Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2017-H-4227)

Complainant

v.

C.W. White, Inc. d/b/a Senatobia Food Mart,

Respondent.

Docket No. T-17-5295

Decision No. TB2713

Date: May 15, 2018

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty (CMP) against Respondent, C.W. White, Inc. d/b/a Senatobia Food Mart, located at 434 West Main Street, Senatobia, Mississippi 38668, for three 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. Specifically, CTP alleges that Respondent violated the Act by selling covered tobacco products to minors and by failing to verify the purchasers were 18 years of age or older. For the reasons discussed below, I find in favor of CTP and impose a \$559 CMP against Respondent.

Background and Procedural History

CTP began this matter by serving an administrative complaint seeking a \$559 civil money penalty on Respondent, at 434 West Main Street, Senatobia, Mississippi

38668, 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 denied the allegations. On August 25, 2017, I issued an Acknowledgment and Pre-Hearing Order (APHO).

On September 25, 2017, CTP filed a Motion for Protective Order (MPO) stating, in part:

... Respondent has served CTP with a request for production of documents ... Some of the documents responsive to Respondent's request include (1) the personal identifying information of the minors who participated in the undercover inspections; (2) information reflecting CTP's pre-decision deliberative process in this matter; (3) communications between CTP and FDA's Office of the Chief Counsel ("OCC") regarding this matter; and (4) documents prepared by OCC in anticipation of litigation in this matter

E-File Docket #9 (MPO) at 1-2.

On September 28, 2017, a letter issued at my direction gave Respondent until October 5, 2017 to file a response to CTP's MPO. *See* E-File Docket #10. Respondent did not file a response to the MPO. Instead, on October 26, 2017, Respondent filed a response regarding CTP's Request for Production, without the attachments referenced in its response. *See* E-File Docket #11. On November 9, 2017, an email sent at my direction to CTP inquired, based on Respondent's October 26, 2017 discovery response, of CTP's intent to pursue the pending MPO. E-File Docket #13. On November 15, 2017, in an email communication, CTP advised "that there is no need for the ALJ to address the motion for protective order." E-File Docket #14.

CTP filed its pre-hearing exchange on November 14, 2017. Respondent filed its pre-hearing exchange on December 5, 2017. On December 22, 2017, I held a prehearing conference in this case. During the pre-hearing conference, counsel for Respondent stated that it wanted to cross-examine CTP's witness Justin Montgomery, the inspector involved in the inspections of its establishment. CTP advised of its intent to cross-examine Respondent's witness Charles White, President of the business entity Senatobia Food Mart. Also during the pre-hearing conference, Respondent sought to subpoena the undercover buyer (UB) minor involved in the April 10, 2017 inspection. I denied Respondent's request, advising that the UB minor's identity is protected from disclosure. Following the prehearing conference, I issued an Order Scheduling Telephone Hearing for January 29, 2018. On January 29, 2018, a hearing was held in this case. The purpose of the hearing was to allow Respondent to cross-examine Inspector Montgomery, and to afford CTP the opportunity to cross-examine Respondent's witness Charles White.¹ During the hearing, CTP's exhibits (Exs.) 1 through 18 and Respondent's (R's) exhibits 1 through 8 were admitted into the record without objection. Hearing Transcript (Tr.) at 7. On February 21, 2018, I informed the parties that the Court had received the transcript of the hearing, and set the deadline for the parties' simultaneous post-hearing brief submissions as March 26, 2018. On March 26, 2018, CTP filed its post-hearing brief. Respondent did not file a post-hearing brief.

Issues

- Whether Respondent Senatobia Food Mart sold covered tobacco products to a minor and failed to verify that the covered tobacco product purchaser was of sufficient age, on January 18, 2017 and April 10, 2017, in violation of 21 C.F.R. §§ 1140.14(b)(1) and 1140.14(b)(2)(i); and
- Whether the penalty amount sought by CTP is reasonable.

Analysis

I. Violations

A. Alleged Violations, Parties' Contentions, and Findings of Fact

CTP determined to impose 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). 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 covered tobacco products to an individual who is under the age of 18 is a violation of implementing regulations. 21 C.F.R. § 1140.14(b)(1). In addition, a retailer's failure to verify, by means of photographic identification containing a purchaser's date of birth, that no covered tobacco product purchaser is younger than 18 years of age is also a violation of the regulations.

