

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

First Choice Grocery Inc.
d/b/a First Choice Food and Deli 2,

Respondent.

Docket No. T-16-2131
FDA Docket No. FDA-2016-H-2953

Decision No. TB2251

Date: November 27, 2017

INITIAL DECISION

The Center for Tobacco Products (“CTP”) seeks to impose a civil money penalty of \$5,501 against Respondent, First Choice Grocery Inc. d/b/a First Choice Food and Deli 2 (“Respondent”), located at 1714 Country Road 1, Dunedin, Florida 34698, 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.

CTP alleges that First Choice Food and Deli 2 violated the Act by impermissibly selling cigarettes to minors and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older.

For the reasons discussed below, I find Respondent violated the applicable regulations as alleged, and impose a civil money penalty of \$4,000 against Respondent.

I. Procedural History.

CTP initiated this action on September 29, 2016, by serving an administrative complaint (“Complaint”) seeking a \$5,501 civil money penalty on Respondent at 1714 Country Road 1, Dunedin, Florida 34698 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 and denied the allegations (“Answer”). On November 30, 2016, I issued an Acknowledgment and Pre-hearing Order that set deadlines for the parties to file their pre-hearing exchanges.

On February 7, 2017, CTP filed a Motion to Compel Discovery and a Motion to Extend Deadlines. I gave Respondent until March 2, 2017 to respond to CTP’s motion. On March 13, 2017, having received no response from Respondent, I granted CTP’s Motion to Compel. I ordered Respondent to comply with CTP’s Request for Production of Documents by March 27, 2017.

On March 29, 2017, Respondent filed a letter indicating it either did not possess documents requested by CTP or was otherwise unable to provide them. On April 19, 2017, CTP filed a Motion to Compel Further Responses and Extend Deadlines. In its motion to compel, CTP requested that I order Respondent to provide all documents responsive to CTP’s production requests, and if it asserted that documents responsive to CTP’s requests did not exist, “. . .state affirmatively that such documents do not exist and detail, with particularity, the basis for its response that such documents do not exist.”

I denied CTP’s Motion to Compel Further Responses on May 1, 2017, but made clear that Respondent would be barred from using or relying on any documents responsive to CTP’s requests that it had not already produced to CTP, and granted CTP’s Motion to File Late Pre-Hearing Exchange. I gave CTP until May 5, 2017 to file its pre-hearing exchange, and Respondent until June 5, 2017 to do the same.

CTP filed its pre-hearing exchange on May 5, 2017, which consisted of its brief and nineteen proposed exhibits that it identified as CTP Ex. 1 through CTP Ex. 19. On the same date, CTP requested leave to submit the declaration of its witness Inspector Shaun Griffin in substitution for CTP Ex. 4, originally filed as a blank document.¹

On June 16, 2017, I issued an Order to Show Cause due to Respondent’s failure to file its pre-hearing exchange by June 5, 2017. I ordered the Respondent to inform me whether it still wished to have a hearing and whether it intended to file a pre-hearing exchange. On

¹ I grant CTP leave to so file, and strike the blank document docketed at 21e in the electronic docket in this case. When citing to CTP Ex. 4, this decision refers to document 22a in the electronic docket.

June 30, 2017, I received a letter from Respondent maintaining its request for a pre-hearing conference.

The pre-hearing conference was held as scheduled on August 16, 2017. Representatives for both parties appeared on the conference call. During the pre-hearing conference call, we discussed the procedural history of the case as well as the pre-hearing exchanges submitted by both parties. The parties agreed that an administrative hearing was not required in this case and consented to a decision based on the administrative record.

Respondent requested additional time to submit evidence it had not previously obtained. I granted Respondent's request and provided it until August 28, 2017 to provide the point-of-sale transaction data for the dates of the alleged violations at issue. I also provided CTP until September 11, 2017 to file a response to such a submission outlining arguments as to the competency of the evidence and weight I should assign it.

Respondent failed to submit any additional evidence by August 28, 2017. Instead, on September 6, 2017, the FDA Division of Dockets Management received a letter from Respondent stating that the evidence was not available and would require efforts by a computer technician to extract. Respondent did not indicate its intent to procure that information or request additional time to do so. Based on Respondent's communication, I find the record in this case complete and the matter ripe for a decision on the record.

II. A Decision on the Record Is Appropriate.

Pursuant to 21 CFR § 17.37(b), all direct testimony of witnesses shall be admitted in the form of a written declaration. In its pre-hearing exchange, CTP offered the direct testimony of two witnesses. Respondent did not offer the direct testimony of any witnesses. The parties have agreed that an administrative hearing is not required in this matter, and neither party has objected to the submissions of the other party. Consequently, I receive the parties' written exchanges and exhibits into evidence and will decide this case based on the administrative record.

