

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-1808)

Complainant

v.

Western Spirits, Inc.
d/b/a T-Joe's Steakhouse and Saloon,

Respondent.

Docket No. T-16-1112

Decision No.

Date: June 15, 2017

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Western Spirits, Inc. d/b/a T-Joe's Steakhouse and Saloon, located at 12700 East Interstate 80 Service Road, Cheyenne, Wyoming 82009, for seven (7) 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 forty-eight month period. Specifically, CTP alleges that Respondent violated the Act by impermissibly selling tobacco products to minors, on three separate occasions, failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, on three separate occasions, and utilizing a vending machine in a non-exempt facility, on three separate occasions.

Procedural History

CTP began this matter by serving an administrative complaint seeking an \$11,000 civil money penalty on Respondent, at 12700 East Interstate 80 Service Road, Cheyenne, Wyoming 82009, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. Respondent timely answered CTP's complaint. In its answer, Respondent denied the allegations.

CTP filed its pre-hearing exchange on December 29, 2016. CTP's pre-hearing exchange included the declarations of two witnesses. Respondent did not file a pre-hearing exchange.

On February 17, 2017, I held a pre-hearing conference in this case. Following the pre-hearing conference, I issued an Order that scheduled the hearing for March 15, 2017. That Order noted that during the pre-hearing conference, Respondent indicated that it wanted to cross examine both of CTP's witnesses, Inspector Steven Melia and Ms. Laurie Sternberg. As noted above, Respondent did not file a pre-hearing exchange and, therefore, did not endorse any witnesses.

On March 15, 2017, a hearing was held in this case. The purpose of the hearing was to admit the exhibits and to allow Respondent to cross examine Inspector Melia and Ms. Sternberg.

On April 4, 2017, I informed the parties that the Court had received the transcript of the hearing, and set the deadline for the parties' post-hearing brief submissions as May 5, 2017. Both parties filed post-hearing briefs.

Analysis

I. Violations

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. 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). FDA 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 failure to verify the photographic identification of an individual who is not over the age of 26 are violations of implementing regulations. 21 C.F.R.

§ 1140.14(a), (b)(1)¹. The use of a vending machine in a non-exempt facility is also a violation of implementing regulations. 21 C.F.R. §§ 1140.14(c).

In its Complaint, CTP alleges that Respondent committed seven violations of the Act and its implementing regulations within a forty-eight month period. Respondent filed an answer that denied selling tobacco products to a minor. Respondent's Answer.

CTP's case against Respondent rests on the testimony of Mr. Melia and Ms. Sternberg plus corroborating evidence. CTP Exs. 4, 8. Mr. Melia is an FDA-commissioned officer whose duties include determining whether retail outlets are unlawfully selling tobacco products to minors. CTP Ex. 8 at 1-2. Mr. Melia's inspections entail accompanying minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id.*

Mr. Melia testified that he went to Respondent's place of business on December 22, 2015. CTP Ex. 8 at 2-3. Mr. Melia further testified that on December 22, 2015, he confirmed that the minor was carrying her photographic identification, and that she did not have tobacco products in her possession. *Id.* at 3. Mr. Melia testified that he observed the minor enter the establishment and purchase a package of cigarettes from the vending machine and that the minor did not provide photographic identification. *Id.*

Mr. Melia stated that after the purchase, the minor and he both exited the establishment and returned to his vehicle, where the minor immediately gave him the pack of cigarettes. The cigarettes were observed to be a package of Marlboro 100's cigarettes. CTP Ex. 8 at 3. Mr. Melia testified that he then labeled the cigarettes as evidence, and took photographs of the package. *Id.* Mr. Melia then testified that shortly after the inspection he recorded the inspection in the FDA's Tobacco Inspection Management System. *Id.* at 3-4.

