

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-R-6130)

Complainant

v.

BKD Oil, Inc.
d/b/a Maplecrest Marathon / Food Center,

Respondent.

Docket No. T-18-122

Decision No. TB2957

Date: August 3, 2018

INITIAL DECISION

Introduction:

The Center for Tobacco Products (Complainant or CTP) presented sufficient evidence and testimony to prove that BKD Oil Inc. d/b/a Maplecrest Marathon / Food Center (Respondent) committed five repeated violations of the Food & Drug Administration (FDA) tobacco regulations within a 36-month period. Respondent is found responsible for its violations and is ordered to stop selling cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and covered tobacco products, regulated under the Federal Food, Drug, and Cosmetic Act, for a period of 20 consecutive days.

Background:

On October 16, 2017, Complainant served its complaint with cover letter on Respondent, through United Parcel Service, at Respondent's business address located at 6303 Stellhorn Road, Fort Wayne, Indiana 46815. On October 17, 2017, Complainant filed a

copy of the complaint, cover letter and proof of service with this court. Departmental Appeals Board E-File Docket (Dkt.) Entries 1, Complaint; 1_a, Cover Letter; and 1_b, Proof of Service. On November 15, 2017, Respondent's Counsel filed its notice of appearance and answer to the complaint. Dkt. Entries 3, Notice of Appearance; and 3_a, Answer. An acknowledgement and prehearing order issued on November 30, 2017, which gave the parties the deadline dates for several filings, including the dates for exchanges. Dkt. Entry 4, Acknowledgment and Pre-Hearing Order. Complainant and Respondent each filed its exchange by the deadline dates. After that, an order issued scheduling the hearing and giving the parties until April 27, 2018, to file any objections to the exhibits submitted as evidence in this case. Dkt. entry 11, Order Scheduling In-Person Telephone Hearing. Neither party filed any objections. On May 1, 2018, Respondent filed a Notice of Waiver of Hearing, and asked that a decision be made based solely on the administrative record. Dkt. Entry 12, Notice of Waiver of Hearing. Complainant agreed and both parties later filed final briefs. The administrative record is now complete and this case is ready for decision.

Allegations/Penalty Proposed:

Complainant claims that Respondent has repeatedly violated the regulations authorized by the Federal Food, Drug and Cosmetic Act (Act). Specifically, Complainant claims that Respondent repeatedly sold cigarettes or smokeless tobacco to minors (persons younger than 18 years old), in violation of 21 C.F.R. § 1140(a)(1)¹. Complainant also claims that Respondent repeatedly failed to verify, by means of photographic identification, that no buyer was younger than 18 years old, in violation of 21 C.F.R. § 1140(a)(2)(i). Complaint at 1-2. As a penalty for the alleged violations, Complainant asks for a No-Tobacco-Sale Order (NTSO) for a 30 consecutive day period. *Id.*

Legal Standards:

Regulation 21 C.F.R. §17.33 states that Complainant must prove, by a preponderance of the evidence, that Respondent is liable for its actions and that the assessed penalty is appropriate. In meeting the preponderance of the evidence standard, the Complainant must show that what it alleges in its complaint is more likely than not true, and the penalty it seeks is fitting. Finding the Respondent liable simply means that the court has determined that Respondent is responsible for its actions.

This regulation also provides that the Respondent must prove its affirmative defenses and mitigating factors by the same preponderance of the evidence standard.

¹ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

The law at 21 U.S.C. § 331(f)(5)(B) requires that when determining the period to be covered by a no-tobacco-sale order, such factors as the nature, circumstances, extent, and gravity of the violation or violations and the effect on the violators ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require, must be taken in account.

Evidence:

As part of its exchange, Complainant offered as evidence an Informal Brief, an exhibit list, and 14 exhibits (CTP Ex. 1-14 inclusive). Complainant also submitted a Final Brief. Without any objections, Complainant's evidence is admitted.

As part of its exchange, Respondent offered as evidence an Informal Brief, an exhibit list, and nine exhibits (Res. Ex. 1-9 inclusive). Respondent also offered a Final Brief with one exhibit (RFB Exh. 1). Without any objections, Respondent's evidence is admitted.