III. Discussion.

A. The record establishes by a preponderance of the evidence that Respondent sold tobacco products (cigarettes) to a minor in violation of federal law.

CTP seeks to impose a civil money penalty against Respondent pursuant to authority conferred by the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations at Part 21 of the Code of Federal Regulations (C.F.R.). 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 Food and Drug Administration 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. § 333(f)(9). The sale of tobacco products to an individual who is under the age of 18 and failing to verify that a tobacco product purchaser is 18 years of age or older are violations of implementing regulations. 21 C.F.R. §§ 1140.14(a), (a)(2)(i).²

There is no dispute in this case that Respondent does business as First Choice Food and Deli 2, located at 1714 Country Road 1, Dunedin, Florida 34698, or that Respondent's business includes the sale of tobacco products to the general public.

CTP alleged in its Complaint that Respondent committed five violations of the Act and its implementing regulations within a 36-month period. This includes three³ violations which were the subject of a prior civil action filed by CTP, which alleged that on October 27, 2014 and March 20, 2015, Respondent unlawfully sold tobacco products to minors and also violated the requirement that retailers 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), (a)(2)(i); Complaint ¶¶ 8-10.

While Respondent denies these allegations in its Answer, I note that Respondent settled the prior action against it by acknowledging that the October 27, 2014 and March 20, 2015 violations had occurred, and waived its right to contest these violations in the future. CTP Ex. 2. These previous allegations of noncompliance are part of an administratively final civil action and therefore are not subject to challenge by Respondent in the matter before me, meaning CTP does not need to prove those three violations took place.

At issue before me are CTP's subsequent allegations of noncompliance, namely that Respondent committed another two violations on March 12, 2016. Specifically, CTP alleges that on that date, at approximately 5:30 PM, a FDA-commissioned inspector documented that a person younger than 18 years of age was able to purchase a package of Camel Crush Menthol cigarettes and that Respondent's staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older. Complaint ¶ 8. In its Answer, Respondent denied these allegations.

CTP submitted evidence to support its description of the violations that allegedly took place on March 12, 2016, including: the declaration of Inspector Shaun Griffin; the inspector's contemporaneous narrative report of the alleged incident; the redacted identification of the minor who was allegedly able to purchase tobacco products; and

² On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

³ CTP in fact alleged four violations, two on each date, but as is its custom, counted the violations at the initial inspection as one violation.

eight photographs of the Camel Crush cigarettes allegedly purchased by a minor on March 12, 2016. CTP Exs. 4-15.

CTP's case rests on the direct testimony provided in a written declaration by Shaun Griffin, an FDA-commissioned officer, as well evidence corroborating that testimony. In his declaration, Inspector Griffin stated that he accompanied a minor to Respondent's facility on March 12, 2016. CTP Ex. 4 ¶10. He confirmed that the minor had photographic identification and did not have any tobacco products before entering the store. *Id.* Inspector Griffin indicated that he did not accompany the minor into the store because he felt his "presence would compromise the undercover nature of the inspection." *Id.* at ¶11. After the minor exited the store, the minor returned to Inspector Griffin's vehicle and "immediately handed me the package of cigarettes." *Id.* at ¶12. Inspector Griffin declared: "I observed that the package of cigarettes were Camel cigarettes . . . I labeled the cigarettes as evidence and photographed all of the panels of the package." *Id.* Inspector Griffin stated that the minor handed him a package of Camel Crush cigarettes and reportedly was not required to present identification to the employee prior to the purchase. *Id.*

Respondent does not specifically rebut any aspect of Inspector Griffin's testimony. Its Answer only broadly states that its principal, Mr. Tajeddine, did not sell tobacco products to a minor, and that an ex-employee did not recall selling cigarettes to a minor. Answer at 1. However, this denial is undermined by Respondent's assertion later, in its own Answer, that it should not be held liable for the mistakes of its employees. *Id.* at 2. Based on these facts, and taking into account all the evidence submitted, I have no reason to question the credibility or veracity of Inspector Griffin's testimony, which is otherwise well-corroborated by other evidence, including images of the cigarettes procured, and the redacted identification of the minor who accompanied Inspector Griffin that day. *See* CTP Exs. 4-15. By contrast, Respondent provides no evidence to dispute the testimony of Inspector Griffin, despite being provided additional time to submit sales data from the March 12, 2016 inspection that it believed to be corroborative of its claims. Respondent offers nothing but a broad denial that it later undermined by conceding that one its employees may have mistakenly sold cigarettes to a minor. Answer at 1-2.

