

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2018-H-3745)

Complainant,

v.

Shanaz Enterprises, Inc.
d/b/a USA Food Store,

Respondent.

Docket No. T-19-36

Decision No. TB4043

Date: July 10, 2019

INITIAL DECISION

The Center for Tobacco Products (“CTP”), of the United States Food and Drug Administration (“FDA”), seeks a civil money penalty against Respondent, Shanaz Enterprises, Inc. d/b/a USA Food Store, for violations of the Federal Food, Drug, and Cosmetic Act (“Act”), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140. CTP alleges that USA Food Store violated the Act by impermissibly selling covered tobacco products to minors and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. Therefore, CTP seeks a \$559 civil money penalty against Respondent USA Food Store for three violations of the Act within a 24-month period. For the reasons set forth in this decision, I find that USA Food Store violated the Act as CTP alleged and impose a \$559 civil money penalty against Respondent.

Procedural History

CTP began this matter by serving an administrative complaint on Respondent, Shanaz Enterprises, Inc. d/b/a USA Food Store, at 8071 Southwest 7th Place, North Lauderdale, Florida 33068, and by filing a copy of the complaint with the FDA's Division of Dockets Management.

On November 2, 2018¹, Respondent timely filed an answer denying the allegations in the complaint and pleading no contest. Answer ¶ 1. On November 21, 2018, I issued an Acknowledgment and Pre-Hearing Order ("APHO") that set out the deadlines for the parties' submissions in this case, and informal briefs for the parties to complete and submit. December 12, 2018, CTP filed a Joint Status Report stating, "[t]he parties have been unable to reach a settlement in this case. CTP remains willing to engage in settlement discussions but, absent an executed settlement agreement, intends to proceed to a hearing."

On February 12, 2019, CTP timely filed its pre-hearing exchange. CTP's exchange included an Informal Brief of Complainant ("CTP Br."), a list of proposed witnesses and exhibits, and 18 numbered exhibits ("CTP Ex. 1- Ex. 18"). CTP's exhibits included written direct testimonies of two witnesses, both FDA-commissioned officers: Inspector Elie Joseph's declaration ("CTP Ex. 3"), and Inspector Krystle Kirkland-Mobley's declaration ("CTP Ex. 4"). Respondent did not submit proposed exhibits or witness testimony.

On April 5, 2019, I held a prehearing telephone conference call with the parties. During the call, I explained my role as an impartial Administrative Law Judge. I determined that Respondent is proceeding without an attorney. We discussed Respondent's Answer, and CTP's pre-hearing exchanges and witness testimony. I noted that Respondent did not submit proposed exhibits or witness testimony. Respondent communicated that he did not have video footage of the violations or additional evidence to submit. I explained that the purpose of a formal hearing is to allow for the cross-examination and re-direct of any witnesses who have provided sworn testimony in exchanges.

I apprised Respondent of CTP's two proposed witnesses and asked whether he wished to cross-examine them. Respondent declined to cross-examine CTP's proposed witnesses. The parties agreed to waive a hearing and to a decision based on the documents in the record. I explained that the parties could file supplementary briefs with additional arguments for my consideration, by a date certain. I noted that this was not an opportunity to present any new evidence that a party did not submit by the pre-hearing exchange deadlines.

¹ This was the postmark date.

On that same day, I issued a Briefing Order Admitting Evidence and Waiving Hearing. As Respondent did not object to CTP's proposed exhibits marked as CTP Ex. 1 to CTP Ex. 18, I admitted those exhibits into the record. Finally, I advised the parties that they had until May 8, 2019, to file supplemental briefs. Neither party submitted a supplemental brief. As the briefing period has passed, I find that the record is complete, and render my decision.

Issues

1. Whether Respondent sold covered tobacco products to minors and failed to verify the age of the purchasers on February 24, 2018, and July 15, 2018, in violation of 21 C.F.R. § 1140.14(b)(1) and 21 C.F.R. § 1140.14(b)(2)(i).
2. Whether the civil money penalty of \$559 that CTP seeks is an appropriate amount, considering any aggravating or mitigating factors, pursuant to the provisions of 21 C.F.R. § 17.33(a).

Applicable Regulations

The Act prohibits the misbranding of tobacco products held for sale after shipment in interstate commerce. 21 U.S.C. § 331(k). The FDA and its agency, CTP, may seek the imposition of remedies against any person who violates the Act's requirements as they relate to the sale of tobacco products. 21 U.S.C. § 333(f)(9). Under 21 C.F.R. § 1140.14(b)(1), no retailer may sell covered tobacco products to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no covered tobacco product purchasers are younger than 18 years of age.

