

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

El Tornado, LLC
d/b/a El Tornado Drive Thru,

Respondent.

Docket No. T-18-2458
FDA Docket No. FDA-2018-H-2169

Decision No. TB 3918

Date: May 31, 2019

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty (CMP) against Respondent, El Tornado, LLC d/b/a El Tornado Drive Thru, located at 5009 North Doffing Road, Mission, Texas 78574, for seven 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 48-month period.¹ Specifically, in this instance, CTP alleges that Respondent violated the Act by 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.

¹ Previously, on June 20, 2017, CTP initiated a CMP action for five 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-3603, CRD Docket T-17-4725. *See also* FDA Docket FDA-2016-H-4070, CRD Docket T-17-947.

Procedural History

CTP began this case by serving an administrative complaint on June 8, 2018, seeking an \$11,182 civil money penalty on Respondent, at 5009 North Doffing Road, Mission, Texas 78574, 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 admitted the allegations, but contested the civil money penalty. Respondent's Answer (Answer) at 1-2.

On July 18, 2018, I issued an Acknowledgment and Pre-Hearing Order, which established the procedure and deadlines in this case. On August 10, 2018, CTP filed an Unopposed Motion to Extend Deadlines and Notice of Pending Settlement (Motion). CRD Docket No. 5. The Motion requested that the deadlines be extended so that Respondent could pay the agreed upon civil money penalty. I granted the motion on August 13, 2018. CRD Docket No. 6.

CTP filed its pre-hearing exchange on November 8, 2018. CTP's pre-hearing exchange included 16 numbered exhibits (CTP Exs. 1-16) and declarations of two witnesses, including Inspector Maria Isabel Martinez. Respondent did not file a pre-hearing exchange.

On December 18, 2018, I held a prehearing conference call in this case. Respondent did not appear at the prehearing conference call, or provide any response to the Order that scheduled the prehearing conference call. Respondent was ordered to show cause for its failure to appear at the prehearing conference no later than January 3, 2019. On January 4, 2019, Respondent answered the order informing that he was away for the holidays and unable to check his mail.

On February 13, 2019, I held a prehearing conference call in this case. During the pre-hearing conference call, the parties agreed that an administrative hearing was not required and consented to a decision based on the administrative record. I admitted the proposed exhibits into the record as there was no objection to any of the proposed exhibits. Following the pre-hearing conference, I gave the parties until March 12, 2019, to submit final briefs or argument.

On March 12, 2019, CTP submitted its final brief on the penalty amount. On April 9, 2019, our office received correspondence postmarked March 12, 2019, from Respondent forwarded from FDA. The correspondence included a Texas Sales and Tax Permit and a sworn declaration of Respondent's owner, Norberto Soto. On April 18, 2019, a letter was issued by my direction to advise the parties that CTP had until May 3, 2019, to indicate whether it objects to the admittance of Respondent's sworn testimony. On May 3, 2019, CTP moved to exclude Respondent's declaration into evidence pursuant to 21 C.F.R. §§ 17.25(a), 17.37(b), and the July 18, 2019 Acknowledgment and Pre-Hearing Order. I

grant CTP's motion as Respondent failed to timely submit its testimony in accordance with the applicable regulations and my July 18, 2019 Acknowledgment and Pre-Hearing Order.

Accordingly, I am issuing a decision on the record in this case.

Issues

1. Whether Respondent sold cigarettes to a minor on December 2, 2017, and failed to verify, by means of photo identification containing a date of birth, that the purchaser was 18 years of age or older, in violation of 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(a)(2)(i).
2. Whether the civil money penalty of \$11,182 that CTP seeks is an appropriate amount, pursuant to the provisions of 21 C.F.R. § 17.33(a).

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).

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). Respondent has the burden to prove any affirmative defenses and any mitigating factors likewise by a preponderance of the evidence. 21 C.F.R. § 17.33(c).

I. Violations

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). A tobacco product is misbranded if distributed or offered for sale in any state 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). 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 cigarettes to an individual who is under the age of 18 years is a violation of implementing regulations. 21 C.F.R. § 1140.14(a)(1). The failure to verify, by means of photo identification containing the bearer's date of birth, that no cigarette purchaser is younger than 18 years of age is also a violation of implementing regulations. 21 C.F.R. § 1140.14(a)(2)(i).