¹ At the close of Respondent's cross-examination of Inspector Montgomery, CTP waived cross-examination of Charles White. *See* Tr. at 22.

1. Alleged Violations

CTP alleges that Respondent committed three² violations of the Act and its implementing regulations within a 24-month period. Complaint at \P 1.

In its Complaint, CTP alleged that at approximately 2:34 PM on January 18, 2017, and at approximately 2:49 PM on April 10, 2017, at Respondent's business establishment, 434 West Main Street, Senatobia, Mississippi 38668, an FDA-commissioned inspector documented Respondent's staff selling a package of two White Owl White Grape cigars to a person younger than 18 years of age. Complaint at ¶¶ 9, 11; *see also*, Informal Brief of Complainant at 4-9. The inspector also documented that the staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older. *Id.*; *see also*, Informal Brief of Complainant at 9-11.

In its Answer, Respondent denies all of the violations alleged in the Complaint, and requests that the Complaint be "dismissed with prejudice." Answer.

- 2. Parties' Contentions and Evidence
- a. CTP's Position

CTP's case against Respondent relies on the testimony of Inspector Justin Montgomery, who accompanied by a state-contracted undercover minor (Minor A), conducted an undercover buy (UB) compliance inspection on January 18, 2017, and a follow-up UB compliance inspection on April 10, 2017. Informal Brief of Complainant at 3. As evidence³, CTP provided a sworn declaration from Inspector Montgomery. *See* CTP Ex. 4 (Montgomery Declaration). Inspector Montgomery is an FDA-commissioned officer with the state of Mississippi. His duties include conducting undercover inspections to determine whether retailers comply with the age and photographic identification requirements relating to the sale of tobacco. *Id.* at ¶¶ 3-4. Inspector Montgomery declared that he conducted a UB compliance check inspection of Respondent's establishment, accompanied by a Minor A, on January 18, 2017. *Id.* at ¶ 10. Inspector Montgomery stated that prior to initiating the inspection, he confirmed Minor A's possession of his/her photographic identification, and that he/she did not possess any tobacco products. *Id.* The inspector stated that he watched Minor A enter Respondent's

 $^{^2}$ Two violations were documented on January 18, 2017, and two were documented on April 10, 2017. 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.

³ The evidence discussed in this paragraph is not exhaustive.

establishment, and that he remained "directly outside the establishment because my identity is known to the retailer or establishment." *Id.* at ¶ 11. Inspector Montgomery asserted that he obtained an unobstructed view of the sales counter and directly observed Minor A purchasing a package of cigars from Respondent's clerk. *Id.* Inspector Montgomery noted that Minor A did not present any identification to the sales clerk, and the sales clerk did not provide a receipt after the sale. *Id.* Inspector Montgomery declared that, after the transaction, he and Minor A returned to the vehicle where the minor immediately handed the inspector the package of cigars. *Id.* at ¶ 12. The inspector observed that the package of cigars contained White Owl White Grape cigars. *Id.* Inspector Montgomery processed the evidence according to procedure and created a narrative report shortly thereafter. *Id.*

Inspector Montgomery further declared that, on April 10, 2017, he and Minor A conducted a follow-up UB compliance check inspection at Respondent's establishment. CTP Ex. 4, at ¶ 15. Again, prior to initiating the inspection, Inspector Montgomery declared that he confirmed Minor A's possession of his/her photographic identification, and that he/she did not possess any tobacco products. Id. The inspector stated that he watched Minor A enter Respondent's establishment, and he "remained directly outside the establishment because I felt my presence would compromise the undercover nature of the inspection." Id. at ¶ 16. Inspector Montgomery asserted that he obtained an unobstructed view of the sales counter and directly observed Minor A purchasing a package of cigars from Respondent's clerk. Id. Inspector Montgomery noted that Minor A did not present any identification to the sales clerk prior to the sale, and that the sales clerk did not provide a receipt after the sale. Id. Inspector Montgomery declared that, after the transaction, he and Minor A returned to the vehicle where the minor immediately handed the inspector the package of cigars. *Id.* at ¶ 17. The inspector observed that the package of cigars contained White Owl White Grape cigars. Id. Inspector Montgomery took pictures and labeled the cigar package. He then processed the evidence according to procedure and created a narrative report shortly thereafter. Id. Beyond Inspector Montgomery's declaration, CTP also provided evidence corroborating his testimony, including: photographs of the pack of cigars Respondent unlawfully sold to Minor A (CTP Exs. 8, 9, 14, 15); copies of the Compliance Check Inspection Notices (CTP Exs. 10, 16); Inspector Montgomery's Narrative Reports of the undercover inspections (CTP Exs. 6, 12); the TIMS Forms (CTP Exs. 7, 13); and a redacted copy of the Minor A's identification establishing his/her age at the time of the sale (CTP Ex. 5).

