form of a written declaration.

Inspector Bishop testified that on February 13, 2016, at approximately 12:37 PM, he and a minor conducted the follow-up compliance inspection at Respondent's establishment Sunoco, located at 21435 West 8 Mile Road, Detroit, Michigan 48219. Before the inspection, Inspector Bishop ensured the minor had photographic identification (ID) and that the minor did not have tobacco products. CTP Ex. 21 at 2-3.

According to his testimony, Inspector Bishop accompanied the minor into Respondent's establishment and took a position where he had an unobstructed view of the sales counter and the minor. *Id.* at 3. Inspector Bishop observed the minor purchase a package of cigarettes directly from a store employee. *Id.* The Inspector also observed that the minor did not present any identification to the employee before the transaction. *Id.*

After purchasing the cigarettes, the minor exited the establishment and the Inspector followed shortly after. *Id.* Both returned to the vehicle where upon entering, the minor handed Inspector Bishop a package of Newport Box 100s cigarettes. *Id.* Inspector Bishop processed the evidence according to procedure and completed a narrative report soon after. *Id.*

On cross-examination, Inspector Bishop testified that his written declaration was executed on May 12, 2017, approximately thirteen months after the February 13, 2016 inspection. Tr. at 9. He also testified that his written declaration is based upon the

narrative report generated on the date of the inspection, along with some assistance from CTP. *Id.* at 9-10. Finally, Inspector Bishop testified that he had no knowledge as to whether the tobacco products in question were in interstate commerce at any point in time. *Id.* at 10-11.

B. Respondent's case

Respondent submitted nine exhibits marked as Respondent's Exhibits 1 through 9. CTP did not object to any of Respondent's exhibits. I admit Respondent's Exhibits 1 through 9, inclusive.

It is Respondent's alleged position that it is unable to confirm or deny that its employee sold tobacco to a minor or failed to verify the identification and age of the purchaser because it did not receive proper service of the February 13, 2016 Notice of Compliance Check Inspection. Respondent's argument was un rebutted by Complainant. Respondent further argued that an NTSO is reserved only for the most egregious offenders, which it is not. Finally, Respondent argued, in its post-hearing brief, that Complainant offered no evidence that the tobacco products were in interstate commerce at any point in time.

i. Mr. Rafata Iwies

Mr. Rafata Iwies, Respondent's owner, testified on behalf of Respondent. Mr. Iwies testified that he has owned Sunoco since it was incorporated. *Resp. Ex.* at 1. He testified that he has informed all employees, by means of written Employee Agreements, that they must card all individuals who attempt to purchase tobacco. *Id.* at 2. In addition, he testified that numerous placards and signs are placed throughout the establishment

indicating that minors are not to attempt to purchase tobacco products. *Id.*

Mr. Iwies also testified that he has installed numerous cameras throughout the location that record individuals who visit and make purchases. *Id.* He testified that the cameras record 24 hours a day, but it will record over previously recorded material once capacity is reached. *Id.*

Mr. Iwies further testified that notice of the violations was not delivered for thirteen days after the alleged violations and was signed by an individual named “ELI.” *Id.*; Resp. Pre-Hearing Br. at 4; CTP Ex. 13. ELI was not the owner of the business nor resident agent of Respondent, and no one named Eli had worked at that establishment in the past three years. *Id.*; Tr. 15-17. Mr. Iwies testified that due to the fact that notice was not properly served, it was unable to preserve the videotapes. *Id.* Again, Respondent’s testimony was un rebutted by Complainant.

C. Credibility determinations

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

X. RULING ON ADMISSIBILITY OF EVIDENCE

Complainant offered and I received into evidence Exhibits 1 through 23, inclusive. Respondent offered and I received into evidence Exhibits 1 through 9, inclusive. There were no objections to the exhibits.

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

Complainant offered and I received into evidence Exhibits 1 through 23, inclusive.

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. § 14.45(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 it is unable to confirm or deny that its employee sold tobacco to a minor or failed to verify the identification and age of the purchaser because Complainant did not properly serve the February 13, 2016 Notice of Compliance Check Inspection. Respondent also argued Complainant offered no evidence that the

tobacco products were in interstate commerce at any point in time. Respondent further argued that an NTSO is reserved only for the most egregious offenders, which it is not.

C. Analysis

- a. 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 February 13, 2016 at 12:37 PM.

Inspector Bishop testified that on February 13, 2016, at approximately 12:37 PM, he and a minor conducted the follow-up compliance inspection at Respondent's establishment Sunoco, located at 21435 West 8 Mile Road, Detroit, Michigan 48219. Before the inspection, Inspector Bishop ensured the minor had photographic identification (ID) and that the minor did not have tobacco products. CTP Ex. 21 at 2-3.