Issues:

1. On June 20, 2017 at approximately 7:33 p.m., as alleged in the complaint:
 - a. Did Respondent commit a repeated violation of 21 C.F.R. § 1140.14(a)(1) by selling cigarettes to a minor?
 - b. Did Respondent commit a repeated violation of 21 C.F.R. § 1140.14(a)(2)(i) by failing to verify, by means of photographic identification, that the buyer was 18 years old or older?
2. If Respondent did commit the claimed repeated violations, is a 30-consecutive day No-Tobacco-Sale Order a fitting penalty?

Analysis:

Complaint/Answer:

a. Complaint

Complainant asserts that on June 20, 2017, an inspector working on behalf of FDA, conducted an inspection of Respondent's business located at 6303 Stellhorn Road, Fort Wayne, Indiana 46815. Complaint at 3-4. It further claims that during that inspection, Respondent violated the regulations that prohibit retailers from selling cigarettes to minors. *Id.* at 4. It also alleges that during the inspection, Respondent failed to verify the age of the buyer by means of photographic identification containing the buyer's picture and date of birth. *Id.* Complainant claims that these two types of violations have happened before at Respondent's business, and that Respondent admitted to those prior violations, paid the required penalties and gave up its right to challenge those violations

again in the future. *Id.* at 5-6. Lastly, Complainant states that it warned Respondent and all retailers that a 30 consecutive day No-Tobacco-Sale Order may be requested when the business has five or more repeated violations of the rules within a 36-month period. *Id.* at 3.

b. Answer

Respondent objects to a restriction on selling tobacco products for any period of time. Answer at 1. Respondent disputes Complainant's claim that it has had five repeated violations and argues that Complainant has "improperly" counted the "incidents." *Id.* Respondent states that it "has had three (3) violations in a thirty six (36) month period. *Id.* Respondent suggests that the "violations which occurred involved rogue employees [who] have been terminated since their incident[s]." *Id.* Respondent admits "the current status of the law" and admits "that CTP has provided public notice to the retailer" about committing five or more repeated violations and the resulting penalties. *Id.* at 3. Respondent confirms that it owns and does business under the name and address listed in the complaint. *Id.* Respondent states that it is "unaware" and "without knowledge...regarding the June 20, 2017 incident" and "therefore denies" the claims made in the complaint. *Id.* Respondent did, however, also contend that it "believed that two (2) rogue employees...may have intentionally sold tobacco to minors to try and get [the business] in trouble or to otherwise 'stick it to the owners'." *Id.* Respondent admits that it had prior violations and has "been the subject of two (2) prior CTP actions" as stated in the complaint. *Id.* at 3-4. Lastly, Respondent asks that this court "not impose any type of no-tobacco-sale order" because it would be "financially crippling" and would "potentially put them out of business." *Id.* at 4.

Complainant's Case:

Among other things, Complainant submitted an Informal Brief of the Complainant (IBC). In this brief, Complainant contends that has "met its burden of proving that Respondent committed five repeated violations of FDA's tobacco regulation in a 36-month period and that a 30-consecutive day no-tobacco-sale order is an appropriate penalty in this case." IBC at 1. Complainant argues that "[i]n light of Respondent's multiple repeated violations, as well as its unwillingness or inability to correct its violative (sic) actions, an NTSO is necessary in order for Respondent to grasp the seriousness and importance of the requirements related to the sale of tobacco products." IBC at 12-13. Complainant further argues that it "sought the 30-consecutive day NTSO in this case because it is... appropriate here because Respondent violated the tobacco regulations seven times in a nineteen-month period, between November 10, 2015, and June 20, 2017." *Id.* at 15. Complainant asserts that it "reminded Respondent about its responsibilities under the law, directed Respondent to resources to help ensure compliance with the law, and notified Respondent that a future violation could result in a civil money penalty, or other enforcement actions." *Id.* at 16.

To prove its case, Complainant submitted several documents, including the sworn statement of inspector Jason L. Baker (CTP Ex. 14). This detailed written testimony describes Inspector Baker's account of what he saw on June 20, 2017. Inspector Baker states that when he conducted a follow-up undercover buy compliance check inspection at Respondent's business location, he took a photograph of Respondent's business sign and confirmed the name of the business before the inspection. *Id.* at 2-3. Along with the inspector were a chaperone and a person younger than 18 years old, who the inspector calls "Minor A." *Id.* at 3. The inspector asserts that before the inspection, he confirmed that Minor A did not have any tobacco products or identification. *Id.*

The inspector described the buy as follows: 1.) He and Minor A entered Respondent's business together while the chaperone remained in the car; 2.) He positioned himself for an "unobstructed view" of the buy; 3.) He saw Respondent's staff sell Minor A tobacco products without Minor A showing any identification before the sale; 4.) Minor A left the store before him to return to the car; and 5.) Immediately after entering the car, Minor A handed him the tobacco products purchased in Respondent's business. CTP Ex. 14.

