

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Hanna Zamunda, Inc.
d/b/a Ecorse Market,

Respondent.

Docket No. T-18-856
FDA Docket No. FDA-2018-H-0109

Decision No. TB3349

Date: December 21, 2018

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty (CMP) against Respondent, Hanna Zamunda, Inc. d/b/a Ecorse Market, located at 585 Visger Road, Ecorse, Michigan 48229, for 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.¹ Specifically, in this instance, CTP alleges that Respondent violated the Act by impermissibly selling covered tobacco products to a minor.

¹ Previously, on June 28, 2017, CTP initiated the first CMP action for three violations, which was resolved after Respondent admitted all of the allegations in the complaint and paid the agreed upon penalty. In acknowledging that the alleged violations occurred, Respondent expressly waived its right to contest such violations in subsequent actions. *See* Notice of Settlement Agreement FDA Docket FDA-2017-H-3890, CRD Docket T-17-4989 (First CMP Acknowledgment Form documenting admission of liability).

Procedural History

CTP began this case by serving an administrative complaint seeking a \$2,236 civil money penalty on Respondent, at 585 Visger Road, Ecorse, Michigan 48229, 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 allegation. Respondent's Answer (Answer) at 2.

On February 9, 2018, I issued an Acknowledgment and Pre-Hearing Order, which established the procedure and deadlines in this case. CTP filed its pre-hearing exchange on May 30, 2018. CTP's pre-hearing exchange included 11 numbered exhibits (CTP Exs. 1-11) and declaration of one witness. Respondent filed its pre-hearing exchange on June 18, 2018, which included four exhibits originally labeled A-D, (R. Exs. 1-4),² and a declaration of one witness.

On July 11, 2018, I held a pre-hearing conference in this case. During the prehearing conference call, we discussed the procedural history of the case as well as the prehearing exchanges submitted by both parties. CTP offered one witness in this case, Inspector Hiram Harris. Respondent also offered one witness, Respondent's manager, Danny Samona. Both parties communicated its desire to cross-examine the opposing party's witness.

On August 9, 2018, I held a hearing in this case. During the hearing, I admitted the exhibits (CTP Exs. 1-11, Respondent Exs. 2-5), and allowed Respondent to cross-examine Inspector Harris and CTP to cross-examine Mr. Samona.

On August 30, 2018, 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 October 5, 2018. Both parties filed post-hearing briefs.

Analysis

In order to prevail, CTP must prove Respondent's liability by a preponderance of the evidence. The U.S. Supreme Court has described the preponderance of the evidence standard as requiring that the trier-of-fact believe that the existence of a fact is more probable than not before finding in favor of the party that had the burden to persuade the judge of the fact's existence. *In re Winship*, 397 U.S. 358, 371-72 (1970); *Concrete Pipe and Products of California, Inc. v. Construction Laborers*, 508 U.S. 602, 622 (1993).

² Respondent submitted and labeled its exhibits as A-D, and then later submitted an amended exhibit A, a declaration of Respondent's manager, Danny Samona, entitled exhibit E. I retitled Respondent's exhibits (R. Ex. 1-5), and admitted Respondent's exhibits 2-5, as exhibit E is an amended version of exhibit A (Ex. 1.).

I. Alleged Violation

CTP determined to impose a CMP 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 covered tobacco products to an individual who is under the age of 18 years is a violation of implementing regulations. 21 C.F.R. § 1140.14(b)(1).

In the instant case, CTP alleged that on December 18, 2017, an FDA-commissioned inspector conducted an inspection of Ecorse Market, and that during this inspection, Respondent committed a violation for selling covered tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(b)(1). Specifically, a person younger than 18 years of age was able to purchase a package of two Swisher Sweets cigars on December 18, 2017, at approximately 7:27 pm. Complaint at ¶ 9.

A. Parties' Contentions and Evidence

i. CTP's Position

In its Complaint, CTP alleges that Respondent committed four violations of the Act and its implementing regulations within a 24-month period. Complaint at ¶ 1. Respondent filed an answer, denying that it had sold covered tobacco products to a minor on the date at issue, December 18, 2017. Answer at 2. Respondent argues that CTP provided no proof of the acts or events whatsoever nor did it provide Respondent with documents establishing such allegations. Answer at 2.

CTP's case against Respondent rests on the testimony of Inspector Harris plus corroborating evidence. CTP Exs. 4, 8-9. Inspector Harris is an FDA-commissioned officer with the Michigan Department of Health and Human Services, whose duties include determining whether retail outlets are unlawfully selling tobacco products to minors. CTP Ex. 4. Inspector Harris's inspections entail accompanying minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id.*

Inspector Harris testified that on December 18, 2017, at approximately 7:27 pm, he conducted a follow-up compliance check inspection at Ecorse Market, located at 585 Visger Road, Ecorse, Michigan 48229. CTP Ex. 4 ¶ 9. Inspector Harris further testified that during the inspection, he was accompanied by Minor A, and with a clear and unobstructed view of both the sales counter and Minor A, he observed Minor A purchase

a package of cigars from an employee at the establishment. CTP Ex. 4 ¶ 10, Transcript (T.) at 12.

