

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-H-1382)

Complainant

v.

State Oil Fuel Center, Inc.
d/b/a State Oil,

Respondent.

Docket No. T-17-2706

Decision No. TB2650

Date: April 18, 2018

INITIAL DECISION

I sustain the determination of the Center for Tobacco Products (CTP) of the United States Food and Drug Administration (FDA) to impose a civil money penalty against Respondent, State Oil Fuel Center, Inc. d/b/a State Oil, for two 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 12-month period. Specifically, Respondent violated the Act by impermissibly selling cigarettes to minors on January 27, 2016, and September 30, 2016. However, I conclude that reducing the civil money penalty from \$275 to \$175, is appropriate.

I. Background

CTP began this matter by serving an administrative complaint seeking a \$275 civil money penalty on Respondent, at 7124 Highway 23, Belle Chasse, Louisiana 70037, and

by filing a copy of the complaint with the FDA Division of Dockets Management. Respondent timely answered CTP's complaint, denying the allegations.

The parties filed pre-hearing exchanges. CTP filed a pre-hearing brief (CTP Br.) and 23 exhibits (CTP Exs. 1-23), including the written direct testimony of two proposed witnesses (CTP Exs. 3-4). Respondent filed a pre-hearing brief (R. Br.) and 18 exhibits (R. Exs. 1-18), including the written direct testimony of four proposed witnesses (R. Exs. 1-4). CTP did not seek to cross-examine any of Respondent's proposed witnesses. Respondent asked to cross-examine CTP's witness, Cole Sisung, an FDA-commissioned inspector.

On December 14, 2017, I conducted a hearing for the purpose of cross-examination and for the admission of the parties' proffered exhibits. During the hearing, I received into evidence CTP's 23 exhibits and Respondent's 18 exhibits. Transcript (Tr.) at 8-9. Respondent filed a post-hearing brief (R. Post-Hrg. Br.).

II. Analysis, Findings of Fact and Conclusions of Law

A. Violations

CTP determined to impose a civil money penalty against Respondent pursuant to the authority conferred by the 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 is a violation of implementing regulations. 21 C.F.R. § 1140.14(a)(1).

CTP premises its case on the results of inspections of Respondent's establishment, conducted on January 27, 2016, and September 30, 2016.

CTP's case against Respondent rests on the testimony of Inspector Sisung and Laurie Sternberg; which are supported by corroborating evidence. CTP Exs. 3-7, 10-12, 14-18, 22-23. Inspector Sisung is an FDA-commissioned officer for the state of Louisiana whose duties include determining whether retail outlets unlawfully sell tobacco products to minors. CTP Ex. 4 at 1-2. Inspector Sisung's inspections entail accompanying minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id.* Inspector Sisung testified that he conducted such an inspection of Respondent's establishment on January 27, 2016, and September 30, 2016. CTP Ex. 4 at 2-4.

Inspector Sisung testified that on both occasions he went to Respondent's establishment accompanied by a minor who was employed for the purpose of attempting to purchase tobacco products from business establishments under inspection. CTP Ex. 4. Inspector Sisung testified that on each occasion he verified that the minor carried photographic identification that included the minor's true age and that the minor did not have any tobacco products in his possession. CTP Ex. 4 ¶¶ 7, 12; Tr. 22-23. During each inspection, Inspector Sisung did not exit the vehicle because he felt his presence would compromise the undercover nature of the inspection, but watched events from his vehicle. CTP Ex. 4 ¶¶ 8, 13. On both occasions, Inspector Sisung watched the minor enter Respondent's establishment, exit the establishment, and return with a package of cigarettes. After each inspection, the minor reported that he provided a valid state issued identification, showing his true date of birth, to the employee. *Id.*

Inspector Sisung stated that after each purchase, the minor immediately gave him the pack of cigarettes. He labeled the cigarettes as evidence, photographed all of the panels of the package, and processed the evidence in accordance with standard procedures. CTP Ex. 4 ¶¶ 9, 13. Shortly after each inspection, Inspector Sisung recorded the inspection in the FDA's Tobacco Inspection Management System and created a Narrative Report. *Id.* ¶¶ 10, 14.

