

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-H-4816)

Complainant

v.

Virk Group Inc.
d/b/a Chevron Mini Mart,

Respondent.

Docket No. T-17-5791

Decision No. TB2913

Date: July 23, 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, Virk Group Inc. d/b/a Chevron Mini Mart, for at four 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 24-month period. Specifically, Respondent violated the Act when it impermissibly sold cigarettes to minors on August 9, 2016 and June 13, 2017; failed to verify, by means of photo identification containing a date of birth, that a purchaser was 18 years of age or older on August 9, 2016; and used a self-service display in a non-exempt facility on November 3, 2015. I conclude that a civil money penalty in the amount of \$2,236, is appropriate.

I. Background

CTP began this matter by serving an administrative complaint seeking a \$2,236 civil money penalty on Respondent, at 5604 Summitview Avenue, Yakima, Washington 98908, and by filing a copy of the complaint with the FDA Division of Dockets Management. Respondent timely answered CTP's complaint, denying the allegations. On August 16, 2017, I issued an Acknowledgement and Pre-Hearing Order (APHO) in which I set a schedule of pre-hearing exchanges and deadlines for submissions. Specifically, I required that the parties submit as a proposed exhibit the complete written direct testimony of any proposed witnesses. APHO ¶¶ 4(c), 9-11.

The parties timely filed pre-hearing exchanges. CTP filed a pre-hearing brief (CTP Br.) and 14 exhibits (CTP Exs. 1-14), including the written direct testimony of two proposed witnesses, CTP's Senior Regulatory Counsel Laurie Sternberg (CTP Ex. 3) and Inspector Julie Rogers (CTP Ex. 4) who conducted the inspection at issue. Respondent filed a pre-hearing brief (R. Br.) and eight numbered exhibits (R. Exs. 1-5, 6a-6e, 7-8). Although Respondent listed two proposed witnesses, Tanjier Virk, Respondent's owner, and Gandeep Manz, Respondent's sales clerk, it only submitted the written direct testimony of Mr. Manz (R. Exs. 7-8). Counsel for Respondent asked to cross-examine CTP's witness Inspector Rogers. Counsel for CTP reserved the right to cross-examine Respondent's witness Mr. Manz.

On March 12, 2018, CTP, filed a motion to seal Respondent's Exhibits 6a, 6b, 6c, 6d, and 6e, arguing that they contain sensitive information and that sealing is necessary to protect the identity of CTP's undercover minor. Respondent did not object. On March 22, 2018, I granted CTP's motion to withhold from public disclosure Respondent's Exhibits 6a, 6b, 6c, 6d, and 6e.

On April 5, 2018, I conducted a hearing in this case. Transcript (Tr.). As a preliminary matter, CTP objected to the voiceover portion of Respondent's Exhibits 6a, 6b, 6c, 6d, and 6e. CTP argued the speaker was unknown and constituted improper direct testimony that Respondent failed to exchange as written direct testimony. Tr. 8-9. I found the voiceover portion of the video not relevant and sustained CTP's limited objection. Tr. 10.

I admitted CTP Exhibits 1 through 14; Respondent's Exhibits 1 through 5, 7, and 8; Respondent's Exhibits 6a, 6b, 6c, 6d, and 6e with the exception of the voiceover portion of the exhibits. Respondent's Exhibits 6a, 6b, 6c, 6d, and 6e, remain under seal and subject to my March 22, 2018 Order. May 1, 2018, Order; *see* Tr. 11.

During the hearing, counsel for Respondent sought to proffer Mr. Virk as a witness. I explained that Respondent had not submitted a written declaration from Mr. Virk as part of its pre-hearing exchange as required. Tr. 7-8; *see* APHO ¶¶ 4(c), 9-11; 21 C.F.R.

§§ 17.25(a), 17.37(b); *see also* Nov. 15, 2017, Ruling Denying Respondent's Motion For Deposition (finding that Respondent's motion to depose Mr. Virk as a witness was premature and did not meet the regulatory criteria, but reminded Respondent to submit the written direct testimony of its witnesses with its forthcoming pre-hearing exchange). Accordingly, I denied counsel's request; however, I welcomed Mr. Virk to audit the hearing. Respondent cross-examined Inspector Rogers (Tr. 11-17), and CTP re-directed its witness (Tr. 17-18). CTP elected not to cross-examine Mr. Manz. Tr. 18.