Inspector Harris testified that once he and Minor A exited the store, they returned to Inspector Harris's vehicle where he immediately obtained the package of cigars from Minor A. Inspector Harris observed that the package contained two Swisher Sweets cigars. Inspector Harris labeled the cigars as evidence, photographed both sides of the package, and then processed the evidence in accordance with standard procedures. CTP Ex. 4 ¶ 11.

ii. Respondent's Position

Respondent vehemently denies CTP's allegation that it sold tobacco products to a minor on December 18, 2017, at approximately 7:27 pm, stating that "[n]o such tobacco violations occurred at Ecorse Market on December 18, 2017." Respondent's Pre-Hearing Brief (Br.) at 3. Respondent questions the reliability of CTP's evidence to support its allegation. Respondent argues that CTP has not satisfied its burden as CTP failed to proffer a sales receipt for confirmation that the illegal sale occurred and that "[Inspector Harris's] recollection of his time spent in Ecorse Market lacks depth." Respondent's Post-Hearing Br. at 4.

Respondent submits that Inspector Harris was unable to recall details about the incident during the hearing. Respondent's Post-Hearing Br. at 3. Respondent notes that Inspector Harris described the cashier, who allegedly sold tobacco to the minor, as an older gentleman with grayish white hair. *Id.* at 4; T. 14. Danny Samona, Respondent's manager, testified that on December 18, 2017, at the time of the alleged tobacco violation, there was no employee on staff fitting the description as stated by the FDA-commissioned officer." Respondent's Ex. 5 ¶ 3.

Respondent argues that, in addition to Inspector Harris's inability to recall the details of the date in question, a sales receipt for the cigars was not provided. Respondent's Post-Hearing Br. at 3. Respondent further argues that the "tobacco product in this case...is not a novel item and can be purchased at virtually any tobacco retailer in Michigan. Respondent asserts that a purchase receipt would have bolstered [Inspector] Harris's claims that tobacco was sold to the decoy that evening." *Id.*

Moreover, Respondent contends that "[h]ad Respondent immediately been notified of the offense, Respondent could have taken the necessary steps to preserve surveillance footage from the business to verify or refute CTP's allegations." Respondent's Pre-Hearing Br. at 4. According to Respondent, "CTP sent a notice to Respondent nearly two weeks later ... [b]eing notified of the incident almost two weeks after the alleged occurrence left Respondent in no position to verify that any offense occurred on that date" *Id.* at 3.

B. Findings of Fact

I find Respondent's arguments to be without merit. Respondent attacks Inspector Harris's credibility by criticizing Inspector Harris's inability to remember insignificant details of the incident, including a detailed description of the cashier, the number of sale registers behind the counter, and the number of staff members behind the counter. Respondent's Post-Hearing at 3; T. at 13-14. Such extraneous factors about the store and incident are irrelevant to the issue at hand, especially considering the voluminous number of inspections conducted by inspectors. During the hearing, Inspector Harris revealed that a significant number of inspections are conducted "... maybe about 120 inspections on a monthly basis." T. 12. As it is possible that Inspector Harris could have conducted as many as 800 inspections during the intervening seven months between the December 18, 2017 inspection and his August 9, 2018 hearing testimony, his inability to independently recall specific details of the cashier's physical features or the layout of the store is not enough to discredit his testimony. Inspector Harris testified that he was in the store no more than five minutes. T. 14. It is reasonable to assume that during this short time period, the Inspector primarily focused on the interaction between the cashier and the minor rather than observing such things as the number of cash registers or the number of staff members behind the counter.

Additionally, Respondent's assertion that the Inspector could not see the actual transaction take place is not sufficient to rebut the allegations. Inspector Harris testified that he was within five feet of the minor and in view of the register and cashier. T. at 13. When questioned as to whether the cigars may have been purchased elsewhere, Inspector Harris testified:

A That's not possible.

Q How so?

A The minor went into -- well, number one, we pick the minors up at the start of the day. We confirm that they have their ID on their person. We also confirm that they have no tobacco products on their person. So, no, it -- it is not possible that, you know, we had a decoy who for whatever reason would like to, you know, I guess fake -- fake a purchase at a location and say that something was sold to them that was not. Along with that, you have myself, you know, a commissioned officer of the FDA, who visually saw the sale, and we began the immediate documentation of that purchase as soon as we left the location.

T. at 22. Furthermore, Respondent's notion that CTP failed to prove the sale by a sales receipt is also insufficient to rebut the allegation. There is no provision in the applicable regulations requiring proof of purchase in the form of a cash register receipt.