Complainant included a copy of Minor A's identification; a picture of Respondent's business sign; a picture of the tobacco products bought from Respondent's business, before and after being placed in the evidence bag; and a copy of the report made by the inspector and uploaded minutes after the buy. CTP Ex. 4-9, inclusive.

Lastly, Complainant's Final Brief (CFB) argues that "Respondent has paid civil money penalties for prior violations, yet it has continued to violate the law...[therefore]...a 30-day NTSO is a necessary and appropriate consequence for Respondent's continued illegal behavior that has constituted a risk to the public health." CFB at 2-3.

Respondent's Case

Among other things, Respondent submitted an Informal Brief of the Respondent (IBR). In this brief, Respondent contends that Complainant "has not and cannot meet its burden of proving that Respondent committed five (5) repeated violations of FDA's tobacco regulation in a thirty six (36) month period." IBR at 1. Respondent argues that the "complaint improperly double counts incidents on December 8, 2016 and June 20, 2017 to obtain the necessary five (5) repeated violations." *Id.* Respondent insists that it only "has had three (3) violations in a thirty six (36) month period." *Id.* Respondent further asserts that the claimed violations "involved rogue employees...[who] have been terminated since the incident." *Id.* at 1-2.

Respondent denies that it "knowingly or intentionally" sold tobacco products to a minor or minors under the age of 18 as alleged, and states that it has "never been provided any proof that [the violations] occurred." IBR at 3. Respondent offered one affirmative

defense to Complainant's claims, when it stated that "it is possible that a false or fake identification was used." *Id.* at 4.

Respondent also offered several mitigating factors. For example, Respondent says that it "has made it a point of emphasis with [its] employees to ID everyone buying tobacco products regardless of their age" and has "instituted a mandatory training program regarding the sale of tobacco products." IBR at 2. Respondent contends that its handbook "informs all employees" of its "zero tolerance policy and employees are warned: 'IF YOU SELL TO A MINOR, PLAN ON LOSING YOUR JOB. PLAN ON BEING CRIMINALLY CHARGED.'" *Id.*

Respondent further states that it "invested thousands of dollars in new software...to prevent [its] employees from selling tobacco products to minors." IBR at 2. According to Respondent, the new software "forces the employee to either scan the customer ID or enter the date of birth to insure the person is of legal age to purchase" when "the tobacco product is scanned for purchase." *Id.* Respondent also submits that "[n]ew cameras were installed to insure that the owners could catch anyone trying to sell to minors and prevent the sale and/or terminate the clerk immediately." *Id.* Further, Respondent states that "signs are posted near the register informing customers and employees that they must be 18 years of age to buy tobacco products." *Id.*

Respondent contends that it "is extremely concerned that any type of NTSO would bankrupt" its business. IBR at 3. Respondent argues that "banning the sale of tobacco products for any period of time would be financially crippling...and would potentially put [it] out of business." *Id.* Respondent explains that it is "concerned that a ban of selling tobacco for any period of time would severely diminish its repeat customer base and be a bigger financial penalty than just losing revenue for a certain number of days of business." *Id.* Respondent also states that it "has done everything it can to prevent further sale of tobacco to minors by employees...[and] is open to other suggestions as to how to prevent employees from selling tobacco to minors in the future." *Id.*

Respondent included a copy of the business employee handbook; a picture of the cash register with the new software system; pictures of the installed cameras; pictures of signs that notify customers they must be 18 years old to buy tobacco products; financial documents that show Respondent's cigarette sales and total department sales. Res. Ex. 1, 4-12, and 15, respectively.

Respondent also filed a Respondent Final Brief (RFB). In that brief, Respondent states that it has hired a private company to spot check their employees to make sure they are not selling tobacco to minors. RFB at 1. Respondent argues "that the thirty (30) day NTSO would be an undue burden to [the business] and as such, is not appropriate in light of the seriousness of the alleged violations." *Id.* Further, Respondent "respectfully asserts that a financial penalty in the amount of \$5,000.00 which would be equal to the

profit lost from the sale of tobacco for thirty (30) days, would be a more appropriate penalty.” RFB at 1-2. Alternatively, “Respondent suggests that an NTSO be issued for two (2) days or some combination of a lesser NTSO plus a fine.” *Id.* at 3.

