

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2018-H-4192)

Complainant,

v.

White Dove Groceries, Inc.
d/b/a Grafton Shop N Save Express,

Respondent.

Docket No. T-19-401

Decision No. TB4137

Date: July 30, 2019

INITIAL DECISION

The Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA) seeks a civil money penalty (CMP) of \$11,182, against Respondent, White Dove Groceries, Inc. d/b/a Grafton Shop N Save Express, 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. Specifically, the Administrative Complaint (Complaint) alleges that Grafton Shop N Save Express impermissibly sold cigarettes to a minor, thereby violating 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. The Complaint also alleges that Respondent previously sold cigarettes or smokeless tobacco to minors and failed to verify, by means of photo identification containing a date of birth, that some of the purchasers were 18 years of age or older. For the reasons discussed below, I find Respondent liable for the violations alleged, and conclude that a CMP of \$11,182 is appropriate.

I. Background

CTP began this matter by serving a Complaint on Respondent at its establishment located at 57 Maple Avenue, Grafton, West Virginia 26354, 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 December 17, 2018, I issued an Acknowledgement and Pre-Hearing Order 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 18 exhibits (CTP Exs. 1-18), including the written direct testimony of two proposed witnesses, CTP's Senior Regulatory Counsel Laurie Sternberg (CTP Ex. 7) and Inspector William Bennett (CTP Ex. 8). Respondent timely filed its pre-hearing exchange, consisting of six exhibits (R. DAB file 7-7e). However, Respondent did not file a pre-hearing brief, submit a list of proposed witnesses, or proffer direct testimony of any witnesses.

On May 16, 2019, I held a pre-hearing conference in this case. I explained to the parties that the purpose of an administrative hearing under the applicable regulations is to afford the parties an opportunity for cross-examination and redirect of exchange witnesses. I further explained that I must determine whether Respondent is liable for the violations alleged in the Complaint as well as the appropriate penalty.

At the pre-hearing conference, Respondent admitted to the violations in the Complaint, but contested the penalty. Since Respondent admitted liability, I informed the parties that there was no real purpose for a hearing to cross-examine CTP's witnesses about the CMP issue. Accordingly, Respondent waived its right to cross-examine CTP's witnesses and both parties indicated that an in-person telephone hearing was unnecessary. Consequently, I informed the parties that I would issue a decision based on the evidence of record. I also informed the parties that the decision, along with the parties' appeal rights, would be sent to the parties, who could then appeal the decision to the Departmental Appeals Board if desired.

During the pre-hearing conference, I admitted CTP's and Respondent's exhibits into the record and informed the parties that no further evidence would be admitted. I also gave the parties an opportunity to submit final briefs with any arguments they wanted me to consider. On June 17, 2019, Respondent filed its final brief (Resp. Final Brief) along with an attachment described as its 2018 tax return (DAB file 15). CTP filed its final brief on June 19, 2019. As the briefing period is over, I now render my decision.

II. ISSUES

- A. Whether Respondent sold cigarettes to a minor on August 12, 2018, in violation of 21 C.F.R. § 1140.14(a)(1); and
- B. Whether the CMP amount of \$11,182 sought by CTP is reasonable.

III. Analysis, Findings of Fact and Conclusions of Law

A. 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). 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 tobacco products to an individual who is under the age of 18 is a violation of an implementing regulation. 21 C.F.R. § 1140.14(a)(1).

CTP alleges that Respondent committed at least six violations of the Act and its implementing regulations within a 48-month period. Complaint at ¶ 1. Specifically, CTP alleges that, on August 12, 2018, Respondent sold cigarettes to a minor, and previously admitted to at least five violations of regulations found at 21 C.F.R. pt. 1140. *Id.* at ¶¶ 7, 9-14.

As indicated above, Respondent has admitted to the violation as alleged at the pre-hearing conference. As a result, I find Respondent liable for six violations under the Act.

B. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Grafton Shop N Save Express is liable for a CMP not to exceed the amount listed in FDA's CMP regulations at 21 C.F.R. § 17.2.

In its Complaint, CTP seeks to impose the maximum penalty amount, \$11,182, against Respondent for six violations of the Act and its implementing regulations within a 48-month period. Complaint at ¶ 1. In its Answer, Respondent requests a lower penalty. In addition, Respondent contends, "a multi-thousand dollar fine during our company's hardship could force us to close our doors for good." Resp. Final Brief.

I find that Respondent committed six violations of the Act and its implementing regulations within a 48-month period. When determining the amount of a CMP, 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).

