

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2015-H-2299)

Complainant

v.

Friends and Brothers, Inc.
d/b/a Amy's Liquor,

Respondent.

Docket No. C-15-3078

Decision No. CR4713

Date: September 28, 2016

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Friends and Brothers, Inc. d/b/a Amy's Liquor, located at 8560 Grand River Avenue, Detroit, Michigan 48204, 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. Specifically, CTP alleges that Amy's Liquor violated the Act by impermissibly selling tobacco products to minors, on three separate occasions, and 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.

Procedural History

CTP began this matter by serving an administrative complaint seeking a \$5,000 civil money penalty on Respondent Amy's Liquor, at 8560 Grand River Avenue, Detroit, Michigan 48204, 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 and asserted that video surveillance showed that Respondent did not sell a tobacco product to a minor. On August 20, 2015, Administrative Law Judge Diane Townsend-Anderson¹ issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for the parties to file their pre-hearing exchanges.

Following two motions to extend the deadlines that were granted, CTP filed its pre-hearing exchange on February 11, 2016. CTP's pre-hearing exchange included the declarations of two witnesses. And, following another motion to extend the deadlines that was granted, Respondent filed its pre-hearing exchange on March 28, 2016. Respondent provided no witnesses of record.

On May 11, 2016, I held a pre-hearing conference in this case. Following the pre-hearing conference, I issued an Order that scheduled the hearing for July 13, 2016. That Order also explained that during the pre-hearing conference we discussed the thumb drive containing video surveillance that was listed as a proposed exhibit in Respondent's Informal Brief, and the fact that this thumb drive had not been provided to the Court. During the pre-hearing conference, the CTP's counsel indicated that it did not oppose the thumb drive being entered into evidence, and so Respondent's counsel was to mail the thumb drive to the Court for review. The Order also noted that during the prehearing conference call, I stated that Respondent had not provided any witnesses of record, and that CTP had provided two witnesses. During the pre-hearing conference, Respondent's counsel indicated that he wanted to cross examine one of CTP's witnesses, Inspector Timothy Shafto.

On May 18, 2016, Respondent filed a motion requesting that I reconsider its proposed witness and exhibit list. Respondent stated that during the prehearing conference I found that Respondent had failed to file a Witness and Exhibit List, but that the March 28, 2016 electronic filing contained a witness and exhibit list. On June 17, 2016, I issued an Order that explained that Respondent had no witnesses because it failed to provide written direct testimony as required by 21 C.F.R. § 17.37(b), and section 9 of the APHO.

On June 20, 2016, I also issued an Order requesting Respondent to provide its surveillance video in AVI format or inform the Court if it is unable to do so. Respondent did not comply with that Order.

¹ On January 14, 2016 this case was reassigned to Administrative Law Judge Steven T. Kessel, and on April 4, 2016 this case was reassigned to me.

On July 13, 2016, a hearing was held in this case. The purpose of the hearing was to allow Respondent to cross examine Inspector Timothy Shafto.

Following the hearing, a letter was issued at my direction that informed the parties of how the post-hearing briefing period would occur. The letter also informed Respondent that the Civil Remedies Division had not received the July 29, 2016 communication that, during the hearing, Respondent's attorney stated provided instructions on how to play the surveillance video.

In an August 1, 2016 Order, I informed the parties that the Court had received the transcript of the hearing, and set the deadline for the parties' post-hearing brief submission as August 31, 2016. 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).

In its Complaint, CTP alleges that Respondent Amy's Liquor committed five violations of the Act and its implementing regulations within a thirty-six month period. Amy's Liquor filed an answer, and informal brief, that denied selling a tobacco product to a minor. Answer; Informal Brief of Respondent.

The Complaint currently before me involves one prior complaint. The prior complaint was settled by the parties and in settling the complaint the Respondent admitted the violations occurred, waived the ability to contest the violations in the future, and stated that Respondent understood that the violations may be counted in determining the total number of violations for future enforcement actions. Complaint; Informal Brief of Complainant. The Complaint currently before me involves two new violations: impermissibly selling cigarettes to a minor, and failing to verify, by means of photo identification containing a date of birth, that the purchaser was 18 years of age or older.

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

Mr. Shafto testified that he went to Respondent's place of business on March 14, 2015. CTP Ex. 4 at 2-3. Mr. Shafto averred that on March 14, 2015 he confirmed that the minor was carrying her photographic identification, and that she did not have tobacco products in her possession. Mr. Shafto stated that he gave the minor the keys to the vehicle when she exited the vehicle so that she would have access to the vehicle after the inspection. Mr. Shafto testified that the minor entered the establishment first and went directly to the counter, and that he entered the establishment soon after and stood where he had a clear view of the sales counter. Mr. Shafto averred that he saw the minor purchase a package of cigarettes from an employee of Respondent, and that the minor did not provide photographic identification to the employee, and that the employee did not provide the minor with a receipt after purchase. *Id.*

Mr. Shafto stated that the minor exited the store a few minutes before him, and that when he returned to the vehicle the minor gave him the cigarettes, which he saw were Newport cigarettes, and the minor confirmed that the Respondent's employee did not request photographic identification. CTP Ex. 4 at 3. Mr. Shafto stated that he then labeled the cigarettes as evidence, and made photographs of the package. *Id.* at 3, 12-13. Mr. Shafto testified that shortly after the inspection he recorded the inspection in the FDA's Tobacco Inspection Management System. *Id.* at 3.