The Act establishes factors that a presiding officer must consider in determining the civil money penalty amount. The presiding officer must "take into account the nature, circumstances, extent, and gravity of the violation or 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).

Analysis

I. Violations

In considering the first issue of whether violations of 21 C.F.R. § 1140.14(b)(1) and 21 C.F.R. § 1140.14(b)(2)(i) occurred on February 24, 2018, and July 15, 2018, I note that Respondent denied the allegations. Answer ¶ 1. However, Respondent further stated that he is pleading "no contest" and leaving the decision "up to the Judge." *Id.* A no-contest plea is not available under the applicable guidelines. While not technically an admission

of the violations under the applicable guidelines, I see it as Respondent conceding the violations without admitting culpability or presenting a defense. Since Respondent did not submit any other evidence to rebut CTP's allegations, Respondent's no contest plea leads me to conclude that the violations likely occurred.

The Complaint states that FDA commissioned inspectors conducted inspections of USA Food Store, at 8071 Southwest 7th Place, North Lauderdale, Florida 33068, on February 24, 2018, and July 15, 2018. The evidence offered by CTP, which includes the Joseph and Kirkland-Mobley declarations, corroborate the allegations in the Complaint. CTP Exs. 3, 4. Specifically, CTP alleges the following violations in its Complaint, which the declarations corroborate:

- At approximately 10:15 AM on February 24, 2018, at Respondent's business establishment, at 8071 Southwest 7th Place, North Lauderdale, Florida 33068, an FDA-commissioned inspector documented Respondent's staff selling a Black & Mild cigar to a person younger than 18 years of age. The inspector also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older. Complaint ¶ 11; CTP Ex. 3 ¶¶ 7-9; CTP Br. at 5-7.
- In a warning letter dated April 5, 2018, CTP informed Respondent of the inspector's February 24, 2018 documented violations, and that such actions violate federal law. The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action. Complaint ¶¶ 11-12; CTP Ex. 1.
- At approximately 12:17 PM on July 15, 2018, at Respondent's business establishment, at 8071 Southwest 7th Place, North Lauderdale, Florida 33068, an FDA-commissioned inspector documented Respondent's staff selling a Black & Mild cigar to a person younger than 18 years of age. The inspector also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older. Complaint ¶ 9; CTP Ex. 4 ¶¶ 7-9; CTP Br. at 7-9.

In addition to the April 5, 2018 warning letter, on February 28, 2018, CTP issued a Notice of Compliance Check Inspection to Respondent about the February 24, 2018 inspection. Complaint ¶ 12; CTP Br. at 7. CTP provided a copy of the notice as part of its exchange. CTP Ex. 10. On July 18, 2018, CTP issued a Notice of Compliance Check Inspection to Respondent about the July 15, 2018 inspection. Complaint ¶ 10; CTP Br. at 9; CTP Ex. 17.

As previously mentioned, Respondent both denied and pled no contest to these violations. Answer ¶ 1. Respondent stated that the owner was not present at the time of the alleged

violations, the employee denied the violations, and Respondent did not see any evidence of the violation when he reviewed the camera. *Id.* Respondent also stated that he is pleading “no contest” and leaving the decision “up to the Judge.” *Id.* As a defense, Respondent asserts that if his employee had made the impermissible sale, he should have gotten “the tickets at that time.” Answer ¶ 2. Finally, Respondent asserted that he always trains his employees not to sell tobacco to anyone without ID. *Id.*

Respondent’s assertion about issuing the tickets at the time of the sale seems to imply that Respondent does not believe that it received timely notice about the violations. I find that the warning letter and the Notices of Compliance Check Inspections provided Respondent with adequate notice of the violations. *See* CTP Exs. 1, 10, 17. I have also considered Respondent’s comments about holding employees responsible for the violation. However, the Board has indicated that employees are acting in the course of their employment when making these sales and “[t]he mere fact that Respondent instructed its clerks not to sell to minors is . . . an inadequate defense because the [business is] obligated to ensure that its policies are enforced and effective.” *TOH, Inc. d/b/a Ridgeville Serv. Ctr.*, DAB No. 2668, at 17-18 (2015) (citation omitted).

Based on the evidence in the record and Respondent’s Answer, I find that Respondent sold covered tobacco products, specifically, Black & Mild cigars, to minors, and failed to verify the age of the purchasers on February 24, 2018, and July 15, 2018, in violation of 21 C.F.R. § 1140.14(b)(1) and 21 C.F.R. § 1140.14(b)(2)(i). CTP counts all violations observed during the initial failed inspection 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). Therefore, Respondent’s actions constitute three violations of the Act within a 24-month period. I find Respondent liable for all of the violations alleged in the complaint. Accordingly, the only issue remaining before me is whether the civil money penalty of \$559 that CTP seeks is an appropriate amount.

