

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2018-H-0080)

Complainant,

v.

Nishva Inc.
d/b/a Woodville Chevron,

Respondent.

Docket No. T-18-830

Decision No. TB003517

Date: February 13, 2019

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty (CMP) of \$279 against Respondent, Nishva Inc. d/b/a Woodville Chevron, located at 8231 Woodville Highway, Tallahassee, Florida 32305, for two 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 period of 12-months. Specifically, CTP alleges that Woodville Chevron violated the Act by impermissibly selling covered tobacco products to minors, and failing to verify, by means of photo identification containing a date of birth, that a purchaser was 18 years of age or older. For the reasons discussed below, I find in favor of CTP and impose a \$279 CMP against Respondent.

Procedural History

CTP began this matter by serving an administrative complaint seeking a \$279 civil money penalty on Respondent Woodville Chevron, at 8231 Woodville Highway,

Tallahassee, Florida 32305, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management.

On February 6, 2018, Respondent, represented by its manager, Angela Williams, timely filed an Answer to CTP's complaint, denying the allegations. On February 13, 2018, I issued an Acknowledgement and Pre-Hearing Order (APHO) that set deadlines for discovery and the parties pre-hearing exchanges.

On April 12, 2018, Respondent filed supplemental documents, which are captioned in the DAB E-File system as "Answer." (Supplemental Answer) The filing included an alcoholic beverages and tobacco license issued by the State of Florida, and letters from Respondent's manager and owner denying the allegations.

On April 23, 2018, CTP filed a Motion to Compel Discovery, requesting "that an order be entered to require Respondent to comply with the Request for Production of Documents in its entirety." Docket ("Dkt.") Entry 8. On April 24, 2018, a letter was issued by my direction informing Respondent that it had until May 8, 2018, to file a response to CTP's Motion to Compel Discovery. Dkt. Entry 11. An order was issued on May 23, 2018, granting that motion and ordering Respondent to comply with CTP's Request for Production of Documents, after Respondent failed to file any response to CTP's Motion or otherwise respond to the April 24, 2018 letter. Dkt. Entry 12. On June 8, 2018, CTP filed a Motion to Impose Sanctions for Respondent's failure to produce documents in response to CTP's request. Dkt. Entry 14. On June 13, 2018, CTP withdrew its June 8, 2018 Motion to Impose Sanctions because Respondent complied with CTP's request. Dkt. Entry 19.

On July 6, 2018, CTP filed its pre-hearing exchange consisting of its Informal Brief, a list of proposed witnesses and exhibits, and 18-numbered exhibits (CTP Exs. 1-18). CTP's exhibits included the written direct testimony of the FDA-commissioned inspector who conducted both inspections at issue, Inspector Marquetta Bowens-White. Respondent did not file a pre-hearing exchange.

On August 22, 2018, I held a pre-hearing conference call. During the pre-hearing conference, we discussed the procedural history of the case and the evidence submitted by CTP. Respondent advised of its intent to cross-examine CTP Inspector Bowens-White, who conducted both the June 5, 2017 and December 12, 2017 inspections.

On September 21, 2018, I conducted a hearing in this case. The purpose of the hearing was to allow Respondent to cross-examine Inspector Bowens-White. During the hearing, I admitted CTP's Exs. 1-18 into the record without objection. Transcript (Tr.) at 7.

On October 10, 2018, I informed the parties that the Court had received the transcript of the hearing. I also set the deadlines for the parties' simultaneous post-hearing brief submissions as December 10, 2018. Neither party filed a post-hearing brief.

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).

I. Violations

A. Alleged Violations, Parties' Contention, 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 products purchaser is younger than 18 years of age is also a violation of the regulations. 21 C.F.R. § 1140.14(b)(2)(i).

1. Alleged Violations

CTP alleges that Respondent committed two violations¹ of the Act and its implementing regulations over a 12-month period. Complaint at ¶ 1.