According to his testimony, Inspector Bishop accompanied the minor into Respondent's establishment and took a position where he had an unobstructed view of the sales counter and the minor. *Id.* at 3. Inspector Bishop observed the minor purchase a package of cigarettes directly from a store employee. *Id.*

After purchasing the cigarettes, the minor exited the establishment and the Inspector followed shortly after. *Id.* Both returned to the vehicle where upon entering, the minor handed Inspector Bishop a package of Newport Box 100s cigarettes. *Id.* Inspector Bishop processed the evidence according to procedure and completed a

narrative report soon after. *Id.*

I find Inspector Bishop's testimony about the February 13, 2016 inspection credible and unbiased. I find that, in conjunction with the corroborating documentary evidence (e.g. the report) and the physical evidence (e.g. the photographs of the Newport Box 100s cigarettes purchased on that date), Complainant has satisfied its burden of proving that Respondent violated § 1140.14(a)(1) on February 13, 2016 at 12:37 PM by a preponderance of the evidence.

- b. I find and conclude that Complainant has shown by a preponderance of the evidence that Respondent violated 21 C.F.R. § 1140.14(a)(2)(i) when, on February 13, 2016 at 12:37 PM, 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.

Inspector Bishop testified that on February 13, 2016, at approximately 12:37 PM, he and a minor conducted the follow-up compliance inspection at Respondent's establishment Sunoco, located at 21435 West 8 Mile Road, Detroit, Michigan 48219. Before the inspection, Inspector Bishop ensured the minor had photographic identification (ID) and that the minor did not have tobacco products. CTP Ex. 21 at 2-3.

According to his testimony, Inspector Bishop accompanied the minor into Respondent's establishment and took a position where he had an unobstructed view of the sales counter and the minor. *Id.* at 3. Inspector Bishop observed the minor purchase a package of cigarettes directly from a store employee. *Id.* The Inspector also observed that the minor did not present any identification to the employee before the transaction.

Id.

After purchasing the cigarettes, the minor exited the establishment and the Inspector followed shortly after. *Id.* Both returned to the vehicle where upon entering, the minor handed Inspector Bishop a package of Newport Box 100s cigarettes. *Id.* Inspector Bishop processed the evidence according to procedure and completed a narrative report soon after. *Id.*

I find Inspector Bishop's testimony about the February 13, 2016 inspection credible and unbiased. I find that, in conjunction with the corroborating documentary evidence (e.g. the report) and the physical evidence (e.g. the photographs of the Newport Box 100s cigarettes purchased on that date), Complainant has satisfied its burden of proving that Respondent violated § 1140.14(a)(2)(i) on February 13, 2016 at 12:37 PM by a preponderance of the evidence.

c. I find and conclude that Respondent committed six (6) repeated violations in a thirty-six (36) month period

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i) on February 13, 2016 in that Respondent violated the requirement that retailers not sell cigarettes to minors and 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 set forth above on February 13, 2016 counts as two (2) additional repeated violations under FDA policy for purposes of computing penalty in this matter.

See Guidance for Industry, at 13-15. Respondent was previously found liable for two (2), and admitted to two (2), violations of FDA policy in the relevant timeframe.

Accordingly, I find and conclude that Respondent is liable for six (6) repeated violations of FDA policy in a thirty-six (36) month period.

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

Respondent argues that it is unable to confirm or deny that its employee sold tobacco to a minor under the age of 18 on February 13, 2016 because it did not receive the Notice of Compliance Check Inspection. Specifically, Respondent argued that the Notice of Compliance Check was signed for by an individual by the name of "ELI." Respondent testified that ELI is not the owner of the business nor the registered agent and that Respondent does not, nor has it ever, employed anyone named ELI.

Section 17.7(a) provides that service of a complaint may be made in one of two ways: either by certified or registered mail or similar mail delivery service (i.e., one which provides a return receipt record reflecting receipt), or by delivery in person. 21 C.F.R. §§ 17.1(a)(1) and (a)(2). Delivery in person must be to either an individual respondent or to an "officer or managing or general agent in the case of a corporation or unincorporated business." 21 C.F.R. §§ 17.7(a)(2)(i) and (a)(2)(ii). If the complaint is served by certified or registered mail or similar mail delivery service, proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service must be provided. 21 C.F.R. § 17.7(b). Nothing in the regulations require me to assume that a UPS Delivery Notification proves that the parcel

delivered to Respondent contained the complaint and not any other printed or non-printed matter handled by the carrier or nothing at all. *See T and M United Corporation d/b/a BP Shop*, DAB No. 2705 (2016).

