

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

TBCO, LLC
d/b/a Big Smoke 107,

Respondent.

Docket No. T-16-1164
FDA Docket No. FDA-2016-H-1870

Decision No. TB1850

Date: September 7, 2017

DECISION

I sustain the determination of the Center for Tobacco Products (CTP) to impose a civil money penalty of \$500 against Respondent, TBCO, LLC d/b/a Big Smoke 107 (Respondent).

I. Background

Respondent requested a hearing in order to challenge CTP's determination to impose a \$500 civil money penalty against it. CTP filed a brief (Complainant's Brief) plus 33 proposed exhibits that are identified as CTP Ex. 1- CTP Ex. 33. Respondent filed a brief (Respondent's Brief) plus six proposed exhibits that are identified as R. Ex. 1-R. Ex. 6. 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.

On May 19, 2017, I issued a By Direction Letter instructing Respondent to inform me by May 30, 2017, as to whether it wished to cross-examine CTP's witnesses. I also informed the parties that if Respondent did not wish to cross-examine CTP's witnesses that I would issue a decision on the record based upon the parties' written filings. On May 22, 2017, Respondent indicated that it did not wish to cross-examine CTP's witnesses. Consequently, I decide this case based on the parties' written exchanges.

I receive the parties' proposed exhibits into evidence.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues are whether:

1. Respondent sold tobacco products (cigarettes) to a minor in violation of federal law;
2. Respondent utilized a self-service display to sell cigarettes in a non-exempt facility; and
3. A civil money penalty of \$500 is reasonable.

B. Findings of Fact and Conclusions of Law

CTP determined to impose a civil money penalty against Respondent pursuant to the authority conferred by the Federal Food, Drug, and Cosmetic Act (Act) and implementing regulations at Part 21 of the Code of Federal Regulations (C.F.R.). 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 Food and Drug Administration and its agency, CTP, may seek civil money penalties from any person who violates the Act's requirements as they relate to the sale of tobacco products. 21 U.S.C. § 331(f)(9). The sale of tobacco products to an individual who is under the age of 18 and the use of self-service displays in non-exempt facilities are violations of implementing regulations. 21 C.F.R. §§ 1140.14(a), 16(c).¹

1. Respondent sold tobacco products (cigarettes) to a minor in violation of federal law.

In its Complaint, CTP alleges that Respondent committed three violations of the Act and its implementing regulations within a 24-month period. Respondent admitted the

¹ On August 8, 2016, the citations to certain tobacco violations changed. For more information, see <https://federalregister.gov/a/2016-10685>. For the purpose of this decision, all citations to the regulations refer to the regulations in effect prior the change.

allegations in the Complaint, but contests the amount of the civil money penalty. Respondent's Brief ¶¶ 3-6.

Specifically, Respondent admits that it sold tobacco products to a minor on October 24, 2015, at approximately 12:46 PM and again on January 3, 2016, at approximately 3:53 PM. *Id.* Respondent also admits it had displays or devices on its premises that provided customers direct access to tobacco products on January 12, 2016, at an unspecified time, and that its establishment did not restrict access to minors. *Id.*

Because Respondent has admitted to the allegations as outlined in the Complaint, I therefore find these facts 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. § 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); 81 Fed. Reg. 28,974, 28,975-76 (May 10, 2016). The regulations prohibit the sale of tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also prohibit a retailer from utilizing a self-service display to sell cigarettes in a facility where minors are present or permitted to enter at anytime. 21 C.F.R. § 1140.16(c).

2. Respondent utilized a self-service display to sell cigarettes in a non-exempt facility.

Although Respondent admits it had displays or devices on its premises that provided customers direct access to tobacco products on January 12, 2016, Respondent asserts that:

CTP . . . [f]ailed to follow their 2-part Inspection Guidelines on multiple occasions. This resulted in the Respondent not being given the benefit of the Warning Letter to correct violations prior to being subjected to penalties; and/or . . . CTP did conduct an A&L inspection following a UB inspection, they never cited Respondent for a self-serve violation prior to Jan 12, 2016 even though the exact same conditions were present on prior dates.

Respondent's Brief ¶ 7. Respondent further argues that had it "gotten both parts of the inspection (including the A&L), [it] would have been notified of the self-service violation" and "would have taken correction at that time." Thus, Respondent concludes, it would "only be guilty of 2 violations in a 2-year period." *Id.* at ¶ 7(1)(a), (e).

Based on this argument, Respondent requests that I dismiss the self-service violation, reducing its violations to two within a 12-month period and subjecting it to a \$250 civil money penalty. *Id.* at ¶ 6.

Respondent's argument that it did not have sufficient warning about the self-service violation is without merit. Respondent acknowledges that it received a warning letter from CTP notifying it of the October 24, 2015 violation. CTP Ex. 2. CTP's warning letter explicitly states, "[t]he violation indicated in this letter may not be a complete list of violations at the establishment." CTP Ex. 1. Furthermore, the presence of a self-service display is only a violation if utilized in a non-exempt establishment. 21 C.F.R. § 1140.16(c)(2)(ii). Thus, if Respondent had ensured that no minors were permitted to enter its establishment on both October 24, 2015 and January 3, 2016, it may have been considered an exempt establishment on January 12, 2016, and the presence of the self-service display would not have been a violation of the law.

As a merchant who conducts sales of tobacco products, Respondent cannot now plead ignorance of the regulations, and certainly not for repeated instances of failing to do so. Tobacco is a highly addictive and dangerous product. The seriousness of Respondent's unlawful conduct is illustrated not just by the fact that it made repeated sales to minors but also by the nature of the product that it sold and the persons to whom it sold that product. Therefore, the repeated violations to which Respondent admits are therefore quite serious in nature, and demand a proportional civil money penalty amount. Respondent's request to dismiss the self-service violation is therefore denied.

3. A civil money penalty of \$500 is reasonable.

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 \$500 against Respondent for three violations of the Act and its implementing regulations within a twenty-four month period. Complaint ¶¶ 1, 5, 14. In its Informal Brief, CTP asserts that a \$500 civil money penalty, the maximum allowable, is appropriate. Complainant's Brief at 13-17.

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).

In addition to its request that I dismiss the self-service violation, Respondent asks that I reduce its civil money penalty by 50%. Respondent's Brief ¶ 6. It asserts that among other measures it has invested resources into registers with "top of the line scanners," reprimands and retrains employees who are in non-compliance with company policy, terminates employees who fail a government compliance shop, and has passed numerous inspections. Respondent's Ex. 1.