Ms. Sternberg is a Senior Regulatory Counsel with the Center for Tobacco Products. CTP Ex. 4 at 1. Ms. Sternberg testified that in her official capacity she has knowledge of the processes used by the FDA regarding the establishment registration and product listing requirements. *Id.* at 2. She further testified that the Marlboro 100's cigarettes purchased on December 22, 2015 at T-Joe's Steakhouse and Saloon were manufactured by Phillip Morris USA in the State of Virginia. *Id.* at 2-3. Ms. Sternberg confirmed that the cigarettes were not manufactured in Wyoming. *Id.*

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

The testimonies of Mr. Melia and Ms. Sternberg plus the corroborating evidence consisting of photographs of the pack of cigarettes that were obtained from the minor on December 22, 2015, and the photographs of the vending machine, are proof that Respondent unlawfully sold tobacco products to a minor, failed to check the minor's identification before making the sales, and used a vending machine in a non-exempt facility.

CTP's post-hearing brief asserts that it has proven by a preponderance of evidence that Respondent sold tobacco products to minors, failed to verify the age of the person purchasing those same tobacco products, and used a vending machine in a non-exempt facility.

Throughout the case, Respondent has denied that the sale of tobacco products to minors occurred. In its post-hearing brief, Respondent again asserts that the tobacco sales did not occur. Respondent also challenges the validity of the FDA's tobacco regulations as well as the administrative law process.

Respondent argues that the sale of tobacco products to a minor on December 22, 2015, could not have occurred and that, if anything, Mr. Melia simply entered the establishment, took a photograph of the vending machine, and left. Resp. Brief at 5-6. Respondent further argues that no sale from the vending machine can occur without first speaking with the bartender. *Id.* This allegedly must occur in order for a switch to be turned on to allow the vending machine to make the sale. *Id.* Respondent also argues that he has video surveillance of the vending machine at all times. *Id.* However, no such evidence was presented in this matter.

Mr. Melia's testimony is that the minor entered the establishment without cigarettes. As a result, the only reasonable explanation that I can find for her emerging from the establishment with cigarettes is that she purchased them in the establishment. The evidence that she made such a purchase is supported by Mr. Melia's testimony plus corroborating evidence. Respondent's argument without supporting evidence that the sale could not have occurred because of a lock on the vending machine is not sufficient to establish that the sale to a minor did not occur on December 22, 2015.

Respondent further argues that the FDA regulations have no authority in Wyoming and that he has a right to a jury trial because the fine sought is over \$20. I find that these arguments are without merit. The Supremacy Clause of The United States Constitution controls. U.S Constitution, Article IV, Clause 2. The Supremacy Clause provides that states are bound by the Constitution and, that in cases of any conflicts between state and federal law, federal law controls. *Id.* In 2009, Congress enacted the Tobacco Control Act. (Pub. L. 111-31, H.R. 1256). The Tobacco Control Act specifically gave the FDA the authority to impose civil

money penalties for a violation of the prohibition against the sale of tobacco products to any person under the age of 18. *See* 21 U.S.C. § 331(f)(9); 21 C.F.R. § 1140.14(a) (1). Therefore, it is clear that Congress intended for the FDA to have the authority to pursue a civil money penalty action against Respondent for violations of the Tobacco Control Act.

I further find that Respondent is not entitled to a jury trial. Respondent has asserted that it is entitled to a jury trial because the amount of the civil money penalty sought by the Complainant is over \$20. Respondent cites generally to the 7th Amendment for this assertion. However, Administrative Officers were authorized to hear Civil Money Penalty actions under the Tobacco Control Act. 21 U.S.C. § 333(f)(5)(A). The 7th Amendment is not a bar to an administrative hearing. I find that the right to a jury trial is not present under the Tobacco Control Act. In *Atlas Roofing Co.*, the Supreme Court held that the “Seventh Amendment was never intended to establish the jury as the exclusive mechanism for factfinding in civil cases.” *Atlas Roofing Co. v. Occupational Safety and Health Review Comm’n*, 430 US, 442, 460 (1977). Further, in *Atlas Roofing Co.*, the Court found that the 7th Amendment was not a bar to Congress’ power to regulate and assign an administrative agency to enforce regulations. *Id.* Congress enacted the Tobacco Control Act and indicated that administrative officers were authorized to hear civil money penalty actions. As a result, the 7th Amendment is not a bar to enforcement of the Tobacco Control Act.