b. <u>Respondent's Position</u>

Respondent filed an answer and an informal brief, denying that covered tobacco products were sold to a minor, or that Respondent failed to verify the minor's age during the inspections at issue. Answer; Informal Brief of Respondent. Respondent asserts that no covered tobacco products were sold during the time period alleged by CTP; that CTP has not provided a receipt; and that CTP's description of the sales clerk alleged to have made each of the violative sales "is based on the faulty observation of Inspector Montgomery ... [t]hus destroys the credibility of all other observations by Inspector Montgomery in his report and in this case" Answer at 2; Informal Brief of Respondent at 3-8. More specifically, Respondent argues:

... CTP alleges that on January 18, 2017 A C.W. White Inc. senior age female employee with white/gray hair and who wore glasses sold tobacco products to a minor. There was no senior age female employee with glasses and white/gray hair working at the Senatobia Food Mart on January 18, 2017. CTP also alleges that on April 10, 2017 a C.W. White Inc. senior age female employee with white/gray hair sold tobacco products to a minor. There was no senior age female employee with white/gray hair working at the Senatobia Food Mart on April 10, 2017.

These two facts alone defeat the CTP's case and its ability to meet its burden of proof

Informal Brief of Respondent at 1.

In support of its assertions, and included as part of its pre-hearing exchange, Respondent submitted the declaration of Charles White, President of C.W. White, Inc., as well as employee time cards for the periods covering January 15-21, 2017 and April 9-15, 2017. R's Exs. 2, 3. In his declaration, Mr. White asserts that none of the employees on duty at Respondent's establishment on either January 18, 2017 or April 10, 2017 fit the physical description given by Inspector Montgomery in his Narrative Reports; *i.e.*, a female of senior age, with gray/white hair, and wore glasses. R. Ex. 2, at ¶¶ 3-8. Further, Respondent contends that the time cards identify the employees on duty during the relevant inspection periods. *See* Informal Brief of Respondent at 3, 6. According to Respondent, the employees on duty do not fit the description provided by Inspector Montgomery in the January 18, 2017 and April 10, 2017 Narrative Reports. *Id*.

c. <u>Hearing Testimony</u>

Respondent cross-examined Inspector Montgomery at the January 29, 2018 hearing. *See* Tr. at 8-22. During the hearing, Respondent's cross-examination of Inspector Montgomery focused substantially on questions regarding the background and experience of the investigator and the minor; the methods used to select minors for participation in the undercover investigations; whether the minor is checked or searched for fake identification; the method of payment used in undercover operations; and the sources of the descriptions of the sales clerks allegedly involved in the violative sales as documented in the Narrative Reports for the dates at issue. *See* Tr. at 10-19.

Specifically, with regard to the description of the sales clerks noted in the Narrative Reports for the inspections conducted on January 18, 2017, and April 10, 2017, Inspector Montgomery testified as follows:

Q. Okay. Now, on both instances on January the 18th and April the 10th, you did not go into the store with the minor, did you? A. No.

Q. Okay. And you - - you only observed from the outside? A. Yes.

Q. On - - on both instances, . . . how far away from the actual counter would you say you were?

A. Probably . . . maybe five - - five feet - - five, six feet because I pulled about right directly in front of the store where the actual front door is, where the actual pump would have been . . .

