

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

Center for Tobacco Products,
Complainant

v.

Mike Petroleum Inc.
d/b/a Plaza BP,
Respondent.

Docket No. T-17-2605
FDA Docket No. FDA-2017-R-1275

Decision No. TB2306

Date: December 18, 2017

DECISION

Found:

- 1) 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) on October 27, 2016 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 seven (7) repeated violations in a thirty-six (36) month period as set forth hereinabove.
- 4) Respondent is hereby assessed a twenty-eight (28) day No Sale Tobacco Order (NTSO) and a civil penalty in the amount of \$9,575.

Glossary:

ALJ
CTP/Complainant
FDCA

administrative law judge¹
Center for Tobacco Products
Federal Food, Drug, and Cosmetic Act

¹ See 5 C.F.R. § 930.204.

FDA	(21 U.S.C.A. Chap. 9)
HHS	Food and Drug Administration
OSC	Dept. of Health and Human Services
PO	Order to Show Cause
POS	Procedural Order
Respondent	UPS Proof of Service
TCA	Mike Petroleum Inc. d/b/a Plaza BP
	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 March 1, 2017 alleging that FDA documented seven (7) repeated violations within a thirty-six (36) month period.

Mike Petroleum Inc. d/b/a Plaza BP was served with process on March 2, 2017 by United Parcel Service. Respondent filed an Answer on April 11, 2017 in which it admitted the current allegations and requested a reduction in the NTSO.

I conducted a hearing on September 12, 2017.

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).

CTP filed its post-hearing brief on November 16, 2017. Respondent filed its post-hearing brief on November 17, 2017.

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 and 21 C.F.R. § 1140.14(a)(2)(i).

V. ISSUES

Respondent admits to violating 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 alleged in the complaint.

Is a six (6) month NTSO appropriate?

VI. ALLEGATIONS

A. Complainant's Recitation of facts

CTP alleged that Respondent owned an establishment, doing business under the name Plaza BP, located at 6220 Reisterstown Road, Baltimore, Maryland 21215.

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 during an inspection of Plaza BP conducted on October 27, 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 October 27, 2016, at approximately 4:29 PM; and

- b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on October 27, 2016, at approximately 4:29 PM.

B. Respondent's recitation of facts

In its Answer and subsequent filings, Respondent admitted the violations as alleged.

VII. PRIOR VIOLATIONS

On July 28, 2016, CTP initiated the first No Tobacco Sale Order action, CRD Docket Number T-16-1503, FDA Docket Number FDA-2016-R-2292, against Respondent for five (5) repeated violations of 21 C.F.R. pt. 1140 within a thirty-six (36) month period. CTP alleged those violations to have occurred at Respondent's business establishment on July 31, 2014, March 10, 2015, and October 16, 2015 as follows:

- a. Sale to a minor (21 C.F.R. § 1140.14(a)(1)) on July 31, 2014, March 10, 2015, and October 16, 2015; 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 July 31, 2014, and October 16, 2015.

The previous action concluded in settlement where Respondent “admit[ted] all of the allegations in the Complaint and agreed to an NTSO, and the ALJ issued the NTSO for the agreed-upon time period.” Further, “Respondent expressly waived its right to contest such violations in subsequent actions.”

I find and conclude Respondent committed seven (7) repeated violations of 21 U.S.C. § 331, specifically four (4) repeated violations of 21 C.F.R. § 1140.14(a)(1) and three (3) repeated violation of 21 C.F.R. § 1140.14(a)(2)(i) based on the conduct as set forth in the prior complaint (CRD T-16-1503, FDA-2016-R-2292).

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/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.

IX. HEARING

The hearing in this matter was held on September 12, 2017 by telephone as set forth in my July 10, 2017 Order of the Court.

James Fraser, Esquire, appeared on behalf of Complainant.

Darrell Chambers, Esquire, appeared on behalf of Respondent.

Witness Jante Reaves testified on behalf of Complainant by way of a sworn affidavit.

Witness Micael Goitom testified on behalf of Respondent by way of a sworn affidavit and live testimony at the hearing. Mr. Goitom's wife, Hiwot Woreta, assisted with Mr. Goitom's testimony.