The parties filed post-hearing briefs (R. Final Br., CTP Final Br.).

II. ISSUES

- A. Whether Respondent sold cigarettes to a minor on June 13, 2017, in violation of 21 C.F.R. § 1140.14(a)(1), and if so;
- B. Whether the civil money penalty amount of \$2,236 sought by CTP is appropriate.

III. 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). Violations of the Act's requirements include the sale of tobacco products to an individual who is under the age of 18, failing to verify the photographic identification of an individual who is not over the age of 26, and the use of a self-service display in a non-exempt facility. 21 C.F.R. §§ 1140.14(a)(1), (a)(2)(i), .16(c). The FDA, and its 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. § 333 (f)(9).

This is the second civil money penalty action against Respondent. CTP Ex. 1. The previous action concluded after Respondent admitted to three violations of regulations within a 24-month period and paid the agreed upon penalty. CTP Ex. 2. Specifically, Respondent admitted to:

- (1) Using a self-service display in a non-exempt facility on November 3, 2015, in violation of 21 C.F.R. § 1140.16(c);
- (2) Selling a cigarettes to a minor on August 9, 2016, in violation of 21 C.F.R. § 1140.14(a)(1); and
- (3) Failing to verify photographic identification of the cigarette purchaser on August 9, 2016, in violation of 21 C.F.R. § 1140.14(a)(2)(i).

CTP Exs. 1-2; *see* Complaint at 3-4. Respondent expressly waived its right to contest these violations in subsequent actions. CTP Ex. 2. These violations are administratively final.

I now turn to whether the remaining allegations in the complaint are true, and, if so, whether Respondent's actions constitute a violation of law. 21 C.F.R. § 17.45(b). Specifically, I must determine:

- Whether Respondent sold cigarettes or smokeless tobacco to a minor on June 13, 2017, in violation of 21 C.F.R. § 1140.14(a)(1).¹

CTP has the burden to prove Respondent's liability and appropriateness of the penalty by a preponderance of the evidence. 21 C.F.R. § 17.33(b). It is Respondent's burden to prove any affirmative defenses and any mitigating factors likewise by a preponderance of the evidence. 21 C.F.R. § 17.33(c). As I detail below, I find that based on the evidence of record, Respondent sold cigarettes to a minor on June 13, 2017, in violation of 21 C.F.R. § 1140.14(a)(1).

CTP asserts that Respondent violated 21 C.F.R. § 1140.14(a)(1), on June 13, 2017, at approximately 4:20 PM, when Respondent allegedly sold cigarettes to a minor. Complaint at 2-3. CTP's case against Respondent rests on the testimony of Inspector Julie Rogers, supported by corroborating evidence including contemporaneous notes and photographs. CTP Exs. 4-9. Inspector Rogers is an FDA-commissioned officer for the state of Washington whose duties include determining whether retail outlets unlawfully sell tobacco products to minors. CTP Ex. 4 at 1. Inspector Rogers testified that the undercover buy inspections entail accompanying minors who attempt to purchase tobacco products from retail establishments, such as the one operated by Respondent. CTP Ex. 4 at 2. Inspector Rogers testified that she conducted such an inspection of Respondent's establishment on June 13, 2017, at approximately 4:20 PM, during which she observed Respondent's clerk sell an undercover minor cigarettes. CTP Ex. 4 at 2.

Inspector Rogers testified that after the purchase, both the minor and she exited the establishment and returned to the vehicle, where the minor immediately handed the inspector the pack of cigarettes. CTP Ex. 4 at 3. Inspector Rogers labeled the cigarettes as evidence, photographed all of the panels of the package, and processed the evidence in accordance with standard procedures. *Id.* Inspector Rogers also recorded the inspection in the FDA's Tobacco Inspection Management System and created a Narrative Report.

¹ Respondent states that "[t]o find respondent liable, CTP has the burden of proving that the clerk 'failed to verify by checking photographic [identification], that the subject cigarette purchaser was over eighteen.' 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(a)(2)(i)." R. Final Br. at 2. However, CTP is only alleging that Respondent sold cigarettes to a minor and not a failure to verify identification. Complaint at 3.