CTP corroborated Inspector Sisung's testimony by offering as evidence photographs that Inspector Sisung made of the cigarettes that the minor purchased on the dates in question. CTP Exs. 10-12, 16-18. CTP also submitted narrative reports by Inspector Sisung created contemporaneously with each inspection. CTP Exs. 6, 14.

Respondent offered no evidence to rebut Inspector Sisung's testimony. Instead, Respondent argues that CTP failed to meet its burden of proof in this case. Tr. 11; R. Post-Hrg. Br. at 9. Respondent asserts that there is no eyewitness testimony to the transactions at issue. R. Post-Hrg. Br. at 9. This is true. It is undisputed that Inspector Sisung did not directly witness the alleged transactions on either January 27, 2016 or September 30, 2016. Tr. 23. However, the regulations do not require such a direct eyewitness. Rather, I must determine whether – based on a preponderance of the evidence – the allegations in the complaint are true, and, if so, whether these actions constitute a violation of law. 21 C.F.R. §§ 17.33, 17.45. As I detail below and based on the evidence of record, I find that it is more likely than not that the minor purchased cigarettes at Respondent's establishment on both January 27, 2016, and September 30, 2016. 21 C.F.R. § 17.33.

Respondent does not dispute that three of the employees who were working at the time of either sale were adult females with dark hair. R. Post-Hrg. Br. at 10-11. Respondent asserts, however, that the employees working at the time of the alleged purchases did not fit the minor's physical description of the employee who sold the tobacco products. R. Br. at 7; R. Post-Hrg. Br. at 10. Although Respondent acknowledges that the minor

described the employees as being female, adult, with dark hair, Respondent relies on the fact that the minor does not identify either employee as wearing glasses.

Respondent provides that Sherry Sylve and Petra Warren were working at the time of the alleged sale on January 27, 2016, and provided the written direct testimony of both employees. R. Exs. 2-3. Ms. Warren, an adult female with dark hair, testified that she did not knowingly sell the tobacco product and that she wears glasses when checking ID's. R. Ex. 2. Ms. Sylve, an adult female with dark hair, also testified that she did not knowingly sell the tobacco product and that she wears glasses at work. R. Ex. 3.

Respondent asserts that Bruni Comeaux and Tamara Chase were working at the time of the alleged sale on September 30, 2016. Respondent submitted only the written direct testimony of Ms. Comeaux. R. Ex. 4. Ms. Comeaux testified that she has red hair and that she did not knowingly sell the product on September 30, 2016. She also testified that Ms. Chase, an adult female with dark hair, wears glasses at work. R. Ex. 4.

On cross-examination, Inspector Sisung admitted that the minors are instructed to look for the physical characteristics of the employee involved in the purchase, including such physical characteristics as glasses. Tr. 32. Although probative, this testimonial evidence is not crucial based on the entire record evidence. It is clear from the record that on both January 27, 2016 and September 30, 2016, an adult female with dark hair, consistent with the minor's description, was working at Respondent's establishment.

Respondent argues that because CTP did not cross-examine its witnesses, I must deem their testimony "credible and uncontradicted." R. Post-Hrg. Br. at 8. Contrary to Respondent's argument, finding Respondent's witnesses to be credible does not undercut CTP's case. In point of fact, I find the witness testimony credible, particularly that of Ms. Warren (R. Ex. 2), Ms. Sylve (R. Ex. 3), and Ms. Comeaux (R. Ex. 4). Each testified that they "did not knowingly sell tobacco products to any minor." R. Exs. 2-4 at ¶ 8. However, these clerks not *knowingly* selling a tobacco product to a minor is not inconsistent with a finding that they in fact sold tobacco products to a minor. Intent is not a necessary element to prove a violation of this regulation.

With respect to the alleged sale on January 27, 2016, both Ms. Warren and Ms. Sylve are adult females with dark hair. Ms. Warren testified that she wears reading glasses when she checks identification. R. Ex. 2 ¶ 9. While this may be her custom, there is nothing in the record to support a finding that she always uses her glasses to check an ID or that she did so on January 27, 2016. In fact, had she used her glasses during the sale on January 27, 2016, she would likely have determined the minor's true age. Accordingly, her failure to use her reading glasses in this instance may explain why she failed to notice the minor's age when viewing his identification.

