

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2018-H-1425)

Complainant

v.

Aloha P and C Corp.
d/b/a Grocery Boy Jr. 44,

Respondent.

Docket No. T-18-1873

Decision No. TB3760

Date: April 25, 2019

INITIAL DECISION

The Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA) seeks a civil money penalty of \$11,182, against Respondent, Aloha P and C Corp. d/b/a Grocery Boy Jr. 44, for at least six 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. Specifically, CTP alleges that Respondent violated the Act when it sold regulated tobacco products to minors, failed to verify, by means of photo identification containing a date of birth, that purchasers were 18 years of age or older, and opened packages of cigarettes intending to sell individual cigarettes. For the reasons discussed below, I find Respondent liable for the violations alleged, and I conclude that a civil money penalty of \$11,182, is appropriate.

I. Background

CTP began this matter by serving an administrative complaint on Respondent at its establishment located at 2201 New Hope Church Road, Raleigh, North Carolina 27604, and by filing a copy of the complaint with the FDA Division of Dockets Management. Respondent timely filed an Answer to CTP's complaint. On May 23, 2018, I issued an Acknowledgement and Pre-Hearing Order (APHO) in which I set a schedule of pre-hearing exchanges and deadlines for submissions.

CTP timely filed its pre-hearing exchange, consisting of a pre-hearing brief, list of proposed witnesses and exhibits, and 16 exhibits (CTP Exs. 1-16), including the written direct testimony of two proposed witnesses, CTP's Senior Regulatory Counsel Laurie Sternberg (CTP Ex. 5) and Inspector Shakeya Brevard (CTP Ex. 6). Respondent did not file a pre-hearing exchange, submit evidence or propose any witnesses.

I held a pre-hearing conference on November 29, 2018, during which Respondent opted to cross-examine CTP's witness Inspector Brevard at a hearing.

On December 20, 2018, I held a hearing in this case. Transcript (Tr.). During the hearing, I admitted CTP Exhibits 1 through 16, absent objection. Tr. 6-7. Respondent cross-examined Inspector Brevard (Tr. 9-15), and CTP conducted re-direct examination of its witness (Tr. 15).

Neither party filed a post-hearing brief.

II. ISSUES

- (1) Whether Respondent sold individual cigarettes to a minor on February 19, 2018, in violation of 21 C.F.R. § 1140.14(a)(1) and (a)(4); and if so,
- (2) Whether the civil money penalty amount of \$11,182 that CTP seeks is appropriate.

III. Analysis, Findings of Fact and Conclusions of Law

A. Violations

CTP seeks a civil money penalty 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). 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. § 331 (f)(9).

The sale of tobacco products to an individual who is under the age of 18 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). Opening packages of cigarettes with the intent to sell individual cigarettes is another violation of implementing regulations. 21 C.F.R. § 1140.14(a)(4).

1. Prior Violations

This is the third civil money penalty action CTP has brought against Respondent. CTP Exs. 1, 3; Complaint ¶ 9; *see* CRD Docket Numbers T-17-826, T-18-61. The most recent prior complaint charged Respondent with:

- (1) selling cigarettes to a minor on December 8, 2015, and May 4, 2016, in violation of 21 C.F.R. § 1140.14(a)(1);
- (2) failing to verify photographic identification of the cigarette purchaser on December 8, 2015, and May 4, 2016, in violation of 21 C.F.R. § 1140.14(a)(2)(i); and
- (3) opening packages of cigarettes with the intent to sell individual cigarettes on September 29, 2017, in violation of 21 C.F.R. § 1140.14(a)(4).

CTP Exs. 1-4; *see* Complaint ¶ 9. The previous action resulted in settlement and concluded after Respondent admitted to four violations¹ of the regulations and paid the agreed upon penalty. CTP Ex. 4; Complaint ¶ 10. In settling the prior complaint, Respondent expressly waived its right to contest these violations in subsequent actions. *Id.* These violations are now administratively final.

2. Current Violations

I now turn to whether the remaining allegations in the complaint are true, and, if so, whether Respondent's actions constitute a violation of law. 21 C.F.R. § 17.45(b).

