

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2018-H-2149)

Complainant,

v.

Hometown Irving, LLC
d/b/a Irving Hometown Market,

Respondent.

Docket No. T-18-2442

Decision No. TB3640

Date: March 22, 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, Hometown Irving, LLC d/b/a Irving Hometown Market (“Irving Hometown Market”), for six 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, within a 48-month period. Specifically, CTP alleges that Irving Hometown Market violated the Act by impermissibly selling a covered tobacco product to a minor. The complaint also alleges that Respondent previously sold cigarettes or smokeless tobacco to minors and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. The complaint further alleges that Respondent Irving Hometown Market previously admitted to five¹ violations of the regulations and,

¹ Complaint ¶¶ 10-11; *see* CRD Docket Number T-18-973 (Most Recent CMP Action, FDA Docket Number FDA-2018-H-0273; *see also* CRD Docket Number T-17-3007, FDA Docket Number FDA-2017-H-1707; CRD Docket Number T-16-1323, FDA Docket Number FDA-2016- H-2067; FDA Docket Number FDA-2015-H-4294.

therefore, CTP seeks an \$11,182 civil money penalty against Respondent for at least six violations within a 48-month period. For the reasons discussed below, I find in favor of CTP and impose an \$11,182 penalty against Respondent.

Procedural History

CTP began this matter by serving an administrative complaint on Respondent, Hometown Irving, LLC d/b/a Irving Hometown Market, at 462 U.S. Route 202, Rindge, New Hampshire 03461, and by filing a copy of the complaint with the FDA's Division of Dockets Management. The complaint alleges that Irving Hometown Market impermissibly sold a covered tobacco product to a minor, thereby violating the Act and its implementing regulations.

On July 5, 2018, Respondent timely filed an answer, admitting all the allegations in the complaint. Answer ¶ 1. As a defense, Respondent asserted, in essence, that its employee did ask for the ID but did not check it properly; it has trained employees in the proper way of checking IDs; and it has documents its employees have signed, indicating they will check IDs. *Id.* ¶ 2. Respondent also indicated that the civil money penalty that CTP requests is too high and it could not afford the penalty. *Id.* ¶ 3. Finally, Respondent asserted that it feels that it is paying for the mistakes of others, and reiterated that it trained its employees on how to check and make sure that they do not sell to minors. *Id.*

On July 10, 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. On July 19, 2018, CTP filed a 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 August 28, 2018, CTP filed a Motion to Compel Discovery and Motion to Extend Deadlines. Docket Nos. 8-9. CTP's supporting documents included copies of its Request for Production of Documents ("CTP's RFP", "CTP Ex. A") and delivery notification ("CTP Ex. B"). On September 25, 2018, CTP withdrew its Motion to Compel. On July 16, 2018, Respondent submitted an Informal Brief of Respondent ("Respondent's Br.") and on September 11, 2018, Respondent submitted five discovery documents in response to CTP's discovery requests. Docket Nos. 12 -12d.

On October 31, 2018, 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 19 numbered exhibits ("CTP Ex. 1- Ex. 19"). CTP's exhibits included the written direct testimony of two witnesses: Ms. Laurie Sternberg, Senior Regulatory Counsel, Office of Compliance and Enforcement, CTP, FDA ("Sternberg Declaration", "CTP Ex. 9"), and Mr. Ben Williams ("Inspector Williams"), FDA-commissioned

Inspector for the state of New Hampshire (“Williams Declaration,” “CTP Ex. 10”). Respondent did not submit proposed exhibits or witness testimony.

On December 14, 2018, I held a pre-hearing telephone conference call with the parties. During the prehearing conference call, I explained my role as an impartial Administrative Law Judge. I determined that Respondent is proceeding pro se. We discussed CTP’s pre-hearing exchanges and witness testimony in this matter. I noted that Respondent did not submit proposed exhibits or witness testimony. I explained that the purpose of a hearing is to allow for the cross-examination and re-direct of any witnesses who have provided sworn testimony in exchanges.

I explained the CTP witnesses’ testimonies to Respondent, 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 agreed to a decision based on the written record. As Respondent did not object to CTP’s proposed exhibits, marked as CTP Ex. 1 to CTP Ex. 19, I entered them into the record.