X. SUMMARY OF TESTIMONY AND EVIDENCE

A. Complainant's case

Complainant submitted evidence and testimony in form of written declarations and photographs. Complainant offered CTP Exhibits 1 through 15, inclusive, the exhibits were marked for identification. Respondent did not object to the exhibits. I admit Complainant's Exhibits 1 through 15, inclusive.

i. Inspector Janet Reaves

Witness Janet Reaves, the FDA-commissioned Inspector who conducted the inspection of Respondent's establishment on October 27, 2016 testified on behalf of

Complainant. Complainant provided Inspector Reaves's written direct testimony as CTP Ex. 15.

Inspector Reaves testified that on October 27, 2016, at approximately 4:29 PM, she and the minor conducted the follow-up compliance inspection at Respondent's establishment Plaza BP, located at 6220 Reisterstown Road, Baltimore, Maryland 21215. Before the inspection, Inspector Reaves physically examined the minor's photographic identification (ID) and prior to entering the establishment Inspector Reaves assured that that the minor had an ID and did not have any tobacco products. CTP Ex. 15 at 2-3.

According to her testimony, Inspector Reaves accompanied the minor into Respondent's establishment and took a position where she had an obstructed view of the sales counter and the minor. CTP Ex. 15 at 3. Inspector Reaves observed that the minor did not give an ID to the clerk. The inspector testified that he witnessed the exchange of money and the clerk provide the minor with a package of cigarettes. CTP Ex. 15 at 3.

The minor exited the establishment and the inspector followed several seconds later. Both returned to the vehicle where immediately upon entering, the minor handed the inspector the package of Newport Box 100s cigarettes. Inspector Reaves processed the evidence according to procedure and completed a narrative report. CTP Ex. 15 at 3-4.

B. Respondent's case

Respondent submitted four exhibits marked as Resp. Exs. 1-4. CTP did not object to any of Respondent's exhibits. I admit Resp. Exs. 1-4, inclusive.

i. Mr. Micael Goitom

Mr. Micael Goitom, Respondent's owner and manager, testified on behalf of Respondent. Mr. Goitom testified that he has owned Plaza BP since 2013 and is responsible for the store's day to day operations. Resp. Ex. 1 at 1. He testified that he has trained all employees on checking identification for tobacco sales. Resp. Ex. 1 at 2. He further testified that employees were aware that they would be terminated if they sold tobacco products to minors. Resp. Ex. 1 at 2.

Mr. Goitom also testified that he installed a Datalogic ID scanner in February 2017 that prevents an employee from processing a tobacco product sale without a valid identification scanned into the system. Resp. Ex. 1 at 3. He testified that the new system worked appropriately when Respondent was subject to a surprise inspection by the local government in July 2017. Resp. Ex. 1 at 3.

Mr. Goitom testified that Respondent is a small store that locals frequent to purchase cigarettes and gas. Resp. Ex. 1 at 3. However, he also testified that there are three other gas stations with convenience stores in the same area that compete directly with Respondent. Resp. Ex. 1 at 3. Mr. Goitom explained that if Respondent is unable to sell cigarettes for 6 months, the business will likely fail and will have to be sold. Resp. Ex. 1 at 3-4. Mr. Goitom testified that during Respondent's previous NTSO, the business lost \$2,281.07 every day. Resp. Ex. 1 at 4.

Mr. Goitom also testified about sales figures exhibits attached to his sworn affidavit to show the potential increase in income loss with a new No Sale Tobacco Order. Hr. Tr. at 10. During cross examination, Mr. Goitom admitted that some of his

receipts for September and October 2016 were missing and that some of his calculations were off for August 2016. Hr. Tr. at 14-20. Mr. Goitom also admitted that his monthly income numbers fluctuate based on fuel prices. Hr. Tr. at 22.

C. Credibility determinations

Mr. Goitom's initial calculations for August 2016 were corrected and resubmitted with Respondent's post hearing brief. As a result, I find and conclude testimony and evidence by both parties was credible.

XI. RULING ON ADMISSIBILITY OF EVIDENCE

Complainant offered and I received into evidence Exhibits 1 through 15, inclusive. Respondent offered and I received into evidence Exhibits 1 through 4, inclusive. There were no objections to the exhibits.

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 15, inclusive.

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

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

B. Respondent's case

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 violations on October 27, 2016 occurred as alleged. However, Respondent argues that a six month NTSO is overly punitive and will result in a closure of its business.