I therefore conclude that the un rebutted evidence submitted by CTP establishes Respondent First Choice Grocery Inc. d/b/a First Choice Food and Deli 2's liability under the Act as to the violations alleged to have taken place on March 12, 2016.

B. Imposition of a \$4,000 Civil Money Penalty Is Appropriate.

Pursuant to 21 U.S.C. § 333(f)(9), Respondent is liable for a civil money penalty not to exceed the amounts listed in FDA's civil money penalty regulations at 21 C.F.R. § 17.2. In its Complaint, CTP sought to impose the maximum penalty amount of \$5,501 against Respondent for five violations of the Act and its implementing regulations within a 36-

month period. Complaint ¶¶ 1, 5, 14. In its Informal Brief, CTP asserts that a \$5,501 civil money penalty is appropriate due to Respondent’s “extensive history of violations the Act’s requirements relating to tobacco products.” Complainant’s Brief at ¶ 5(D).

Respondent did not submit its own Informal Brief, but in its Answer asserted that the civil money penalty sought by CTP was too high, arguing that it should not be held liable for the mistakes of its employees. *See* Answer at 2. Respondent also noted that it did “everything in our power to train and advice all of our employees . . . notification.” and that it utilized a “POS system with age” to provide its employees with the necessary tools to avoid mistakes with regards to selling tobacco products to minors. *Id.*

In determining the appropriate penalty, I am required to consider the following statutory factors:

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

When determining the amount of a civil money penalty, I am required to take into account, as aggravating factors, “the nature, circumstances, extent, and gravity of the violations. . .” 21 U.S.C. § 333(f)(5)(B).

These factors also militate towards a higher penalty amount. I note that Respondent has consistently failed to comply with the Act and its implementing regulations. Respondent previously admitted to two violations of 21 C.F.R. § 1140.14(a) (sale of tobacco products to a minor) and one violation of 21 C.F.R. § 1140.14(a)(2)(i) (failure to verify the age of a tobacco product purchaser). CTP Ex. 2. The current violations represent the fourth and fifth violations within 36 months, a relatively short period. The maximum civil money penalty corresponding to this number of violations in this period of time is meant to deter retailers from selling highly addictive and extremely harmful products to minors, and to encourage retailers to take every measure to ensure these violations do not occur. Respondent’s repeated sale of tobacco products to a minor, in violation of law, creates the risk of serious harm and demand a proportional civil money penalty amount.

Respondent’s argument that the civil money penalty should be imposed against the store clerk and not the owner suggests a failure to appreciate the gravity of the violations, as well as a failure on Respondent’s part to acknowledge the significant responsibility the law imposes upon it to avoid selling tobacco to minors. Its argument is also without merit; federal tobacco regulations specifically place the responsibility to uphold the law on the retailer. “Each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements under this part.” 21 C.F.R. § 1140.10; *see also United States v. Dotterweich*, 320 U.S. 277, 281-285 (1943) (holding the only way in which a corporation can act is through the

individuals who act on its behalf). The civil money penalty imposed in this matter is properly assessed against Respondent, not its employees.

2. Respondent's Ability to Pay, Effect of the Penalty on Its Ability to do Business, Degree of Culpability, and Other Matters.

I must also give consideration to Respondent's ". . . ability to pay, effect [of the penalty] on [its] 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). On March 29, 2017, Respondent filed, presumably in response to CTP's Motion to Produce Documents, [REDACTED]

This evidence is irrelevant to my statutorily mandated inquiry, and Respondent offered no other financial documents or evidence to show that it is incapable of paying the penalty amount sought by CTP. Similarly, Respondent has provided no evidence as to the effect the penalty amount will have on its ability to do business. I have already discussed the history of prior violations, and there is nothing in the record to indicate Respondent is anything less than fully culpable.

Respondent did, however, assert that it was a small business owner, that it provided regular training and reminders to its employees, that it gave a verbal warning to an employee after one violation, and that it utilized a point-of-sale transaction system with age verification to minimize employee mistakes. Answer at 2. Despite the number of factors suggesting that imposition of the maximum penalty would be entirely warranted, I find it appropriate to take these other factors into account and reduce the penalty amount proportionally. After carefully considering the statutory factors, as discussed above, I find that a civil money penalty of \$4,000 is warranted.

ORDER

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$4,000 against Respondent, First Choice Grocery Inc. d/b/a First Choice Food and Deli 2, 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.

/s/

Bill Thomas
Administrative Law Judge