II. Appropriateness of the Civil Money Penalty of \$559

After considering the factors under the applicable statute, I find that the civil money penalty of \$559 that CTP seeks against Respondent, for at least three violations of the Act and its implementing regulations over a 24-month period, is an appropriate amount. When determining an appropriate penalty, the presiding officer must evaluate any circumstances that mitigate or aggravate the violation. 21 C.F.R. § 17.34. As noted above, under the applicable statute, I must “take into account the nature, circumstances, extent, and gravity of the violation or 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. Nature, Circumstances, Extent and Gravity of the Violations

I have found that Respondent committed at least three violations of the Act within a 24-month period. Respondent pleads no contest to the allegation that on February 24, 2018, its employee sold a covered tobacco product to a minor and failed to verify the age of the purchaser. Answer ¶ 1. As I mentioned previously, despite a warning letter from CTP, on July 15, 2018, once again, Respondent failed to comply with the Act and regulations. This repeated inability of Respondent to comply with federal tobacco regulations within 24-month period demonstrates these violations are serious in nature and a civil monetary penalty is appropriate.

b. Respondent's Ability to Pay

Respondent checked a box in its Answer indicating that the penalty of \$559 is too high and stated, “[a]nything [you] can do for the civil penalty . . . will be appreciate[d] thanks.” Answer ¶ 3. However, Respondent has not provided any evidence that it does not have the ability to pay the \$559 penalty. As a result, there is no evidence in the written record to establish an inability to pay the penalty.

c. Effect on Ability to do Business

Similarly, Respondent has not presented any evidence regarding the effect of the civil money penalty on its ability to do business. Absent evidence in the record to the contrary, I find that the \$559 penalty will not have a substantial effect on Respondent's ability to do business.

d. History of Prior Violations

Respondent is a repeat violator of FDA tobacco regulations prohibiting the sale of covered tobacco products to minors. As mentioned previously, Respondent sold a covered tobacco product to a minor and failed to verify the age of the purchaser on February 24, 2018, in violation of 21 C.F.R. § 1140.14(b)(1) and 21 C.F.R. § 1140.14(b)(2)(i). On April 5, 2018, CTP issued a warning letter about these violations. Despite the warning letter, on July 15, 2018, Respondent again sold a covered tobacco product to a minor and failed to verify the age of the purchaser. Respondent's repeated inability to comply with FDA tobacco regulations supports the imposition of a civil money penalty.

e. Degree of Culpability

The record shows that Respondent sold covered tobacco products to minors in violation of 21 C.F.R. § 1140.14(b)(1) on February 24, 2018, and July 15, 2018. The record shows that on those same dates, Respondent failed to verify the identification of the purchasers, in violation of 21 C.F.R. § 1140.14(b)(2)(i). Based on Respondent's written Answer

regarding the current and previous violations and the evidence in the record, I find Respondent fully culpable for three violations of the Act and its implementing regulations within a 24-month period.

f. Additional Mitigating Factors

After reviewing Respondent's Answer, I do not find any additional mitigating factors. In addition to pleading no contest, Respondent stated that he did not see evidence of the sales when he reviewed the video tape and that he did not save the video clips. Answer ¶ 1. I previously noted that during the April 5, 2019 prehearing conference, Respondent blamed his employees for the violation. Respondent argued that it should not be responsible for its employees' mistakes, especially after it provided its employees with training. As noted above, employers are liable for their employees' actions and the fact that Respondent trained its clerks not to sell to minors is not an adequate defense. *TOH, Inc. d/b/a Ridgeville Serv. Ctr*, DAB No. 2668, at 17-18 (2015) (citation omitted).

Within four months of the April 5, 2018 Warning Letter concerning the February 24, 2018 violations, Respondent violated the Act again by selling a covered tobacco product to a minor and failing to verify the age of the purchaser on July 15, 2018. I do not find that Respondent took any corrective actions that I may consider as mitigating factors.

I find no basis to reduce the penalty. Accordingly, I find a civil money penalty amount of \$559 to be appropriate, under the provisions of 21 U.S.C. § 333(f)(5)(B) and 21 U.S.C. § 333(f)(9).

Conclusion

Pursuant to 21 C.F.R. § 17.45, I impose a civil money penalty of \$559 against Respondent, Shanaz Enterprises, Inc. d/b/a USA Food Store, for three violations of the Act, 21 U.S.C. § 301 *et. seq.*, within a 24-month period. Pursuant to 21 C.F.R. § 17.45(d), this decision becomes final and binding upon both parties after 30 days of the date of its issuance.

/s/
Margaret G. Brakebusch
Administrative Law Judge