C. Analysis

- i. I find and conclude that Respondent committed seven (7) repeated violations in a thirty-six (36) month period

XIII. LIABILITY

When a retailer such as Respondent is found to have "misbranded" a tobacco product in interstate commerce, it can be liable to pay a civil monetary penalty.

21 U.S.C. §§ 331, 333.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R.

§ 1140.14(a)(1), in that a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes on October 27, 2016, at approximately 4:29 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 U.S.C. § 331, specifically 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 October 27, 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 previously admitted to five (5) repeated violations of FDA policy in the relevant timeframe. Accordingly, I find and conclude that Respondent is liable for seven (7) 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. 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 to a six (6) month NTSO against Respondent for seven (7) repeated violations of the Act and its implementing regulations

within a thirty-six (36) month period. In its Post-Hearing Brief, CTP continued to assert that a six (6) month NTSO is appropriate. Complainant's Post Hearing Brief at 3.

Respondent objects to the six (6) month NTSO and instead requests that a three (3) week NTSO be imposed as well as a substantial 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 seven (7) 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 four repeated violations of selling tobacco products to minors, and three repeated violations for failure to id, totaling seven 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

Respondent has presented extensive evidence regarding the effect of a six month NTSO on its ability to do business. Respondent has argued that prohibiting it from selling tobacco six month is essentially a death sentence. Respondent has shown that the

inability to sell tobacco products for six months will drive its customers to surrounding businesses and that they would be unlikely to return.

C. History of Prior Violations

The current action is the fourth action brought against Respondent for violations of the Act and its implementing regulations. On January 23, 2015, CTP initiated the first civil money penalty action, CRD Docket Number C-15-992, FDA Docket Number FDA-2015-H-0178, 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 violations occurred on March 27, 2014, and July 31, 2014. 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 5.

On July 22, 2015, CTP initiated the second civil money penalty action, CRD Docket Number C-15-3262, FDA Docket Number FDA-2015-H-2422, 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). The violation occurred on March 10, 2015. CTP Ex. 2 at 6-8. Respondent settled the second prior complaint with CTP for an undisclosed penalty amount and admitted that the violations occurred as described in the complaint. Complaint at 5.

On July 28, 2016, CTP initiated the first No Tobacco Sale Order action, CRD Docket Number T-16-1503, FDA Docket Number FDA-2016-R-2292. In the third action, Respondent again violation 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 violations occurred on October 16, 2015. Respondent settled the third prior complaint with CTP for an NTSO for the agreed upon time and admitted that the violations occurred as described in the complaint. Complaint at 6.

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

Respondent has admitted to all of the violations including the violations alleged in the current Complaint. Based on my finding that Respondent committed the most recent violation in the current complaint, I hold it fully culpable for seven (7) 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. Resp. Ex. 1 at 2. Respondent also had a new system installed on its register that will help ensure accuracy in checking identification for the sale of tobacco products. Specifically, Respondent had a Datalogic ID scanner installed in February 2017 that prevents the sale

of tobacco products without scanning a valid identification into the system. Resp. Ex. 1 at 4.

F. Penalty

Based on the foregoing reasoning, I conclude that a twenty-eight (28) day NTSO and a \$9,575 civil money is appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9). I find this penalty appropriate as it represents an increase a punitive in the length of the prior NTSO and a penalty amount equal to an additional day of Respondent's sales.⁴

XV. CONCLUSION

Respondent committed seven (7) repeated violations in a thirty-six (36) month period as set forth in the Complaint.

Respondent is liable for a twenty-eight (28) day NTSO and a civil money penalty of \$9,575. *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) and (a)(2)(i) on October 27, 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. § 331, specifically 21 C.F.R. § 1140.14(a)(1) on March 27, 2014, July

⁴ As noted above, Respondent's post hearing brief includes updated sales figures for July 2017. These figures show an average daily income of \$2,434.11 in merchandise and \$7,139.02 in fuel sales.

31, 2014, March 10, 2015, and October 16, 2015, and 21 C.F.R. § 1140.14(a)(2)(i) on March 27, 2014, July 31, 2014, and October 16, 2015 as stipulated in the settlement agreement of the most recent action, CRD Docket Number T-16-1503, FDA Docket Number FDA-2016-R-2292; and

- d. I find and conclude Respondent committed seven (7) repeated violations of the regulations within a thirty-six (36) month period; and
- e. I assess a twenty-eight (28) day No Sale Tobacco Order and a civil monetary penalty in the amount of \$9,575.00

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