Q. And that's - - that's the same on both instances? A. Yeah.

* * * * * *

Q. Okay. So you weren't inside. So you don't know what may have been said between the person who allegedly sold tobacco and the minor inside the store, do you? A. No.

* * * * * *

Q. Okay. And the - - the only description of the person who allegedly sold the tobacco comes from your observations, correct? A. They come from the minor as well. He comes in, describes, you know, any type of his characteristic that the - - that the clerk had and I can also visually see as well.

* * * * * *

Q. Mr. Montgomery, we've got the two minor narrative reports which have been admitted as respondent's Exhibits 4 and Exhibit 5.

And neither one of those reports contain a description of the person who allegedly sold the tobacco, do they?

A. No, they don't.

Q. Okay. So the only documentation we have of the description of the person who allegedly sold the tobacco comes from your observation, is that correct?

A. ... For paper wise documentation, yes, because it's not listed on the minor narrative form, there's not a - there's not a section on there for characteristics.

Q. Okay. So . . . your report and your description . . . on CTP Exhibits 6 and Exhibit 12 which are your - - it's your narrative reports from January the 18th, 2017, and April the 10th of 2017. Under Section 16 of both those reports, does - - those descriptions you provided there match what the minor provided you, is that correct?

A. Yes.

Q. Okay. So is it fair to say that your knowledge of what took place came from your observations?

A. Yes. And also, along with the teen.

Q. Right. Okay. But outside the minor's report, the only knowledge you had comes from your observations, is that right? A. Yes.

Tr. at 15-16, 17-19.

3. Findings of Fact

Respondent offered no evidence to rebut Inspector Montgomery's statements regarding the sale of the covered tobacco products, in the instance cigars, or the failure to verify the purchaser's age. However, based on Respondent's line of questioning at the hearing, Respondent sought to attack the inspector's description of the sales clerks involved in the respective alleged transactions. It is undisputed that Inspector Montgomery did not witness the alleged transactions from within Respondent's establishment on either January 18, 2017 or April 10, 2017. Tr. at 15-16; CTP Ex. 4, at ¶¶ 11, 15. Instead, the inspector states that in each instance, he had an unobstructed view of each transaction from the window outside of the establishment. *Id.* However, the regulations do not require a direct eyewitness. Rather, I must determine whether - based on a preponderance of the evidence - the allegations are true, and, if so, whether these actions constitute a violation of law. 21 C.F.R. §§ 17.33, 17.45.

As previously discussed, Respondent's primary contention is that the employees on duty at the time in Respondent's establishment on January 18, 2017 and April 10, 2017 do not match the physical description of the employees involved in the alleged transactions given by Inspector Montgomery in his Narrative Reports. Answer at 2-3; Informal Brief of Respondent at 2, 3-4, 6-7. In his declaration, Mr. White states that the two female employees on duty January 18, 2017 had blond/blond-brown hair, and one wore glasses "sparingly." R. Ex. 2, at ¶¶ 3, 5, 6. Mr. White further states that of the three female employees working on April 10, 2017, two were the same employees on duty during the January 18, 2017 inspection. *Id.* at ¶¶ 4-7. However, Mr. White expressly states that: "[t]here was no employee of C.W. White, Inc. working at the Senatobia Food Mart on January 18, 2017 . . . [or] April 10, 2017, who was senior age, with gray/white hair and who would have been wearing glasses. *Id.* at ¶¶ 8, 9.

On cross-examination, Inspector Montgomery testified that the two minor Narrative Reports do not contain physical descriptions of the clerks who allegedly sold the cigars because those forms do not include a section for characteristics. Tr. at 18. The inspector further testified that the clerk descriptions are based on both the description provided by the minor and the inspector's own observations. *Id.* at 18-19. Although probative, this testimonial evidence is not crucial based on the entirety of the evidentiary record. It is clear from the record that on both January 18, 2017 and April 10, 2017, an adult female with light colored hair (blond/blondbrown as described by Mr. White, or possibly gray/white as seen by Inspector Montgomery through the store front window) and glasses was working at Respondent's establishment.