Specifically, I must determine whether on February 19, 2018, at approximately 8:19 PM, Respondent:

- (1) sold cigarettes to a minor in violation of 21 C.F.R. § 1140.14(a)(1); and
- (2) sold individual cigarettes in violation of 21 C.F.R. § 1140.14(a)(4).

¹ In accordance with FDA guidance, CTP counted the violations identified during the initial inspection as a single violation, and counted the violations identified during subsequent inspections individually. *See Orton Motor, Inc. d/b/a Orton's Bagley v. U.S. Dep't of Health & Human Serv.*, 884 F.3d 1205 (D.C. Cir. 2018).

CTP has the burden of proving Respondent's liability by a preponderance of the evidence. 21 C.F.R. § 17.33(b). It is Respondent's burden to prove any affirmative defenses also by a preponderance of the evidence. 21 C.F.R. § 17.33(c). As detailed below, I find that based on the evidence of record, it is more likely than not that Respondent sold individual cigarettes to a minor on February 19, 2018, at approximately 8:19 PM, in violation of 21 C.F.R. § 1140.14(a)(1) and (a)(4).

CTP's case against Respondent rests on the testimony of Inspector Brevard who conducted the inspection at issue, supported by corroborating evidence including contemporaneous notes and photographs. CTP Exs. 6-11. Inspector Brevard is an FDA-commissioned officer with the state of North Carolina, whose duties include determining whether retail outlets unlawfully sell tobacco products to minors through undercover buy inspections. CTP Ex. 6 at 1. Inspector Brevard testified that she conducted such an inspection of Respondent's establishment on February 19, 2018, at approximately 8:19 PM, during which she observed Respondent's clerk sell an undercover minor four single cigarettes. CTP Ex. 6 at 2-3.

Inspector Brevard testified that after the purchase, both the minor and she exited the establishment and returned to the vehicle, where the minor immediately handed the inspector the single cigarettes. CTP Ex. 6 at 3. Inspector Brevard labeled the cigarettes as evidence, photographed the cigarettes, and processed the evidence in accordance with standard procedures. *Id.* Inspector Brevard also contemporaneously recorded the inspection in the FDA's Tobacco Inspection Management System and created a Narrative Report. *Id.* CTP corroborated Inspector Brevard's testimony by offering as evidence photographs that the inspector made of the cigarettes on the date in question. CTP Exs. 10-11. CTP further corroborated Inspector Brevard's account by submitting a copy of her contemporaneously recorded Narrative Report and Tobacco Inspection Management System (TIMS) report. CTP Exs. 7-8.

CTP also offered as a witness, Laurie Sternberg, Senior Regulatory Counsel in CTP's Office of Compliance and Enforcement. CTP Ex. 5. In her written declaration, Ms. Sternberg testified that in her official capacity she has knowledge of the processes used by the FDA regarding the establishment registration and product listing requirements. *Id.* at 1-2. She further testified that RJ Reynolds manufactured the cigarettes purchased during the inspection on February 19, 2018, at Respondent's establishment, and that many of the components RJ Reynolds uses in manufacturing its products, including Newport cigarettes, are shipped to RJ Reynolds' manufacturing facility in North Carolina from out of state. *Id.* at 2-3; *see* CTP Ex. 16.

Respondent takes issue with CTP policy and inspection procedures. Specifically, Respondent takes exception to CTP's policy not to notify the establishment at the time of the asserted violation and not to ask for a receipt. Answer at 2. However, how CTP conducts its inspections is not at issue before me. At issue is whether Respondent sold

individual cigarettes to a minor on February 19, 2018, not CTP's procedures for determining whether Respondent was in compliance.

Respondent argues that it stopped selling individual cigarettes in November of 2017. Answer at 1. However, Respondent provides no evidence to support its argument. CTP, on the other hand, provides evidence in the form of sworn testimony and photographic evidence supporting its position that Respondent sold individual cigarettes. Respondent essentially argues that the Inspector's testimony is untrue and that it did not sell individual cigarettes to a minor during the February 19, 2018 inspection.