Therefore, I find that the facts as outlined above establish Respondent Western Spirits, Inc. d/b/a T-Joe’s Steakhouse and Saloon’s liability under the Act.

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent T-Joe’s Steakhouse and Saloon 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, \$11,000, against Respondent for seven violations of the Act and its implementing regulations within a forty-eight month period. Complaint ¶ 13. In its Informal Brief, CTP continues to assert that an \$11,000 civil money penalty is appropriate. Informal Brief of Complainant at 9-11.

In both its Answer and its post-hearing brief, Respondent denied any obligation to pay a civil money penalty; asserting that it did not violate the regulations.

I have found that Respondent committed seven violations of the Act and its implementing regulations within a forty-eight month period. 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). Respondent has not provided any arguments with regards to the nature, circumstances, extent and gravity of the violations, any history of prior such violations, the degree of culpability, etc. Instead, Respondent’s sole argument has been that it should not have to pay a civil money penalty because it did not commit the violations.

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

Time and again, Respondent T-Joe’s Steakhouse and Saloon has failed to comply with the Act and its implementing regulations. Over the course of the seven violations discussed in this Complaint, Respondent was previously found liable for four violations, and I have found that Respondent committed the three most recent violations; specifically Respondent has committed: three violations of selling tobacco products to minors, three violations for failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, and three violations of the use of a vending machine in a non-exempt facility. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the civil money penalty amount should be set accordingly.

ii. Respondent’s Ability to Pay And Effect on Ability to do Business

Respondent has not provided any evidence with regard to its ability or inability to pay the \$11,000 civil money penalty.

iii. History of Prior Violations

The current action is the second civil money penalty action brought against Respondent since September 2, 2015 for violations of the Act and its implementing regulations. In the first civil money penalty action, CRD Docket Number C-15-3920, FDA Docket Number FDA-2015-H-3131, Respondent twice violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), twice violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no tobacco purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(b)(1), and twice violated the prohibition against the use of a vending

machine in a non-exempt facility, 21 C.F.R. § 1140.14(c)². Respondent was found liable for the previous violations by way of a default judgment entered on October 29, 2015. In its Answer, Respondent denies that it was made aware of any default judgment because “no violation could’ve occurred because of all the precautions in place.” Respondent’s Answer at 5. I find Respondent’s position disingenuous as the prior decision in CRD Docket Number C-15-3920, FDA Docket Number FDA-2015-H-313, Decision No. CR 4382 was delivered by certified mail to 12700 East Interstate 80 Service Road, Cheyenne Wyoming 82009. CTP Ex. 3.

I agree with CTP that “[t]hese repeat violations show an unwillingness or inability to sell tobacco products in accordance with federal tobacco regulations.” Complainant’s Informal Brief at 11. While Respondent has already paid a civil money penalty for its previous violations, its continued inability to comply with the federal tobacco regulations calls for a more severe penalty.

iv. Degree of Culpability

Respondent T-Joe’s Steakhouse and Saloon was previously found liable for four violations. Based on my finding that Respondent committed the three most recent violations in the current complaint, I hold it fully culpable for all seven violations of the Act and its implementing regulations.

v. Additional Mitigating Factors

Respondent has not asserted any mitigating factors.

vi. Penalty

Based on the foregoing reasoning, I find a penalty amount of \$11,000 to be appropriate under 21 U.S.C. §§ 303(f)(5)(B) and 333(f)(9).

² Three violations were documented on December 12, 2014, and three on April 25, 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.

Conclusion

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$11,000 against Respondent, Western Spirits, Inc. d/b/a T-Joe's Steakhouse and Saloon, for seven (7) 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 forty-eight month period.

/s/

Margaret G. Brakebusch
Administrative Law Judge