

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

D and P Operations Inc.
d/b/a Marathon,

Respondent.

Docket No. T-18-1716
FDA Docket No. FDA-2018-H-1236

Decision No. TB3871

Date: June 6, 2019

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty (CMP) against Respondent, D and P Operations Inc. d/b/a Marathon, located at 7390 Southwest 8th Street, Miami, Florida 33144, 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 February 5, 2018, CTP initiated its 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. CTP Exs. 1-2. *See* Notice of Settlement Agreement, FDA Docket FDA-2018-H-0520, CRD Docket T-18-1160.

Procedural History

CTP began this case by serving an administrative complaint on March 27, 2018, seeking a \$5,591 civil money penalty on Respondent, at 7390 Southwest 8th Street, Miami, Florida 33144, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. On April 25, 2018, Respondent timely answered CTP's Complaint. In its answer, Respondent, through its counsel, denied the allegations. Respondent's Answer (Answer) at 2.

On April 27, 2018, I issued an Acknowledgment and Pre-Hearing Order, which established the procedure and deadlines in this case. On June 14, 2018, CTP filed a Motion for a Protective Order. On June 22, 2018, Respondent filed its response. CTP filed its Memorandum of Law in Support of the Motion for Protective Order on July 5, 2018. On July 24, 2018, Respondent filed its revised response to CTP's motion. On August 16, 2018, I issued an order granting in part and denying in part CTP's Motion for a Protective Order. I ordered CTP to provide the redacted identification of the minor. I denied the request for a non-redacted copy of the minor's identification and the request for CTP Guidelines Regarding Use of Minors.

On September 18, 2018, CTP filed its pre-hearing exchange. CTP's pre-hearing exchange included 18-numbered exhibits (CTP Exs. 1-18) which contained declarations of two witnesses, including Inspector Elie Joseph. On October 9, 2018, Respondent filed its pre-hearing exchange including 6 exhibits (R. Exs. 1-6).

On December 13, 2018, I held a prehearing conference call in this case. During the prehearing conference call, we discussed the parties' witnesses and exhibits list. CTP proposed two witnesses, a senior regulatory counsel and an inspector, and CTP's exhibits 1-18. Respondent proposed Respondent's exhibits 1-6. Respondent was instructed to mail its exhibit 4, the store surveillance video for the court to review. Respondent also requested to cross-examine Inspector Joseph, CTP's proposed witness.

On January 24, 2019, I held a telephone hearing in this case. On the same date, Respondent also filed its exhibits 7 and 8. During the hearing, I admitted CTP Exs. 1-18 and R. Exs. 1-8. Transcript (T.) 7-8. Respondent cross-examined Inspector Joseph, who stated that he did not review the video recordings Respondent submitted as evidence, and therefore, was unable to testify to the line of questioning pertaining to the recordings. A supplemental hearing was proposed in order for Inspector Joseph to review the video recordings. T. 9-10.

On February 19, 2019, Respondent moved to cancel the supplemental hearing and establish post-hearing procedures. On February 20, 2019, I granted the motion and allowed the parties until March 22, 2019, to simultaneously file post-hearing briefs. On March 22, 2019, both parties filed post-hearing briefs.

Issues

1. Whether Respondent sold cigarettes to a minor on March 10, 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 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 1:16 pm on March 10, 2018, an FDA-commissioned inspector conducted an inspection of Marathon, located at 7390 Southwest 8th Street,

Miami, Florida 33144. 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 Newport Box cigarettes. Complaint at 3.

To support the March 10, 2018 allegations, CTP submitted evidence including the declaration of Inspector Elie Joseph, the inspector at the time of the incident, Inspector Joseph's narrative report of the alleged incident, and photographs of the package of Newport Box cigarettes allegedly purchased on March 10, 2018. CTP Exs. 4-5, 8-9.