Respondent included a copy of an email showing its enrollment in the “We Card ID CHECK-UP Service.” RFB Ex. 1.

Discussion:

a. Prior violations

As stated in the Informal Brief of the Complainant (IBC), this is the third case CTP has brought against Respondent for its sale of tobacco products to persons younger than 18 years old and failure to confirm the age of the buyers. IBC at 2. Two prior civil money penalty (CMP) actions were brought by Complainant against Respondent for violations occurring on November 10, 2015, March 10, 2016 and December 8, 2016. *Id.* at 3. Respondent argues “The Complaint improperly double counts incidents on December 8, 2016 and June 20, 2017 to obtain the necessary five (5) repeated violations in an effort to impose a NTSO.” IBR at 1. I note, however, that in both CMP actions, Respondent admitted the violations of selling tobacco products to minors and failing to confirm, by asking for identification, that no buyer was younger than 18 years old. IBC at 3-4. By virtue of these admissions, Respondent gave up its right to future challenges of these violations. Complainant correctly notes, “Respondent’s liability for the [prior] violations is administratively final” and is not available for review in this case. *Id.* at 3. Because the violations that occurred before June 20, 2017, are not open for review, Respondent’s argument challenging the December 8, 2016 violations is barred.

b. Violation count

Even if Respondent were allowed to raise the December 8, 2016, violations as part of its argument about the count used to meet the threshold for the penalty sought, Respondent’s argument would still fail. As pointed out in Complainant’s Final Brief (CFB), “CTP’s counting scheme, which was followed in this case, has been upheld both by the Departmental Appeals Board in *Orton Motor, Inc. d/b/a Orton’s Bagley*, DAB No. 2717, 2016 WL 4076361 (H.H.S. June 30, 2016) and by the United States Court of Appeals for the District of Columbia Circuit in *Orton Motor, Inc. d/b/a Orton’s Bagley v. United States Department of Health and Human Services*, 884 F.3d 1205 (D.C. Cir. 2018).”

c. Current violations

This case, solely focuses on the violations which Complainant claims occurred on June 20, 2017. In order to prevail, Complainant must show that the alleged violations occurred. The evidence Complainant provided in this case convincingly shows that Respondent committed the claimed violations. Inspector Baker’s sworn statement says that he had an unobstructed view of the sales counter and the minor. CTP Ex. 14 at 2. His eyewitness testimony is believable and the supporting evidence appears to be true.

Complainant met its burden of proving that Respondent committed the violations at issue. Respondent did not make any statements or offer any evidence to dispute the testimony and evidence submitted by Complainant.

Instead, Respondent's arguments tend to support a finding that the violations as alleged occurred on June 20, 2017. Respondent argues that it either didn't "knowingly or intentionally" commit the violations, or in the alternative, that the violations were committed by "rogue employees" who wanted to "stick it to the owner." It appears that both arguments are made by Respondent in an attempt to relieve it of its liability, but these arguments actually have the opposite effect, and they both fail. First, whether or not the violations were committed "knowingly or intentionally" is not the standard. Complainant does not have to prove intent. Complainant only has to prove that the violations occurred, which it has done. And arguing that specific employees committed the acts to hurt the owner would actually prove that the acts were intentional. Second, as Respondent admits, the violations were committed by *employees* of Respondent's business – "rogue" or not – and that fact alone makes Respondent liable for the violations. As Complainant rightly states the "Respondent is liable for the actions of all [its] employees." CFB at 2.

Respondent also made one affirmative defense² to Complainant's claims, when it stated that "it is possible that a false or fake identification was used." IBR at 4. Respondent, however, did not offer any evidence in support of this claim, so Respondent failed to meet its burden of proving this defense.

d. Mitigating Factors

When deciding whether or not the penalty asked for is the right penalty, the court must look at the following: the nature, circumstances, extent, and gravity of the violation or violations; the effect on the violator's ability to continue to do business; any history of prior such violations; the degree of culpability; and such other matters as justice may require.