Respondent may, in its response or answer to the complaint, raise a challenge to jurisdiction or defective service. However, if Respondent files a response or answer that does not specifically challenge jurisdiction, then Respondent is considered served and subject to the jurisdiction of this Court.

While Respondent's argument about the ineffective service of the Notice of Compliance Check may be considered in the mitigation of penalty, it has no merit in determining liability. In its Answer, Respondent stated it is "unable to confirm or deny" the allegations of February 13, 2016 and points to the lack of notice as a reason it is unable to confirm or deny the allegations. The regulations provide that in its answer, Respondent "[s]hall admit or deny each of the allegations of liability made in the complaint; *allegations not specifically denied in the answer are deemed admitted.*" 21 C.F.R. § 17.9(b)(1) (emphasis added). Therefore, because Respondent did not expressly deny the allegations in the complaint, it is deemed admitted.

Respondent, in the hearing and in its post-hearing brief, argued that Complainant did not establish that the tobacco products were in interstate commerce at any point in time.

I find this argument to be without merit. While Respondent is correct that Complainant seeks relief under 21 U.S.C. § 333(f)(8), there is nothing in that statute that requires Complainant to show that the tobacco products were held in interstate

commerce.

The Act authorizes FDA to assess civil money penalties under 21 U.S.C. §333(f)(9) for any violations of the Act related to tobacco products. 21 U.S.C. § 331(k), in turn, prohibits doing an act that causes the misbranding of tobacco products while they are held for sale after shipment in interstate commerce; thus, Complainant must prove that the tobacco products traveled in interstate commerce in its civil money penalty cases.

However, Complainant is not seeking a civil money penalty. Rather, Complainant is asking for an NTSO, authorized by 21 U.S.C. § 333(f)(8). In relevant part, 21 U.S.C. §333(f)(8) states “[i]f the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 387f(d) of this title at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet.” Section 387f(d) authorizes the 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). Nothing in 21 U.S.C. § 333(f)(8), 21 U.S.C. § 387f(d), or the applicable regulations requires Complainant to demonstrate that the tobacco products were held in interstate commerce. Accordingly, Complainant need only to show that there have been five or more repeated violations of regulations found at 21 C.F.R. § 1140.

Therefore, so long as Respondent is found in repeated violation of the regulations found at 21 C.F.R. 1140, an NTSO may be imposed.

XII. LIABILITY

When a retailer such as Respondent is found to have committed repeated

violations of the regulations promulgated under section 387f(d), a no-tobacco-sale-order may be imposed. 21 U.S.C. § 333(f)(8).

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 C.F.R. § 1140.14(a)(1), in that a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes on February 13, 2016, at approximately 12:37 PM as set forth in the complaint.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 C.F.R. § 1140.14(a)(2)(i) on that same date in that Respondent also 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 set forth above on February 13, 2016 counts as two (2) additional repeated violations under FDA policy for purposes of computing penalty in this matter. *See Guidance for Industry*, at 13-15. Respondent was previously found liable for two (2), and admitted to two (2), violations of FDA policy in the relevant timeframe.

Accordingly, I find and conclude that Respondent is liable for six (6) repeated violations of FDA policy in a thirty-six (36) month period.

XIV. PENALTY

There being liability under the relevant statute, I must now determine the appropriate penalty to impose. NTSOs are authorized at 21 U.S.C. § 333(f)(8). The section allows for the imposition of an NTSO against a person who has committed

“repeated violations” of restrictions on the sale of tobacco products, promulgated under section 387f(d). 21 U.S.C. § 333(f)(8). The term “repeated violations” is defined to mean “at least 5 violations of particular requirements over a 36-month period at a particular retail outlet” *See* FDA Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers: Guidance for Industry (December 2016) at 3, 5-6, *available at* <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm447308.htm>.

In its Complaint, Complainant sought a thirty (30) day NTSO against Respondent for six (6) repeated violations of the Act and its implementing regulations within a thirty-six (36) month period. In its Post-Hearing Brief, Complainant continued to assert that a thirty (30) day NTSO is appropriate. Complainant’s Post Hearing Br. at 5.

Respondent objects to the thirty (30) day NTSO. Respondent requests that the NTSO be denied, or that I consider an NTSO of minimal duration in addition to an appropriate CMP. Resp. Post Hearing Br. at 3.

As discussed, I found that Complainant met its burden by a preponderance of the evidence and concluded that Respondent committed six (6) repeated violations of the Act and its implementing regulations within a thirty-six (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 (3) repeated violations of selling tobacco products to minors and three (3) repeated violations for failure to verify, by means of photo identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age, totaling six (6) repeated violations of the tobacco violations. 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

Respondent has presented evidence regarding the effect of an NTSO on its ability to do business. Respondent has argued that legitimate tobacco sales account for a large majority of its profits. Respondent has presented evidence of its tax returns, indicating its annual gross profits. However, none of the data presented by Respondent has shown what portions of its profits are derived from the sale of tobacco products.