With respect to the alleged sale on September 30, 2016, CTP's case is stronger. The fact that Respondent presented the testimony of all clerks on staff, yet did not present Ms. Chase's testimony or explain why it was not offered, is telling. Respondent relies on Ms. Comeaux to make its argument that Ms. Chase wears glasses. But, as Ms. Chase does not testify, there is no direct testimony to rebut the premise that she was the employee involved in the unlawful sale on September 30, 2016.

Respondent also makes the argument that the minor obtained the cigarettes from a third party in the store or that the minor presented a second or fake identification to the cashier to obtain the cigarettes. R. Post-Hrg. Br. at 9. I find it incredible that the minor obtained the cigarettes from a third party in the establishment or presented false identification. Based on the record evidence, there is no reason for him to do so. Inspector Sisung testified that the minors do not receive any type of financial bonus or incentive for successfully purchasing tobacco products. CTP Ex. 4 ¶ 6. There is simply no evidence to support that the minor had an incentive to plant false evidence or to trick Respondent's staff. I would also note that it would be highly unlikely that this same minor devised a plan to obtain the cigarettes from a third party on each of these purchases; occurring approximately 8 months apart. Additionally, I found Inspector Sisung's testimony regarding the character of this specific minor particularly convincing. Namely, Inspector Sisung testified that this minor worked on a lot of inspections, that he found the minor "very consistent, conscientious," and "of high character and integrity." Tr. 40. Finally, I credit the Inspector's testimony that the minor was in the store each time for an appropriate amount of time to accomplish the sale as described. Tr. 29.

Simply, the minor entered the establishment without cigarettes and returned with them. Based on the evidence of record, the most reasonable explanation for the minor to emerge from the establishment with cigarettes is that he purchased them in the establishment.

The testimony of Inspector Sisung supported by corroborating evidence is sufficient to establish that it is more likely than not that Respondent unlawfully sold cigarettes to a minor in violation of 21 C.F.R. § 1140.14(a)(1). 21 C.F.R. § 17.33(b); *see* CTP Exs. 3-7, 10-12, 14-18, 22-23. Further, Respondent failed to establish any affirmative defense by a preponderance of the evidence. 21 C.F.R. § 17.33(c).

Accordingly, I find that the facts as outlined above establish Respondent's liability under the Act.

II. Civil Money Penalty

I have found that Respondent committed two violations of the Act and its implementing regulations within a 12-month period. In its Complaint, CTP sought to impose the maximum penalty amount, \$275, against Respondent for two violations of the Act and its implementing regulations within a 12-month period. Complaint ¶ 1. 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).

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

Respondent has failed to comply with the Act and its implementing regulations on two occasions. 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 \$275 civil money penalty.

iii. History of Prior Violations

I agree with CTP that “[t]hese...violations show an unwillingness or inability to sell tobacco products in accordance with federal tobacco regulations.” CTP Br. at 12. Respondent’s continued inability to comply with the federal tobacco regulations calls for a penalty in this instance.

iv. Degree of Culpability

Respondent is culpable for both violations of the Act and its implementing regulations.

v. Additional Mitigating Factors

After the first violation, Respondent retrained its employees on its tobacco policy to not sell tobacco to minors and check photo identification of all persons under 30 years old. After the second alleged violation, Respondent updated its equipment to allow scanning of identifications, modified its tobacco policy to require employees to scan tobacco customers’ identifications with an electronic scanning device, and trained its employees on the modified tobacco policy. R. Br. at 7-8.

I find Respondent’s subsequent actions persuasive and conclude that a reduced penalty is appropriate.

vi. Penalty

I acknowledge that Respondent has taken responsible measures in order to prevent future violations. Based on the foregoing reasoning, I find a penalty amount of \$175 to be appropriate under 21 U.S.C. §§ 303(f)(5)(B) and 333(f)(9).

Conclusion

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$175 against Respondent, State Oil Fuel Center, Inc. d/b/a State Oil, for two 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 12-month period.

/s/

Margaret G. Brakebusch
Administrative Law Judge