

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

Center for Tobacco Products,
(FDA No. FDA-2017-H-1492)

Complainant

v.

R and A Sales, Inc.
d/b/a TobacCorner,

Respondent.

Docket No. T-17-2804

Decision No. TB2142

Date: November 7, 2017

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty of \$5,501 against Respondent, R and A Sales, Inc. d/b/a TobacCorner, located at 1535 3rd Avenue, Seattle, Washington 98101, for five 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 thirty-six month period.

CTP alleges that TobacCorner violated the Act by: impermissibly selling cigarettes 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.

For the reasons discussed below, I impose a civil money penalty of \$5,501 against Respondent, TobacCorner.

I. Procedural History

CTP began this matter by serving an administrative complaint seeking an \$5,501 civil money penalty on Respondent TobacCorner (Respondent), at 1535 3rd Avenue, Seattle, Washington 98101, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. On April 26, 2017 Respondent requested an extension of time to file an answer, I granted the extension request on April 28, 2017. Respondent timely answered CTP's complaint. On May 24, 2017, I issued an Acknowledgment and Prehearing Order (APHO) that set deadlines for the parties to file their pre-hearing exchanges.

CTP filed its pre-hearing exchange on August 14, 2017. CTP's exchange consists of a brief; witness and exhibit list; and twenty-one proposed exhibits. The proposed exhibits are identified as CTP Ex. 1- CTP Ex. 21. Subsequently, Respondent timely filed its pre-hearing exchange, admitting all allegations in the Complaint but contesting the amount of the civil money penalty. Respondent's exchange consists of a brief and no exhibits.

II. A Decision on the Record Is Appropriate

Pursuant to 21 CFR § 17.37(b), all direct testimony of witnesses shall be admitted in the form of a written declaration. In its pre-hearing exchange, CTP offered the direct testimony of two witnesses. Respondent did not offer the direct testimony of any witnesses. The parties have agreed that an administrative hearing is not required in this matter. Consequently, I receive the parties' written exchanges and exhibits into evidence and decide this case based on the administrative record.

III. Discussion

A. Respondent has committed five violations of the Act within a 36-month period.

In its Complaint, CTP alleges that Respondent committed five violations of the Act and its implementing regulations within a 36-month period. These violations consist of a combination of violations from a prior complaint and two new violations. Complaint ¶¶ 8-10. While Respondent initially denied the new violations occurred, it failed to provide any supporting evidence or testimony to dispute the violations. *See generally*, Respondent's Answer. In its brief, Respondent admitted the allegations in the Complaint, but contested the amount of the civil money penalty. Informal Brief of Respondent ¶¶ 4-6. The allegations to which Respondent admitted are as follows:

- On September 2, 2015, CTP initiated the first civil money penalty action, CRD Docket Number C-15-3921, FDA Docket Number FDA-2015-H-3132, against Respondent for three¹ violations of 21 C.F.R. pt. 1140 within a twenty-four month period. CTP alleged that Respondent unlawfully sold cigarettes 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. CTP alleged those violations to have occurred on January 16, 2015 and April 28, 2015. Complaint ¶ 10, CTP Ex. 1.
- The previous action concluded when Syed Saifee Ahsan, Respondent's authorized representative, settled the claims on Respondent's behalf. On October 5, 2015, Syed Ahsan signed an Acknowledgment Form in which he "admit[ted] that the violations . . . occurred, waiv[ed] [his] ability to contest the violations in the future, and stat[ed] that [he] understood that violations may be counted in determining the total number of violations for purposes of future enforcement actions." Complaint ¶ 11, CTP Ex. 2.
- At approximately 3:31 p.m. on October 6, 2016, at Respondent's business establishment, 1535 3rd Avenue, Seattle, Washington 98101, an FDA-commissioned inspector documented that a person younger than 18 years of age was able to purchase a package of Camel Blue cigarettes. 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 ¶ 8.

Because Respondent has admitted to these allegations, I therefore find they establish Respondent's liability under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387f(d); *see* 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010).

Under 21 C.F.R. § 1140.14(a)(1), no retailer may sell cigarettes to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i), retailers

¹ Two violations were documented on January 16, 2015, and two on April 28, 2015. 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.

must verify, by means of photographic identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age.