Respondent also argues that a discrepancy in the testimony of Inspector Harris and Respondent's owner and manager further supports Respondent's position. In Inspector Harris's December 18, 2017 narrative summary of the transaction, Inspector Harris describes the cashier as an adult male with gray/white hair. During Inspector's Harris's testimony, he also recalled the cashier as an older gentleman with grayish white hair. He did not recall the cashier's ethnicity, however, he testified that he didn't believe that cashier was African American. Tr. At 15. Danny Samona; Respondent's owner and manager, testified that he does not have gray hair and that he was the only employee on staff that night who was not African American. Tr. At 27. Prior to the hearing and in response to CTP's request for production of documents, Respondent submitted a schedule for the persons working at the establishment on December 18, 2017. The document included a list of the first names of four individuals who were scheduled to work at 7:27 p.m.; the time of the alleged sale. Respondent submitted no employee or personnel records to document the age or ethnicity of the individuals working at 7:27 p.m. on December 18, 2017. Thus, I do not find the argued discrepancy in testimony sufficient to discredit Inspector Harris's testimony.

Respondent suggested that video surveillance of the alleged violation could have been preserved had earlier notice been provided. The incident took place on December 18, 2017, CTP issued a notice of inspection on December 22, 2017. According to Respondent's Policy and Procedures, "...cameras continuously record sales transaction at the cash register and such recording will retained for at least thirty (30) days." Respondent Ex. 4 at 4. When questioned on when that provision was included in the manual, Mr. Samona testified:

A It would have been done after the first alleged offense that we received from CTP.

T. at 24. The first CMP initiated by CTP was on June 28, 2017. Complaint ¶ 11. Therefore, Respondent had ample time to preserve any recording related to this incident and submit as evidence to support its argument. However, Respondent failed to do so.

The evidence of record establishes to my satisfaction that the violation charged in this case in fact took place on the date in question. The testimony of Inspector Harris, plus the corroborating evidence is sufficient to establish that it is more likely than not that Respondent unlawfully sold a package of cigars to a minor in violation of 21 C.F.R. § 1140.14(b)(1).

Therefore, I find that the facts as outlined above establish Respondent, Hanna Zamunda, Inc. d/b/a Ecorse Market's liability under the Act for four violations within a 24-month period.

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Ecorse Market 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 penalty amount of \$2,236, against Respondent for four violations of the Act and its implementing regulations within a twenty-four month period. Complaint at ¶ 1.

In its Answer and Pre-Hearing Brief, Respondent asserted that no penalty should be assessed as Respondent's position is that no violations occurred. Answer at 2; Respondent's Pre-Hearing Br. at 3.

I have found that Respondent committed four violations of the Act and its implementing regulations within a 24-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).

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

I find that Respondent sold the cigars to the minor on December 18, 2017, in violation of federal regulations. This is the second CMP initiated by CTP. 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 maintains that it has already suffered a major financial loss resulting from this Complaint and requests the Court to assess the detriment that would be incurred by the Respondent if it is found liable for the \$2,236 penalty. Respondent's Post-Hearing Br. at 2, 6. Although Respondent argues that the penalty amount is detrimental to its business, Respondent has not provided adequate evidence to substantiate this argument, including, but not limited to, annual tax documents, income statements, etc. Respondent has not presented any evidence that it does not have the ability to pay the \$2,236 CMP sought by CTP.

iii. History of Prior Violations

Respondent contends that it has proven to treat this as a serious matter – as Respondent has spent tremendous resources on re-training staff, adding adequate camera systems and computers, and has spent a considerable amount of time and resources related directly to this Complaint. Respondent's Post-Hearing Br. at 6. However, the current action is the second civil money penalty action brought against Respondent for violations of the Act and its implementing regulations.

As noted, this is Respondent's second CMP. Respondent has three times violated the prohibition against selling covered tobacco products or cigarettes to persons younger than 18 years of age, and twice violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no cigarette or covered tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(1), (b)(1); 21 C.F.R. § 1140.14(a)(2)(i), (b)(2)(i).

iv. Degree of Culpability

Based on my finding that Respondent committed the most recent violation in the current complaint, I hold it fully culpable for all four violations of the Act and its implementing regulations.

v. Additional Mitigating Factors

Mitigation is an affirmative defense for which Respondent bears the burden of proof. Respondent must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence. 21 C.F.R. § 17.33(c). Respondent argued that it did not commit the alleged violation and has devoted considerable time and resources to rebut this allegation. While I understand Respondent's position, the record of evidence establishes that it is more likely than not that Respondent unlawfully sold a package of cigars to a minor. This violation, coupled with the prior violations, proves that Respondent committed 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. The regulations were created as an initiative to avert minors from purchasing tobacco products.

The purpose of The Family Smoking Prevention and Tobacco Control Act is to prevent unlawful sales of tobacco products to minors. Tobacco is a highly addictive and dangerous product. The reason that sales of tobacco products to minors is unlawful is that consumption of these products at an early age can lead to a lifetime of addiction, to illness, and ultimately to premature death. Sales of tobacco products to minors are unlawful because younger individuals often lack the maturity and judgment to make informed decisions about whether to consume such inherently dangerous and addictive