With respect to both of the alleged sales on January 18, 2017 and April 10, 2017, employee Wanda Moore is a 56-year-old adult female with blond-brown hair "who only wears glasses sparingly and does not wear glasses while at work." R. Ex. 2, at ¶ 6. While this may be her custom, there is nothing in the record that she <u>never</u> uses her glasses at work, or that she may not have done so on January 18, 2017, or April 10, 2017.

Respondent also makes the argument that the minor obtained the cigars from a "non-employee" of C.W. White, Inc. Informal Brief of Respondent at 5. Respondent further asserts:

... the minor would also have ulterior motives to produce evidence of tobacco sale as confidential informants or undercover operators such as the minor in this case generally serve in that capacity in exchange for leniency or as part of an arrangement such as a "plea deal" with an investigative or enforcement body.

Id. I find it incredible that the minor obtained the cigars from a third party in the establishment. Based on the evidentiary record, there is no reason for the minor to

do so. Inspector Montgomery testified that minors' involvement in undercover buy operations is strictly voluntary and not subject to a plea deal or any arrangement. Tr. at 15. There is no evidence to support that the minor had an incentive to trick Respondent's staff.

Simply, the minor entered Respondent's establishment without cigars and returned to the inspector with them. Based on the evidence, the most reasonable explanation for the minor to emerge from the establishment with cigars is that he/she purchased then in the establishment.

The testimony of Inspector Montgomery, supported by corroborating evidence, is sufficient to establish that it is more likely than not that Respondent unlawfully sold covered tobacco products to a minor and failed to verify that the purchaser was of sufficient age, in violation of 21 C.F.R. §§ 1140.14(b)(1) and 1140.14(b)(2)(i). 21 C.F.R. § 17.33(b); *see also*, Tr. at 15-19; CTP Exs. 4-7, 8-9, 12-15.

Therefore, I find that CTP has met its burden to establish Respondent Senatobia Food Mart's liability under the Act for three violations within a 24-month period.

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent C.W. White, Inc. d/b/a Senatobia Food Mart 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, \$559, against Respondent for three violations of the Act and its implementing regulations within a 24-month period. Complaint at ¶ 1.

In both its Answer and Informal Brief, Respondent denied any obligation to pay a civil money penalty because there is insufficient proof it violated the regulations.

I have found that Respondent committed three violations of the Act and its implementing regulations within a 24-month period. When determining the amount of a civil money penalty, I am required to take into account "the nature, circumstances, extent and gravity of the 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).

I have found that Respondent committed two violations of selling covered tobacco products to minors, and two violations of failing to verify that the covered tobacco product purchaser was of sufficient age, although it is only being held liable for three of those violations. 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 Ability to do Business

Respondent has not presented any evidence that it does not have the ability to pay the \$559 CMP sought by CTP.

C. History of Prior Violations

The current action is the first civil money penalty action brought against Respondent for violations of the Act and its implementing regulations. As noted above, Respondent has, at least three times, violated the prohibition against selling covered tobacco products to persons younger than 18 years of age, and failing to verify that the covered tobacco product purchaser was of sufficient age. 21 C.F.R. §§ 1140.14(b)(1) and 1140.14(b)(2)(i).

D. Degree of Culpability

Based on my finding that Respondent committed the three violations in the Complaint, I hold it fully culpable for three violations of the Act and its implementing regulations.

E. Additional Mitigating Factors

Respondent has asserted it provided training to its employees, and that it "takes extraordinary precaution and measures to guard against the sale of tobacco products to minors and the verification and identification of the age of those purchasing tobacco products." Informal Brief of Respondent at 8. However, this in itself is not a mitigating factor, since Respondent through its employee failed to actually prevent the sale. Moreover, rather than make assurances as to reinforced training or other procedures that could promote compliance, Respondent simply notes distribution of additional documentation to employees which advises "check photo ID for anyone under 27." *Id.* at 9. Accordingly, I have no basis in the record before me to find mitigating factors that would allow me to reduce the penalty requested by CTP, which I find proportional and appropriate in this case.

F. Penalty

Based on the foregoing reasoning, I find a penalty amount of \$559 to be appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).

Conclusion

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$559 against Respondent, C.W. White, Inc. d/b/a Senatobia Food Mart, for three 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 24-month period.

/s/ Catherine Ravinski Administrative Law Judge