Mr. Shafto testified that when he started the inspection the time on his iPhone was 10:43 am, and that he and the minor exited the vehicle and entered the store between 10:43 am and 10:48 am. CTP Ex. 4 at 3. Mr. Shafto averred that he took photographs of the Respondent's exterior and signs from 10:48 am to 10:50 am. *Id.* at 3-4, 10-11. Mr. Shafto testified that he took the first photograph of the evidence at 10:59 am, and that the time on his iPhone was 11:10 when he completed the inspection. *Id.* at 4.

Mr. Shafto's testimony plus the corroborating evidence consisting of photographs of the pack of cigarettes that he obtained from the minor on March 14, 2015 are proof that Respondent unlawfully: sold a tobacco product to a minor, and failed to check the minor's identification before making the sale.

Throughout the case Respondent's counsel has asserted that video surveillance of the time at issue shows that Respondent did not commit the violations. During the cross examination and redirect testimony of Mr. Shafto it became evident that while the time stamp on the video was before the time stated in the complaint the video contained only the end of Mr. Shafto's inspection. Mr. Shafto's testimony indicated that after the undercover buy occurred he returned to the car, and then once again exited the car to take photographs of the outside of the establishment. As soon as the surveillance video begins, you see a man leave his car and walk to different points around the establishment and apparently take photographs of the establishment before returning to his car. While there is evidently an issue in determining exactly what specific time the violations occurred, the specific minute that the violations occurred is not material in determining that the violations did in fact occur.

In its post-hearing brief, Respondent asserts that CTP violated its due process rights and that CTP's actions constitute prejudice. Respondent states that CTP requested additional video but that that additional video was already recorded over by the time it was requested. Respondent also states that it was never informed that Mr. Shafto saw himself in the video.

CTP's post-hearing brief asserts that "any deficiencies with the Respondent's evidence should properly fall on the Respondent's shoulders." I agree. Further, CTP had no duty to inform Respondent that Mr. Shafto appeared on the video. Mr. Shafto's testimony described the sequence of events, and Respondent possessed the video to review to see if any of those events occurred. Additionally, Respondent could have requested a description of Mr. Shafto, or a picture, as part of discovery to assist in their viewing of the video. But, there is no indication in the record that Respondent did so.

I find that these facts establish Respondent Friends and Brothers, Inc. d/b/a Amy's Liquor's liability under the Act.

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Amy's Liquor 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, \$5,000, against Respondent for five violations of the Act and its implementing regulations within a thirty-six month period. Complaint ¶ 13. In its Informal Brief, CTP continues to assert that a \$5,000 civil money penalty is appropriate. Informal Brief of Complainant at 9-11.

In both its Answer and its Informal Brief, Respondent denied any obligation to pay a civil money penalty because it did not violate the regulations.

I have found that Respondent committed at least five violations of the Act and its implementing regulations within a thirty-six 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. § 303(f)(5)(B). Respondent has not provided any arguments with regards to the nature, circumstances, extent and gravity of the violations, the Respondent’s ability to pay, the effect on Respondent’s ability to continue to do business, any history of prior such violations, the degree of culpability, etc. Instead, Respondent’s sole argument is 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 Amy’s Liquor has failed to comply with the Act and its implementing regulations. Over the course of the six violations discussed in this Complaint, Respondent has admitted to four violations², and I have found that Respondent committed the two most recent violations; specifically Respondent has committed: three violations of selling tobacco products to minors, and 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. 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

There is nothing in the evidentiary record that shows Respondent’s ability to pay a civil money penalty or shows the effect a civil money penalty will have on Respondent’s ability to do business. Respondent had the opportunity to show an inability to pay a \$5,000 civil money penalty, and the effect that a \$5,000 civil money penalty would have on its business, but it did not do so.

iii. History of Prior Violations

The current action is the second civil money penalty action brought against Respondent since August 29, 2014 for violations of the Act and its implementing regulations. In the first civil money penalty action, CRD Docket Number

² I note that CTP’s requested CMP is based upon 5 violations.

C-14-1799, FDA Docket Number FDA-2014-H-1272, Respondent twice violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), and 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). Respondent settled the prior complaint with CTP for an undisclosed penalty amount.

I agree with CTP that “[t]hese repeat violations show an unwillingness or inability to sell tobacco products in accordance with federal tobacco regulations.” 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 Amy's Liquor admitted to four violations. Based on Respondent's own admissions and my finding that Respondent committed the two most recent violations in the current complaint, I hold it fully culpable for all six violations of the Act and its implementing regulations.³

v. Additional Mitigating Factors

Respondent has not asserted any mitigating factors.

vi. Penalty

Based on the foregoing reasoning, I find a penalty amount of \$5,000 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 \$5,000 against Respondent, Friends and Brothers, Inc. d/b/a Amy's Liquor, 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/
Catherine Ravinski
Administrative Law Judge

³ I note that CTP's requested CMP is based upon 5 violations.