

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

ARW Properties LLC
d/b/a In and Out Drive Thru,

Respondent.

Docket No. T-18-2201
FDA Docket No. FDA-2018-H-1844

Decision No. TB3672

Date: April 2, 2019

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty (CMP) against Respondent, ARW Properties LLC d/b/a In and Out Drive Thru, located at 14734 7th Street, Dade City, Florida 33523, 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 36-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 March 1, 2018, CTP initiated a 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-2018-H-0902, CRD Docket T-18-1470. *See also* FDA Docket FDA-2017-H-6987, CRD Docket T-18-749.

Procedural History

CTP began this case by serving an administrative complaint on May 14, 2018, seeking a \$5,591 civil money penalty on Respondent, at 14734 7th Street, Dade City, Florida 33523, 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 June 1, 2018, I issued an Acknowledgment and Status Report Order. Based on Respondent admitting the allegations, and only requesting a lower penalty, I inferred that the parties might not have intended to proceed to a hearing in this case. CRD Docket Number (No.) 5. On July 30, 2018, CTP filed a Joint Status Report indicating that the parties were unable to reach a settlement agreement and intended to proceed to hearing. CRD Docket No. 7.

On August 3, 2018, I issued an Acknowledgment and Pre-Hearing Order, which established the procedures and deadlines in this case. CTP filed its pre-hearing exchange on October 23, 2018. CTP's pre-hearing exchange included 15 numbered exhibits (CTP Exs. 1-15) and declarations of two witnesses, including Inspector Tonja Johnson. Respondent did not file a pre-hearing exchange.

On December 19, 2018, I held a pre-hearing conference 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. Respondent declined the opportunity to cross-examine CTP's witnesses. Following the pre-hearing conference, I gave the parties a deadline to submit objections to any exhibits and to submit supplemental briefs. Neither party filed a supplemental brief or objections to any exhibits.

Accordingly, I am issuing a decision on the record in this case. I admit Respondent's answer, CTP's informal brief, and CTP Exs. 1-15 into the record without objection.

Issues

1. Whether Respondent sold cigarettes to a minor on April 9, 2018, 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 \$5,591 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 7:17 pm on April 9, 2018, an FDA-commissioned inspector conducted an inspection of In and Out Drive Thru, located at 14734 7th Street, Dade City, Florida 33523. 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 Marlboro cigarettes. Complaint at 3.

To support the April 9, 2018 allegations, CTP submitted evidence including the declaration of Inspector Tonja Johnson, the inspector at the time of the incident, Inspector

Johnson's narrative report of the alleged incident, and two photographs of the package of Marlboro cigarettes allegedly purchased on April 9, 2018. CTP Exs. 6, 8-10.

In her declaration, Inspector Johnson stated that at approximately 7:17 pm on April 9, 2018, she conducted a follow-up compliance check inspection at Respondent's location, 14734 7th Street, Dade City, Florida 33523. CTP Ex. 6 at 2. Inspector Johnson further stated:

During the inspection, I drove my car into In and Out Drive Thru. I was driving the vehicle and Minor A was directly behind me in the left back seat inside my vehicle. From my location, I had a clear, unobstructed view of the sales clerk and 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 Johnson retrieved the cigarette package from Minor A, which she observed were Marlboro cigarettes. Inspector Johnson 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 April 9, 2018. In fact, Respondent admitted to the alleged violations in its Answer. Therefore, I find that Respondent violated the regulations on April 9, 2018. 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 five violations of the Act and its implementing regulations within a 36-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, \$5,591, against Respondent. Complaint at 1. Accordingly, I now turn to whether a \$5,591 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 five 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. Rahul Walia, argued that In and Out Drive Thru is a small business and that he is "struggling to pay bills and trying [his] best to keep cashiers employed." Answer at 2. Although, Respondent provided very little documentary evidence to support this assertion, I find Mr. Walia to be sincere and credible. I conclude that this assertion, in conjunction with the subsequent measures taken to rectify the violations, are testaments to his credibility.

iii. History of Prior Violations

As noted, Respondent has five times violated the prohibition against selling cigarettes and/or smokeless tobacco 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 smokeless tobacco 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). However, Respondent contends that it has proven to treat this as a serious matter – as Respondent has spent substantial resources and a considerable amount of time re-training staff and adding adequate camera systems and computers to prevent future violations. Answer 5-8.

iv. Degree of Culpability

Respondent is culpable for five 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). Mr. Walia asserts that he "took each violation very seriously." Answer at 5. After the first violation on March 24, 2017, Mr. Walia installed cameras in the store and held weekly meetings with staff to discuss the importance of verifying customer identification. *Id.* After the subsequent violations, Mr. Walia terminated the employee responsible for selling tobacco products to minors due to age miscalculation. *Id.* To prevent this from reoccurring, Mr. Walia purchased an age verification system to ensure accurate age calculations. Mr. Walia also required staff,