On that same day, I issued an Order Granting Waiver of Hearing and advised the parties that they may file supplemental briefs by no later than January 17, 2019. On December 21, 2019, Respondent filed a document labelled Final Submission (“Respondent’s Supplemental Br.”). On January 16, 2019, CTP submitted a Supplemental Brief of Complainant (“CTP Supplemental Br.”), and two attachments. Dockets Nos. 19-19b. Accordingly, I find that the record is complete.

Issues

1. Whether Respondent sold a covered tobacco product to a minor on April 27, 2018, in violation of 21 C.F.R. § 1140.14(b)(1).
2. Whether the civil money penalty of \$11,182 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 while they are 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(a)(1) and 21 C.F.R. § 1140.14(b)(1),² no retailer may sell cigarettes, smokeless tobacco, or covered tobacco products to any person younger than 18 years of

² On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

age. Under 21 C.F.R. § 1140.14(a)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no cigarette or smokeless tobacco 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 a violation of 21 C.F.R. § 1140.14(b)(1) occurred on April 27, 2018, I note that Respondent admitted in both the answer and the brief that the violation occurred. Answer ¶ 1, Respondent's Br. ¶ 4. The evidence offered by CTP, which includes the Williams Declaration, corroborates Respondent's admission. CTP Ex. 10.

April 27, 2018 Inspection

Inspector Williams' declaration stated that on April 27, 2018, he conducted a follow-up inspection of Respondent's establishment accompanied by a minor. CTP Ex. 10 ¶ 7. Before the inspection, he confirmed that the minor had "true and accurate photographic identification establishing [her] actual date of birth," confirmed that the minor was under the age of 18, on the day of the inspection, and confirmed that she did not have "any tobacco products in [her] possession." *Id.* During the inspection, Inspector Williams parked "around the corner from the front door" of Respondent's establishment. *Id.* ¶ 8. He observed the minor exit from his "vehicle's passenger door and round the corner toward the front of the establishment." *Id.* After a few minutes, he observed the minor "round the same corner and return to [the] vehicle." *Id.* ¶ 9. The minor "immediately handed him the package of ENDS/E-liquid." *Id.* He "observed that the package of ENDS/E-liquid was JUUL cool mint." *Id.* He "labeled [it] as evidence and photographed all of the panels of the package." *Id.* In accordance with standard procedures at the time of the inspection, he stated, "he remained in the same location and then processed the evidence." *Id.* CTP has also offered corroborating evidence, including a redacted photocopy of the minor's ID and photographs that Inspector Williams took of the JUUL cool mint e-liquid product purchased in Respondent's store by the minor purchaser. CTP Ex. 13-15.

Previous Civil Money Penalty Actions

CTP also alleges that in a previous civil money penalty action, Respondent admitted to five violations of the Act within a 36-month period. Complaint ¶¶ 10-11; CTP Br. at 2-4. Specifically, CTP alleged five violations for selling cigarettes or smokeless tobacco to minors on the following dates: April 30, 2015, August 12, 2015, January 14, 2016, October 16, 2016, and December 28, 2017. CTP also alleged one violation for failing to verify the age of a person with photographic identification on April 30, 2015. Complaint ¶ 10. In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations. *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). Respondent does not dispute that the five alleged violations occurred and “expressly waived its right to contest such violations in subsequent actions.” Complaint ¶ 11.

Respondent submits, as a defense, that the April 27, 2018 violation was due to the carelessness of its employee, who failed to check the minor’s ID correctly. Answer ¶ 2; Respondent’s Br. at ¶¶ 4, 6; Respondent’s Supplemental Br. While I have considered this statement as a defense, the Board has indicated that employees are acting in the course of their employment in 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 Service Center*, DAB No. 2668, at 17-18 (2015) (citation omitted).

Based on the evidence in the record and the admissions of Respondent, I find that Respondent sold a covered tobacco product, specifically, JUUL cool mint e-liquid product, to a minor, in violation of 21 CFR 1140.14(b)(1), on April 27, 2018. I further find there is no dispute that Respondent committed at least six violations of the Act and its implementing regulations over a 48-month period. As Respondent admitted to the current and previous allegations, there is no dispute as to the material facts in the case before me. As a result, 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 \$11,182 that CTP seeks is an appropriate amount.