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

I find that Respondent committed five violations of selling cigarettes or smokeless tobacco to minors, and two violations for failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older.¹ The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the CMP amount should be set accordingly.

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

As stated above, Respondent requests a lower fine and argues, “a multi-thousand dollar fine during our company’s hardship could force us to close our doors for good.” Answer; Resp. Final Brief. Respondent asserts “[w]e have been trying to cut costs everywhere we can,” and “have even had to cut the owners/managers pay.” Resp. Final Brief. Respondent also provided an attachment described as its 2018 tax return (DAB file 15). *Id.*

As a preliminary matter, I will not admit Respondent’s attachment into evidence. Respondent did not submit this document with its pre-hearing exchange. In my May 20, 2019 pre-hearing conference order, I informed the parties that no further evidence would be admitted. *See* Order Scheduling Briefs. Further, CTP asserts that Respondent did not produce the tax return in response to its Requests for Production sent to Respondent on December 28, 2018. CTP Final Brief. For these reasons, I will not admit Respondent’s 2018 tax return into evidence or consider the information contained therein.

While it is understandable that Respondent is concerned about the future of its business, Respondent did not provide sufficient evidence to demonstrate that the \$11,182 CMP sought by CTP would force it into bankruptcy, or make it close its doors. Respondent provided a profit/loss statement (DAB file 7a). However, it is unclear how the information contained in this document relates to Respondent’s ability to pay the penalty. There is no other evidence in the record that demonstrates Respondent’s inability to pay the penalty. Therefore, I find that Respondent has not presented any evidence that it does not have the ability to pay the \$11,182 CMP sought by CTP.

¹ In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

c. History of Prior Violations

The current action is the fourth CMP action that CTP has brought against Respondent.² On October 20, 2017, CTP initiated the most recent, third CMP action, CRD Docket Number T-18-189, FDA Docket Number FDA-2017-H-6215, against Respondent for two violations of 21 C.F.R. pt. 1140. Complaint at ¶ 9. The third action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and paid the agreed upon penalty. *Id.* at ¶ 10. On June 30, 2017, CTP initiated the second CMP action, CRD Docket Number T-17-5000, FDA Docket Number FDA-2017-H-3902, against Respondent for violations of 21 C.F.R. pt. 1140. *Id.* at ¶ 11. The second action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and paid the agreed upon penalty. *Id.* at ¶ 12. On September 16, 2015, CTP initiated the first CMP action, CRD Docket Number C-15-4022, FDA Docket Number FDA-2015-H-3242, against Respondent for violations of 21 C.F.R. pt. 1140. *Id.* at ¶ 13. The first action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and paid the agreed upon penalty. *Id.* at ¶ 14. While Respondent has already paid civil money penalties for its previous violations, its continued inability to comply with the federal tobacco regulations calls for a more severe penalty.

d. Degree of Culpability

Respondent suggests its employees should be held responsible for the violations. Resp. Final Brief. Although I understand that Respondent's owner cannot be at its business all the time, it is Respondent's responsibility to ensure its employees comply with the law. I find that Respondent committed the six violations as alleged in the Complaint, and I hold it fully culpable for all six violations of the Act and its implementing regulations.

e. Additional Mitigating Factors

Respondent has taken responsibility for its actions by admitting the violations. At the pre-hearing conference, Respondent acknowledged that it was liable for the violation in the current Complaint. *See* Order Scheduling Briefs (DAB file 13; order memorializing pre-hearing conference). To prevent future violations, Respondent asserts that every cashier receives additional training for tobacco sales, it has dates on its cash registers for employees to verify the ages of tobacco product purchasers, and frequently reminds all register clerks not to sell tobacco products to minors. Answer; Resp. Final Brief. Additionally, Respondent states that it performs "in house stings" and has implemented

² Respondent's prior violations include violations for sale to a minor on September 4, 2014, June 3, 2015, May 24, 2017, October 11, 2017, and August 12, 2018, and failure to verify identification on September 4, 2014, and June 3, 2015.

stricter rules for employees, including automatic and immediate termination for employees who are caught selling regulated tobacco products to minors. *Id.*

Respondent's attempts to train employees and deter tobacco sales to minor are commendable. However, this is Respondent's fourth CMP action, and Respondent has had ample opportunity to correct its violations and come into compliance. Thus, I find that a CMP of \$11,182 is appropriate.

IV. PENALTY

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

V. CONCLUSION

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$11,182, against Respondent, White Dove Groceries, Inc. d/b/a Grafton Shop N Save Express, for six violations of the Federal Food, Drug, and Cosmetic 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