In his declaration, Inspector Joseph stated that on March 10, 2018, at approximately 1:16 pm, he conducted a follow-up compliance check inspection at Respondent's location at 7390 Southwest 8th Street, Miami, Florida 33144. CTP Ex. 4 at 2. Inspector Joseph further stated:

During the inspection, I parked my car near the Marathon and Minor A and I exited the vehicle. I watched Minor A enter Marathon. I did not accompany Minor A into the establishment because I felt my presence would compromise the undercover nature of the inspection. From my location outside the door, I had a clear, unobstructed view through the establishment window of the sales counter 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 Joseph retrieved the cigarette package from Minor A, which he observed were Newport Box cigarettes. Inspector Joseph stated that he then labeled the cigarettes as evidence, photographed all of the panels of the package, and processed the evidence in accordance with standard procedures at the time of the inspection. *Id.*

Respondent contests the allegations and argues: (1) that CTP failed to submit evidence that Inspector Joseph was employed as a health officer or employee as required by the regulations; (2) that Inspector Joseph was without authority to conduct compliance inspections at the establishment as the FDA and Florida do not have a contract to perform compliance inspections; (3) that Minor A was not representative of the racial/ethnic composition of the area; (4) that CTP failed to submit evidence of compliance with the requirements that the minor be provided with immunity; and (5) that the inspection was tainted, alleging that the inspector gained access to behind-the-counter area.

I find Respondent's arguments are without merit as Respondent attempts to invalidate the inspection, but fails to rebut that the actual sale took place. However, I will address why the aforementioned arguments are without merit and irrelevant to the issue at hand.

To Respondent's point that "[t]here is no evidence that Mr. Joseph was employed as a health officer or employee, a food officer or employee, or a drug officer or employee of any state or local jurisdiction." R. Post-Hearing Br. at 4; T. 18. However, Inspector Joseph was duly commissioned by the FDA to perform such inspections. Further, it is noted, as Respondent has also conceded, that Inspector Joseph is employed by the state as a daytime school teacher. The pertinent statute permits the Secretary to conduct examinations and investigations through officers and employees of the Department or through any health, food, or drug officer or *employee of any State*. 21 U.S.C. § 372(a)(1)(A). Here, Inspector Joseph, as a teacher for the State of Florida, is an employee of the state, therefore the applicable statute authorized him to conduct said investigation.

Respondent further argues that as an FDA-commissioned officer, Inspector Joseph's employment through Information Systems and Networks Corporation (ISN), a private company, did not authorize him to conduct the inspection because there was no contract between the FDA and State of Florida to perform compliance inspections. R. Pre-Hearing Brief at 3. Respondent also argues that the applicable statute, 21 U.S.C. § 372(a)(1)(A), does not authorize the Secretary to contract with a private contractor to conduct compliance inspections. *Id.* Respondent contends that the Florida Department of Business and Professional Regulation, Division of Alcoholic Beverages and Tobacco, is responsible for conducting inspections. *Id.* However, the FDA issues contracts to assist with compliance check inspections of retail establishments. R. Ex. 8 at 9. Contrary to Respondent's argument, it is public knowledge that ISN is a contractor for Florida and is authorized to conduct compliance inspections.² Additionally, Inspector Joseph testified that he was an FDA-commissioned inspector at the time of the inspection. CTP Ex. 4 at 1; T. 5.

Respondent also argued that Inspector Joseph did not comply with FDA's contract policy, as the policy requires that the minor reflect the racial/ethnic composition of the population where the undercover buy is conducted. R. Post-Hearing Br. at 4. Respondent contends that because the minor was Black, the minor was not representative of the racial/ethnic composition of the area. *Id.* In support of this position, Respondent has submitted a partial copy of an agency manual received from the FDA in response to a discovery request. R. Ex. 7. Section C.1.5. A of that document contains information regarding compliance check inspections. It states "a representative mix of 16 and 17 year

² U.S. Food & Drug Admin., FDA Tobacco Retail Inspection Contracts (Jul. 24, 2018), <https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm228914.htm> (last visited Apr. 30, 2019).

old Minors who look their age should be used. The Minor group should also reflect a representative mix of male and female Minors and should reflect the racial/ethnic composition of the population where the undercover buy is conducted.” *Id.* at 20. The use of the word “should” is in contrast to the word “shall” that is used for mandatory provisions elsewhere in that manual for guidance in inspection program and contracts for compliance checks. According to the manual:

Section C.1 indicates the number of FDA directed undercover buy inspections and the number of contractor directed undercover buy inspections for each jurisdiction. The Contractor *shall* ensure that FDA protocol for conducting compliance check inspections is followed. Generally, undercover buy inspections *shall* be conducted by teams comprised of an Inspector and a Minor. The Minor must be supervised at all times, with limited exceptions A representative mix of 16 and 17 year old Minors who look their age *should* be used. The Minor group *should* also reflect a representative mix of male and female Minors and *should* reflect the racial/ethnic composition of the population where the undercover buy is conducted.