II. Appropriateness of the Civil Money Penalty of \$11,182

After considering the factors under the applicable statute, I find that the civil money penalty of \$11,182 that CTP seeks against Respondent, for at least six violations of the Act and its implementing regulations over a 48-month period, is an appropriate amount. When determining an appropriate penalty, the presiding officer must evaluate any circumstances that mitigate or aggravate the violation. 17 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 six violations of the Act with a 48-month period. Respondent admits that on April 27, 2018, its employee failed to check the minor’s ID correctly. Answer ¶ 2; Respondent’s Br. at ¶¶ 4, 6; Respondent’s Supplemental Br. As previously discussed, Respondent has now failed to comply with the Act and regulations on six separate occasions: April 30, 2015, August 12, 2015, January 14, 2016, October 16, 2016, December 28, 2017, and April 27, 2018. This repeated inability of Respondent to comply with federal tobacco regulations over a period of 48 months demonstrates these violations are serious in nature and a civil monetary penalty is appropriate.

b. Respondent’s Ability to Pay

Respondent asserted in its brief that the penalty of \$11,182 is “prohibitively high and will have a severely negative effect on our operation.” Respondent’s Br. ¶ 5. However, Respondent has not provided any evidence that it does not have the ability to pay the \$11,182 penalty, despite requests for production of financial information from CTP. CTP’s RFP, CTP Ex. A., at 4. 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. As noted above, in its brief, Respondent asserts that the penalty would have a “severely negative effect” on its business. Respondent’s Br. ¶ 5. However, as asserted by CTP, the penalty will not affect respondent’s ability to do business since it may continue to sell tobacco products and other products at the business. CTP Br. at 11-12. Absent evidence in the record to the contrary, I find that the \$11,182 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 cigarettes, smokeless tobacco, and covered tobacco products to minors. This is the sixth admitted violation of the Act and its implementing regulations by Respondent within a 48-month period. As discussed above, Respondent committed five prior violations for selling cigarettes or smokeless tobacco to minors on the following dates: April 30, 2015, August 12, 2015, January 14, 2016, October 16, 2016, and December 28, 2017.

Complaint ¶ 10. Respondent also committed one violation for failing to verify the age of a person with photographic identification on April 30, 2015. *Id.* Respondent's repeated inability to comply with FDA tobacco regulations supports the imposition of a higher penalty.

e. Degree of Culpability

The record shows that Respondent sold a covered tobacco product to a minor in violation of 21 C.F.R. § 1140.14(b)(1) on April 27, 2018. The record also shows that Respondent sold cigarettes or smokeless tobacco to minors in violation of 21 C.F.R. § 1140.14(a)(1) on April 30, 2015, August 12, 2015, January 14, 2016, October 16, 2016, and December 28, 2017. Finally, the record shows that on April 30, 2015, Respondent failed to verify the identification of the purchaser, in violation of 21 C.F.R. § 1140.14(a)(2)(i). Based on Respondent's admissions regarding the current and previous violations and the evidence in the record, I find Respondent fully culpable for six violations of the Act and its implementing regulations within a 48-month period.

f. Additional Mitigating Factors

After reviewing Respondent's arguments, I do not find any additional mitigating factors. In requesting a lower civil money penalty, Respondent argued that the infraction was due to an employee who made a mistake in evaluating the minor's ID and it should not be responsible for its employees' mistakes, especially after it provided its employees with training. Answer ¶¶ 2, 3; Respondent's Br. at 5-7. As noted above, however, 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 Service Center*, DAB No. 2668, at 17-18 (2015) (citation omitted).

Respondent further asserts that it has taken a number of corrective actions to guard against future violations. Respondent's Supplemental Br. As CTP correctly notes, these statements do not conform to the requirements of 21 CFR 17.37(b) and are not considered evidence on the issue of mitigation. CTP's Supplemental Br. at 2. However, even assuming that Respondent's statements are valid and taking the statements at face value, any such corrective steps have been ineffective. Within four months of the previous civil money penalty action on January 22, 2018, which involved sales to minors on five different occasions, Respondent violated the federal tobacco regulations again by selling a covered tobacco product to a minor on April 27, 2018. Accordingly, I do not find that any corrective actions taken by Respondent are mitigating factors.

I find no basis to reduce the penalty. Accordingly, I find a civil money penalty amount of \$11,182 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 \$11,182 against Respondent, Hometown Irving, LLC d/b/a Irving Hometown Market, for six violations of the Act, 21 U.S.C. § 301 *et. seq.*, within a 48-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/
Mary M. Kunz
Administrative Law Judge