C. History of Prior Violations

The current action is the third brought against Respondent for violations of the Act and its implementing regulations. On June 10, 2014, Complainant initiated the first civil money penalty action, CRD Docket Number C-14-1217, FDA Docket Number FDA-2014-H-0719, 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 first

action concluded with an Initial Decision and Default Judgment finding Respondent liable for the violations. Complaint ¶ 8.

On April 6, 2015, Complainant initiated its second civil money penalty action against Respondent, CRD Docket Number C-15-1875, FDA Docket Number FDA-2015-H-1044, against Respondent. 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). Complaint ¶ 9. Respondent settled the prior complaint with Complainant for \$2,500. R. Pre-Hearing Br. at 3.

Respondent's history of noncompliance demonstrates its continued inability to comply with the federal tobacco regulations.

D. Degree of Culpability

Respondent has been found liable for two (2), and admitted to two (2), repeated violations of the Act. In addition, I have found Respondent committed the most recent violations in the current complaint. Therefore, I hold it fully culpable for six (6) 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 un rebutted evidence of a new VeriFone system installed on its register that will help ensure accuracy in checking identification for the sale of tobacco products. Resp. Post-Hearing Br. at 2-3.

Specifically, the VeriFone system, installed in July 2016, requires the store clerk to enter the purchaser's date of birth or scan the purchaser's license before completing a tobacco product sale. *Id.*

In addition, Respondent presented un rebutted testimony it is unable to confirm or deny that its employee sold tobacco to a minor under the age of 18 on February 13, 2016 because it did not receive the Notice of Compliance Check Inspection in a timely manner. Specifically, Respondent argued that the Notice of Compliance Check was signed for by an individual by the name of "ELI." Respondent's un rebutted testimony that ELI is not the owner of the business nor the registered agent and that Respondent does not, nor has it ever, employed anyone named ELI. Respondent also took issue that the Notice of Compliance Check Inspection was not delivered for thirteen (13) days. Specifically, Respondent argued that the thirteen (13) days substantially prejudiced Respondent's ability to defend the allegations because it was unable to preserve the videotapes from its surveillance system. Complainant provided no evidence that ELI is related to Respondent in any way.

In this instance, I find and conclude Complainant's ineffective service of process prejudiced Respondent's ability to defend the claim. Had an objection to service of process been raised as a preliminary objection to service and jurisdiction, we may have reached a different conclusion. Respondent failed to raise the matter preliminarily and by filing its answer waived objection to service of process and jurisdiction.

F. Penalty

Based on the foregoing reasoning, I conclude that a two (2) day NTSO and a

\$7,500 civil money penalty is appropriate under 21 U.S.C. § 333(f)(8). I find a two (2) day NTSO appropriate as Respondent was substantially prejudiced by not receiving proper service of the February 13, 2016 Notice of Compliance Check Inspection. Furthermore, I find that the CMP is appropriate as it is the amount of a CMP for six violations of the regulations less the cost of installing the VeriFone system.⁸

XV. CONCLUSION

Respondent committed six (6) repeated violations in a thirty-six (36) month period as set forth in the Complaint.

Respondent is liable for a two (2) day NTSO and a civil money penalty of \$7,500. *See* 21 C.F.R. § 17.2.

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

- a. I find Respondent has been served with process herein and is subject to this forum.
- b. I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 387f(d), specifically 21 C.F.R. §§ 1140.14(a)(1) and (a)(2)(i) on February 13, 2016, in that a person younger than 18 years of age was able to purchase a package of Newport Box 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. § 387f(d), specifically 21 C.F.R. §§ 1140.14(a)(1) and (a)(2)(i) on March 9, 2013, November 2, 2013, and December 5, 2014, as stipulated in the settlement agreement of the most recent action. CRD Docket Number C-15-1875, FDA Docket Number FDA-2015-H-1044.
- d. I find and conclude Respondent committed six (6) repeated violations of the regulations within a thirty-six (36) month period.

⁸ Respondent presented evidence that it spent \$3,500 to purchase and install the VeriFone system.

- e. I find and conclude Respondent was prejudiced in its ability to defend against this claim by reason of Complainant's ineffective service of process, but waived objection to service and jurisdiction by filing an answer which failed to raise the objections.

- f. I assess a two (2) day No-Tobacco-Sale-Order and a monetary penalty in the amount of \$7,500.

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