Id. CTP corroborated Inspector Rogers' testimony by offering as evidence photographs that the inspector made of the cigarettes, on the date in question. CTP Exs. 8-9. CTP further corroborated Inspector Rogers' account by submitting a copy of her contemporaneously recorded Narrative Report and Tobacco Inspection Management System report. CTP Exs. 6-7.

CTP also offered as a witness, Laurie Sternberg, Senior Regulatory Counsel in CTP's Office of Compliance and Enforcement. CTP Ex. 3 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 Philip Morris USA manufactured the cigarettes purchased during the inspection on June 13, 2017, at Respondent's establishment, and that Philip Morris USA does not have a tobacco production facility in the state of Washington. *Id.* at 2-3.

Respondent challenges the integrity of the undercover inspection by attacking the credibility of the minor. Respondent's sales clerk testified that he was presented an identification different from that produced as CTP Ex. 5. R. Ex. 8 at 2. Respondent's primary argument focuses on verification of the minor's identification and assertions that CTP cannot prove that the minor was not carrying two identifications, one showing her true and actual age, and a second false identification showing that she was age 18 or older. R. Br. at 4-5; R. Final Br. at 3-4; R. Ex. 7 at 2-3; R. Ex. 8 at 2. Accordingly, Respondent concludes that CTP failed to meet its burden of proof to establish that Respondent violated 21 C.F.R. § 1140.14(a)(1). R. Br. at 6.

I find that Respondent's argument is speculative and misguided. Inspector Rogers testified credibly and comprehensively about her observations during the June 13, 2017, inspection at which she observed Respondent selling tobacco products to the minor.

Inspector Rogers testified that, prior to the inspection at issue, she verified that the minor carried photographic identification that included the minor's true age. Inspector Rogers also verified that the minor did not have any tobacco products in her possession. CTP Ex. 4 at 2. At Respondent's establishment located at 5604 Summitview Avenue, Yakima, Washington 98908, Inspector Rogers and the minor exited the vehicle, the inspector watched the minor enter Respondent's establishment, and followed thereafter. *Id.* at 3. Inspector Rogers testified that she took a position at a location in the store from which she had a clear, unobstructed view of the sales counter, the minor, and the transaction in question. *Id.* at 3; Tr. at 17-18. From this location, Inspector Rogers observed the minor purchase a package of cigarettes from an employee at the establishment. CTP Ex. 4 at 3; CTP Ex. 6 at 1; Tr. at 17-18. Specifically, Inspector Rogers testified that she observed Respondent's employee check the minor's identification, manually enter data into Respondent's point of sale system, sell cigarettes directly to the minor, and not provide a sales receipt. CTP Ex. 4 at 3; *see* CTP Ex. 6 at 1; Tr. at 16. Inspector Rogers' testimony is supported by her contemporaneous narrative,

Tobacco Inspection Management System report, photographic evidence, and Respondent's video submissions. CTP Exs. 6-9; R. Ex. 6a-6e.

Respondent relies heavily on the video evidence submitted.² However, neither Respondent's video nor testimonial evidence supports Respondent's assertion that the minor provided a false identification to Respondent's sales clerk. Instead, the video shows that the minor presented the clerk an identification with a vertical orientation. The identification in the video is consistent with the evidence submitted by CTP, which reflects the minor's date of birth as March 31, 2000. CTP Ex. 5.

Respondent asserts that its sales clerk verified the cigarette purchaser's age by means of photographic identification, correctly entered the license information into its "computerized state connected electronic identification system" which verified that the tobacco purchaser was over 18 years of age. R. Final Br. at 1-2. Respondent relies on the testimony of Mr. Manz: "I know I accurately entered into the computer system, the date of birth shown on the identification I was given." R. Ex. 8 at 2. "I entered that driver's license information into the system and the system informed me that the license was accurate and that the woman presenting the license was in fact over 18." R. Ex. 7 at 2-3. Mr. Manz concludes, "If the identification now produced and claimed to have been given me shows an age less than 18, that (sic) was not the identification I was presented at the time of the purchase." R. Ex. 8 at 2.