Inspector Brevard testified credibly and comprehensively about her observations during the February 19, 2018, inspection at which she observed Respondent's staff sell four individual cigarettes to a minor. *See* CTP Ex. 6 at 3; Tr. 11-12. Respondent questioned Inspector Brevard about whether she conducted inspections in the evening on federal holidays. Tr. 13-14. The inspector testified credibly that they conduct inspections any day of the week and in the evenings. *Id.*

Inspector Brevard testified that, prior to the inspection at issue, she verified that the minor carried photographic identification that included the minor's true age. Inspector Brevard also verified that the minor did not have any tobacco products in the minor's possession. CTP Ex. 6 at 2-3. At Respondent's establishment located at 2201 New Hope Church Road, Raleigh, North Carolina 27604, Inspector Brevard and the minor exited the vehicle, the inspector watched the minor enter Respondent's establishment, and followed thereafter. *Id.* at 3. Inspector Brevard testified that she took a position in the store from which she had a clear, unobstructed view of the sales counter, the minor, and the transaction in question. *Id.*; Tr. 12. From this location, Inspector Brevard observed the minor purchase individual cigarettes from an employee at the establishment. CTP Ex. 6 at 3. Specifically, Inspector Brevard testified that she observed Respondent's employee sell the minor four single cigarettes and not provide the minor a sales receipt following the transaction. *Id.* Inspector Brevard's testimony is supported by her contemporaneous narrative, TIMS report, and photographic evidence. CTP Exs. 7-11.

I find that CTP has provided sufficient evidence to support its allegation that Respondent is subject to the Act and sold individual cigarettes to a minor on February 19, 2018, in violation of 21 C.F.R. § 1140.14(a)(1) and (a)(4). Respondent has failed to provide evidence sufficient to rebut CTP's allegations.

The facts as outlined above, establish that Respondent's actions constitute a violation of law and that Respondent is liable under the Act. Accordingly, CTP is entitled to a civil money penalty from Respondent. 21 U.S.C. § 333 (f)(9).

B. Civil Money Penalty

I have found that Respondent committed six violations of the Act and its implementing regulations within a 48-month period. In its Complaint, CTP sought the maximum penalty amount, \$11,182, against Respondent. Complaint ¶ 1. Accordingly, I now turn to whether an \$11,182 civil money penalty is appropriate.

1. Determining Amount of Civil Money Penalty

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.

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

I found that Respondent committed three violations of selling cigarettes to minors, two violation for failing to verify, by means of photo identification containing a date of birth, that the purchaser was 18 years of age or older, and two violations for selling individual cigarettes. Each violation was serious because it contravened federal laws enacted to protect minors from the adverse health effects associated with tobacco use. 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.

b. Respondent’s Ability to Pay And Effect on Respondent’s Ability to Continue to Do Business

Respondent has not presented any evidence that it does not have the ability to pay the \$11,182 civil money penalty sought by CTP.

c. History of Prior Violations

The current action is the third civil money penalty action that CTP has brought against Respondent. Respondent sold regulated tobacco products to minors on December 8, 2015, May 4, 2016, and February 19, 2018. Respondent failed to verify that the purchaser was over 18 years of age on December 8, 2015, and May 4, 2016. Respondent opened packages of cigarettes to sell individual cigarettes on September 29, 2017, and February 19, 2018. Respondent’s continued unwillingness or inability to comply with the federal tobacco regulations calls for a more severe penalty.

d. Degree of Culpability

I find Respondent fully culpable for all six violations of the Act and its implementing regulations.

e. Other Matters as Justice May Require

Sales of tobacco products to minors are unlawful because younger individuals are more susceptible to making decisions that will endanger their lives down the road. Retailers who choose to sell such a highly dangerous and addictive product bear a heavy burden to assure that they make their sales in compliance with law. In its Answer, Respondent appears to understand the gravity of its decision to sell regulated tobacco products. Respondent states, “we strongly believe cigarettes cause cancer and I myself have tried to help customers stop smoking.” Answer at 3. Although Respondent may understand the gravity of these violations, Respondent has taken no additional action to ensure its compliance with federal law. I am unable to determine that a reduced penalty is appropriate based on the record before me.

2. Penalty

Based on the foregoing reasoning, I find a penalty amount of \$11,182 appropriate under 21 U.S.C. § 333(f)(5)(B) and (f)(9).

CONCLUSION

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$11,182 against Respondent, Aloha P and C Corp. d/b/a Grocery Boy Jr. 44, for six 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. § 17.45(d), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

/s/

Catherine Ravinski
Administrative Law Judge