Complainant contends that "[a]ll of Respondent's violations are serious in nature" because they breach "FDA's efforts to protect minors from the multiple adverse health effects associated with tobacco use." IBC at 12. Respondent is clearly liable for its actions and the actions of its employees. Respondent has, however, provided sufficient evidence that demonstrates that after the June 20, 2017 violations, it has taken effective steps to try to prevent the violations from happening again. Respondent has shown that it has a written policy against selling tobacco products to persons under 18 years old and that it has informed its employees of the applicable laws. Respondent has done this through its training program, employee handbook, and signs at the counters. Respondent

² Respondent made other claims (e.g. entrapment), but failed to substantiate these claims with evidence, testimony or legal arguments. The claims, therefore, will not be addressed.

has also shown that it has established disciplinary consequences for employees who don't follow these rules. Respondent has already fired two employees, and its written policy clearly lists termination as a consequence of employee noncompliance. Lastly, Respondent has implemented new software that requires its employees to verify age using photographic identification, and installed cameras to monitor employee conduct. All of the actions Respondent has taken are consistent with CTP guidance for preventing additional tobacco sales to minors.

While it is understandable that Respondent is concerned about the future of its business, Respondent did not provide sufficient evidence to demonstrate that an NTSO would force it into bankruptcy or make it close its doors. Respondent provided extensive tax filings for recent years and a sales report generated on January 23, 2018. Respondent did not, however, provide any suggested interpretation of the data in the documents to demonstrate a certainty of bankruptcy or the extent of financial loss as alleged. Although Respondent asserts that a 30-day NTSO would impact sales other than tobacco products as customers may be lost during the mandatory period of the NTSO, there is not sufficient evidence more than speculation to demonstrate the impact that Respondent suggests. Respondent argues that cigarette sales constitute 65 percent of its total sales. While Respondent contends that there is a low profit margin on the sale of cigarettes, Respondent also suggests a civil money penalty of five thousand dollars (\$5,000) in lieu of a mandatory NTSO. Respondent argues that this amount would equal the profits for tobacco sales during a 30 day period. Although it is somewhat unclear how \$5,000 can constitute the profits for 65 percent of Respondent's sales for a 30 day period, I do not find the suggested penalty appropriate in lieu of the NTSO.

What Respondent is requesting as a penalty, is not an adequate penalty given its repeated violations. Respondent had ample warnings from Complainant about the consequences of repeat violations. Respondent wants to blame its employees, but ultimately, Respondent is responsible for what occurs in its business. As Complainant pointed out, Respondent "continued employment of such 'rogue' employees for many months and through several acknowledged illegal sales of tobacco to minors." CFB at 2. Also, if Respondent had implemented the preventive measures after receiving the initial warnings and civil money penalties, perhaps it could have stopped the unlawful sales to minors and avoided the imposition of an increased penalty. The penalty Respondent suggests is not appropriate given Respondent's history of previous violations and its degree of culpability. I find, however, that Respondent has taken very deliberate steps to prevent these unlawful sales from reoccurring. On June 23, 2017, Complainant issued a Notice of Compliance Check Inspection notifying Respondent of the June 20, 2017 inspection and the alleged violations. Respondent submitted evidence to show that by mid-July 2017, Respondent installed new software that imposed age verification before the sale of tobacco products. The installation of this software, along with the posting of numerous signs and the installation of extension security cameras are demonstrable signs that

Respondent has attempted to prevent further unlawful sales. For that reason, I find that it is appropriate to reduce the penalty sought by the Complainant.

Findings of Fact:

Complainant has met its burden of proving, by a preponderance of the evidence, that Respondent committed a repeated violation of 21 C.F.R. § 1140.14(a)(1), when it sold cigarettes to a person younger than 18 years old on June 20, 2017.

Complainant has met its burden of proving, by a preponderance of the evidence, that Respondent committed a repeated violation of 21 C.F.R. § 1140.14(a)(2)(i), when it failed to confirm, by asking for identification, that no buyer was younger than 18 years old.

Respondent has met its burden by proving, by a preponderance of the evidence, that there are mitigating factors to show that a reduced penalty is fitting.

Conclusions of Law:

Respondent committed five repeated violations of FDA's tobacco regulation in a 36-month period.

Respondent is liable for a No-Tobacco-Sale Order.

Penalty Imposed:

A No-Tobacco-Sale Order is imposed on Respondent for a period of 20 consecutive days.

Order

For these reasons Respondent is found liable for its violations and is ordered to stop selling cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and covered tobacco products, regulated under the Federal Food, Drug, and Cosmetic Act, for a period of 20 consecutive days.

IT IS SO ORDERED.

_____/s/_____
Margaret G. Brakebusch
Administrative Law Judge