First, I find it implausible that the minor possessed two *valid* identifications, one with her true age and one with an incorrect date of birth showing her of majority age. Further, I note that even if Respondent's point of sale system was not functioning properly and incorrectly "approved" its sale of a tobacco product to a minor, Respondent would still be in violation of the regulation. The regulation is clear - it is a violation to sell cigarettes, smokeless tobacco, or any covered tobacco product to a minor. 21 C.F.R. § 1140.14(a)(1), (b)(1).

Inspector Rogers' testimony, supported by contemporaneous evidence and Respondent's video submission is sufficient for me to conclude that the minor presented her true and accurate identification as a minor and presented as CTP Ex. 5.

Respondent also attempts to attack the credibility of the inspector. R. Br. at 3; R. Ex. 7 at 3. Respondent's clerk testified:

² The video Respondent submitted is not the original footage obtained from its security recordings. Instead, the video submitted is a secondary recording, taken with an external device, which recorded a video monitor as it played selected surveillance footage. I note that the recording is incomplete and frequently fails to capture the full scope of what is shown on the monitor. I find this particular evidence of limited value.

I have read the “narrative report” which it is claimed was prepared by the inspector, Julie Rogers. In that report, in paragraphs 9, 10 and 11, it is stated that Ms. Rogers was in the store and “observed” my selling tobacco product to the purchasing customer. That is incorrect. The woman I sold the tobacco product to was alone in the store at the time of the sale.

R. Ex. 7 at 3.

However, the video evidence shows that the inspector was present during the sale. R. Ex. 6a, at 37 seconds. The clerk’s memory of what occurred during the inspection is not supported by evidence. On the other hand, the evidence of record supports CTP’s position.

I find that CTP has provided sufficient evidence to support its allegation that Respondent is subject to the Act and sold cigarettes to a minor on July 13, 2017, in violation of 21 C.F.R. § 1140.14(a)(1). Respondent has failed to provide evidence sufficient to rebut CTP’s allegations.

The facts as outlined above, establish that Respondent’s actions constitute a violation of law and that Respondent is liable 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). Under 21 C.F.R. § 1140.14(a)(1), no retailer may sell tobacco products to any person younger than 18 years of 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. Under 21 C.F.R. § 1140.16(c), no retailer may use a self-service display in a non-exempt facility. Accordingly, CTP is entitled to seek a civil money penalty from Respondent. 21 U.S.C. § 333 (f)(9).

B. Civil Money Penalty

I have found that Respondent committed four violations of the Act and its implementing regulations within a 24-month period. In its Complaint, CTP sought to impose the maximum penalty amount, \$2,236, against Respondent. Complaint at 1. Accordingly, I now turn to whether a \$2,236 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).

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

I found that Respondent committed two violations of selling cigarettes to minors, one violation for failing to verify, by means of photo identification containing a date of birth, that the purchaser was 18 years of age or older, and one violation for utilizing a self-service display 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.

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

Respondent has not presented any evidence that it does not have the ability to pay the \$2,236 civil money penalty sought by CTP.

c. History of Prior Violations

The current action is the second civil money penalty action that CTP has brought against Respondent. On February 16, 2017, CTP initiated its first civil money penalty action, CRD Docket Number T-17- 2304, FDA Docket Number FDA-2017-H- 0925, against Respondent for three violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP Ex. 1; Complaint at 3. On May 8, 2017, Respondent settled its first civil money penalty action, which included a violation for selling tobacco products to a minor. CTP Ex. 2. Yet, about five weeks later, on June 13, 2017, Respondent once again sold tobacco products to a minor. Respondent’s continued inability to comply with the federal tobacco regulations calls for a more severe penalty.

d. Degree of Culpability

I find Respondent fully culpable for all four violations of the Act and its implementing regulations.

e. Additional Mitigating Factors

Respondent had not provided evidence of any remedial measures it has taken subsequent to its most recent violation. At some point prior to the most recent violation, Respondent seemingly invested in mechanisms to minimize violations of the tobacco regulations, such as its point of sale device and video monitoring system. Although Respondent only