In the instant case, at approximately 3:15 PM on December 2, 2017, an FDA-commissioned inspector conducted an inspection of El Tornado Drive Thru, located at 5009 North Doffing Road, Mission, Texas 78574. CTP alleged that during the inspection, Respondent committed violations of selling cigarettes to a minor, in violation of 21 C.F.R. § 1140.14(a)(1), and failing to verify the age of the purchaser by means of photographic identification containing the bearer's date of birth, in violation of 21 C.F.R. § 1140.14(a)(2)(i). Specifically, a person younger than 18 years of age was able to purchase a package of Camel Crush Regular Fresh cigarettes. Complaint at 3.

To support the December 2, 2017 allegations, CTP submitted evidence including the declaration of Inspector Maria Isabel Martinez, the inspector at the time of the incident, Inspector Martinez's narrative report of the alleged incident, and photographs of the package of Camel Crush Regular Fresh Cigarettes allegedly purchased on December 2, 2017. CTP Exs. 6, 8-11.

In her declaration, Inspector Martinez stated that at approximately 3:15 PM on December 2, 2017, she conducted a follow-up compliance check inspection at Respondent's location, 5009 North Doffing Road, Mission, Texas 78574. CTP Ex. 6 at 2. Inspector Martinez further stated:

During the inspection, Minor A drove my car into El Tornado Drive Thru. I was directly behind Minor A in the left back seat inside my vehicle. From my location, I had a clear, unobstructed view of the sales clerk come out to Minor A. During the inspection, I observed Minor A purchase a package of cigarettes from an employee at the establishment. Prior to the purchase, I observed that Minor A did not present any identification to the employee. The employee did not provide Minor A with a receipt after the purchase.

Id. at 3. After the inspection, Inspector Martinez retrieved the cigarette package from Minor A, which she observed were Camel Crush Regular Fresh cigarettes. Inspector Martinez stated that she then labeled the cigarettes as evidence, photographed all of the panels of the package, and processed the evidence with standard procedures at the time of the inspection. *Id.* at 3.

On its face, this evidence is more than sufficient to prove that Respondent violated the law on December 2, 2017. In fact, Respondent's owner, Mr. Soto admitted to the alleged

violations in its Answer. Therefore, I find that Respondent violated the regulations on December 2, 2017. 21 C.F.R. § 1140.14(a)(1); 21 C.F.R. § 1140.14(a)(2)(i).

II. Civil Money Penalty

I have found that Respondent committed seven violations of the Act and its implementing regulations within a 48-month period. 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). In its Complaint, CTP sought to impose the maximum penalty amount, \$11,182, against Respondent. Complaint ¶ 1. Accordingly, I now turn to whether an \$11,182 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 violation or 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); *see also* 21 C.F.R. § 17.34.

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

Respondent has failed to comply with the Act and its implementing regulations on seven 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's owner, Mr. Soto, argued that El Tornado Drive Thru is a family business and that he does not have the money to pay the full penalty amount as business has been slow. Answer at 1. However, Respondent has not presented any documentary evidence to corroborate the assertion that it does not have the ability to pay the \$11,182 civil money penalty sought by CTP.

iii. History of Prior Violations

As noted, Respondent has seven times violated the prohibition against selling tobacco products to persons younger than 18 years of age, and failing to verify, by means of photo identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(1); 21 C.F.R. § 1140.14(a)(2)(i). Respondent's continued unwillingness or inability to comply with the federal tobacco regulations calls for a more severe penalty.

iv. Degree of Culpability

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

v. Matters as Justice May Require/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 has not presented any mitigating factors that have been admitted into evidence.

vi. Penalty

Based on the foregoing reasoning, I find a penalty amount of \$11,182 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 \$11,182 against Respondent, El Tornado, LLC d/b/a El Tornado Drive Thru, for seven 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 48-month period. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

/s/

Wallace Hubbard
Administrative Law Judge