R. Ex. 7 at 20 (emphasis added). It recommends that the Minor group used in the undercover buy inspections should reflect a representative mix of males and females and the racial/ethnic composition of the population, however the manual does not require the contractor approximate the racial/ethnic mix of every locality. Moreover, the manual references only the “Minor group” and does not require that the individual minor assisting the FDA and contractor in performing an undercover buy inspection must reflect the racial/ethnic composition of the population of the location where the inspection occurred. Further, whether the FDA followed its internal policies is not relevant to the issue of the improper sale. This argument is without merit and is not relevant to the improper sale.

Respondent contends that CTP failed to submit evidence of compliance with the requirements that the minor was provided with immunity from the proper authorities prior to using the minor in any jurisdiction where the minor’s possession of tobacco products is illegal. R. Post-Hearing Br. at 5; R. Ex. 8 at 12. Respondent argues that the letter received from CTP during discovery “does not address any authorization for the contractor to conduct compliance inspections; does not address non-criminal liability for the minor under section 569.11, Florida Statutes; and is issued by a State Attorney, not the Division of Alcoholic and Tobacco Products” R. Post-Hearing Br. at 8. Respondent’s conclusion that there is no immunity agreement is unsupported as it solely relies on the letter provided during discovery, which is an inquiry from Miami-Dade County State Attorney to a FDA contractor as to whether immunity is needed. This does not support the contention that there is no immunity agreement for the minor.

Furthermore, an immunity agreement would not negate evidence of an improper sale to the minor and is not relevant in finding that the sale occurred.

Respondent's final argument is that the inspection was tainted because Inspector Joseph accessed the behind-the-counter area of the store where the tobacco products were secured without consent is without merit for the undercover buy inspection. R. Pre-Hearing Br. at 3. While Respondent notes that acceptance of a retail tobacco products dealer permit constitutes consent to an inspection without warrant by Florida Division of Alcoholic Beverages and Tobacco or its authorized assistants, Respondent argues that there is no evidence of coordination with the Division or local authorities, therefore knowing consent to this area was required. R. Pre-Hearing Br. at 4 n1. As previously discussed, the inspection by Inspector Joseph was authorized, but even if that was not the case, the surveillance video submitted by Respondent does not show Inspector Joseph accessing behind-the-counter during the undercover buy. Respondent also admits that the video fails to corroborate this claim. R. Pre-Hearing Br. at 4. Further, Inspector Joseph testified that he observed the sale of cigarettes to the minor through the window. CTP Ex. 4 at 3; T. 12-13. Respondent has not provided any evidence to refute Inspector Joseph's testimony.

I find that the evidence shows CTP has fulfilled its burden that Respondent violated the regulations on March 10, 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 ¶ 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 has not presented any evidence that it does not have the ability to pay the \$5,591 civil money penalty sought by CTP.

iii. History of Prior Violations

As noted, Respondent has five times violated the prohibition against selling cigarettes or smokeless tobacco to persons younger than 18 years of age, and failed to 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). 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 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). Respondent argues for a reduction in the CMP amount based on its remedial conduct of implementing the "We Card" program to educate employees as to proper tobacco sale procedures in order to prevent sales to underage persons. R. Pre-Hearing Br. at 4.

While I acknowledge Respondent's efforts, I do not find it sufficient to reduce the penalty as Respondent did not timely implement the measures to prevent reoccurrences. The most recent inspection occurred on March 10, 2018, but according to the evidence submitted, it was not until September 18, 2018, that Respondent educated its employees on the federal law as it pertains to tobacco sales. Therefore, I do not believe that a reduced penalty is appropriate. Accordingly, I affirm the \$5,591 penalty.

vi. Penalty

Based on the foregoing reasoning, I find a penalty amount of \$5,591 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 \$5,591 against Respondent, D and P Operations Inc. d/b/a Marathon, 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. Pursuant to 21 C.F.R. § 17.45(d), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

/s/

Wallace Hubbard
Administrative Law Judge