B. Imposition of a \$5,501 Civil Money Penalty Is Appropriate.

When determining the amount of a civil money 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).

Pursuant to 21 U.S.C. § 333(f)(9), Respondent is liable for a civil money penalty not to exceed the amounts listed in FDA's civil money penalty regulations at 21 C.F.R. § 17.2. In its Complaint, CTP sought to impose the maximum penalty amount of \$5,501 against Respondent for five violations of the Act and its implementing regulations within a thirty-six month period. Complaint ¶¶ 1, 14. In its brief, CTP asserts that a \$5,501 civil money penalty, the maximum allowable, is appropriate. Informal Brief of Complainant at 8-12.

Respondent asserts that a \$5,501 penalty “will have a very negative and discouraging impact on the business.” Respondent further states that it is “small identity [sic] working on a slim margin of profit in this highly competitive market environment.” Informal Brief of Respondent ¶ 6.

1. Nature, Circumstances, Extent and Gravity of the Violations

Despite Respondent's claim that it, “has been training and retraining cashiers to deal with this difficult problem and the store was successfully able to discourage individuals who collaborated with minors to acquire prohibited cigarettes...,” Respondent did not provide any evidence to support this claim and has consistently failed to comply with the Act and its implementing regulations. Respondent's Answer ¶ 10. In the prior civil monetary penalty action, respondent admitted to two violations for selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1) and two violations for failing to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(a)(2)(i).²

² In the prior action, while Respondent admitted to all four of the violations as alleged, CTP only held Respondent liable for three violations in accordance with the customary practice outlined in footnote 1.

In the current action, Respondent admits to two additional violations: one violation for selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1) and one violation for failing to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(a)(2)(i), bringing the total to five violations.

I must take into account Respondent's ongoing failure to comply with federal tobacco regulations. The regulations governing the sale of tobacco products are set forth to protect public health, in particular the health of minors. The repeated violations to which Respondent admits are therefore quite serious in nature, and demand a proportional civil money penalty amount.

2. Respondent's Ability to Pay and Effect of the Penalty on Ability to do Business

I must also give consideration to Respondent's ability to pay and the effect of the civil money penalty on its ability to do business. 21 U.S.C. § 333(f)(5)(B). CTP seeks a \$5,501 civil money penalty against Respondent, which is also the maximum amount permissible under the regulations in effect during the relevant time period. Informal Brief of Complainant at 9. CTP states in its brief that in response to its Request for Production of Documents, Respondent provided a tax return from 2015, which it attached to its brief as an exhibit. *Id.* at 11, CTP Ex. 21.

According to the 2015 tax returns, [REDACTED] *Id.* Beyond these tax documents, there is nothing in the evidentiary record that shows the effect a \$5,501 civil money penalty would have on Respondent's ability to do business. CTP cites *CTP v. Joy and Evergreen Petro, Inc.*, Docket No C-15-2362 to support its assertion that the 2015 tax document is "inadequate to prove that Respondent is incapable of paying the \$5,501 penalty at issue here." Informal Brief of Complainant at 11. CTP also asserts that "Respondent may continue to sell tobacco products and other products at the establishment." *Id.* at 12.

I agree with CTP that the 2015 tax document alone does not establish that a civil money penalty of \$5,501 would have a significant effect on Respondent's ability to do business.

3. History of Prior Violations

As previously discussed, the current action is the second civil money penalty action brought against Respondent for violations of the Act and its implementing

regulations. The current action brings Respondent's total violation count to five violations in a 36-month period. Informal Brief of Complainant at 9. I agree with CTP that "[t]hese repeat violations show an unwillingness or inability to sell tobacco products in accordance with federal tobacco regulations." *Id.* at 12. While Respondent has already paid civil money penalties for its previous violations, its continued inability or unwillingness to take significant and affirmative steps to comply with federal tobacco laws and regulations militates towards a more severe penalty.

4. Degree of Culpability

Respondent admitted to all violations in its informal brief. Based on Respondent's own admissions, it is fully culpable for all five violations of the Act and its implementing regulations.

ORDER

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$5,501 against Respondent, R and A Sales, Inc. d/b/a TobacCorner, for five 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 thirty-six month period.

/s/
Wallace Hubbard
Administrative Law Judge