In its Complaint, CTP asserts the following:

¹ Two violations were documented on June 5, 2017, and one on December 12, 2017. In accordance with FDA guidance, CTP counted the violations observed at the initial inspection as a single violation, and the violations observed at subsequent inspections as separate individual violations. *See Orton Motor Co. d/b/a Orton's Bagley v. HHS*, 884 F.3d 1205 (D.C. Cir. 2018).

- At approximately 12:40 p.m. on June 5, 2017, at Respondent's business establishment, 8231 Woodville Highway, Tallahassee, Florida 32305, an FDA-commissioned inspector documented Respondent's staff selling a package of two Swisher Sweets Grape cigars to a person younger than 18 years of age. The inspector also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older;
- In a warning letter dated June 22, 2017, CTP informed Respondent of the inspector's June 5, 2017 documented violations, and that such actions violate federal law. The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action;
- At approximately 5:34 p.m. on December 12, 2017, at Respondent's business establishment, 8231 Woodville Highway, Tallahassee, Florida 32305, an FDA-commissioned inspector documented Respondent's staff selling a package of two Swisher Sweets cigars to a person younger than 18 years of age.

In its Answer, Respondent denied all of the violations alleged in the Complaint. Answer at 1. Ms. Williams argued that she was the clerk on duty at the time of the inspection on December 12, 2017, and that she did not sell a Swisher Sweet cigarillo to a minor. *Id.* at 3.

2. Parties' Contentions and Evidence

a. CTP's Position

CTP's case against Respondent rests on the testimony of FDA-commissioned Inspector Bowens-White plus corroborating evidence. CTP Exs. 4, 6-9, 12. At the time of the respective inspections, Inspector Bowens-White was an FDA-commissioned officer with the state of Florida. Inspector Bowens-White's duties included determining whether retailers were compliant with the age and photo identification requirements relating to the sale of tobacco products. CTP Ex. 4, at ¶¶ 1-4. The inspections entailed accompanying contract undercover buy minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id.* at ¶ 2.

i. **June 5, 2017 Violations**

Inspector Bowens-White's declaration states that she conducted a compliance check inspection at Woodville Chevron, located at 8231 Woodville Highway, Tallahassee, Florida 32305 on June 5, 2017, at approximately 12:40 p.m. CTP Ex. 4, at ¶ 7. Inspector

Bowens-White testified that during the inspection she “observed Minor A purchase a package of cigars from an employee at the establishment. Prior to the purchase [she] observed that Minor A did not present any identification to the employee.” *Id.* at ¶ 8.

The Inspector’s report further states that she parked her car near Respondent’s establishment, watched Minor A enter the establishment, and entered the business moments after the Minor. From the Inspector’s location, inside the business, she had a clear, unobstructed view of the sales counter and Minor A. Minor A purchased a package of cigars and the employee did not provide a receipt. Both she and the minor exited the store and returned to the car. *Id.* at ¶ 8.

ii. December 12, 2017 Violation

Inspector Bowens-White’s declaration states that she conducted a subsequent compliance check inspection at Woodville Chevron, located at 8231 Woodville Highway, Tallahassee, Florida 32305 on December 12, 2017, at approximately 5:34 p.m. CTP Ex. 4, at ¶ 11. Inspector Bowens-White further stated that during the inspection she “observed Minor A purchase a package of cigars from an employee at the establishment. The employee did not provide Minor A with a receipt after the purchase.” *Id.* at ¶ 12.

During cross-examination of Inspector Bowens-White, in reference to the December 12, 2017 inspection, Ms. Williams inquired whether the Inspector entered the establishment before or after Minor A. Inspector Bowens-White confirmed that she entered after the minor. Tr. at 10.

b. Respondent’s Position

Respondent filed both an Answer and a Supplemental Answer, denying that cigars were sold to minors, or that Respondent failed to verify the minor’s age during the inspections at issue. *See* Answer at 1. Ms. Williams argued that she received conflicting information with no factual basis regarding the alleged violations. She contends that she was informed that the minor who purchased the covered tobacco product was requested to present identification and, subsequently, she was informed that the minor was not requested to present identification for verification. Answer at 2, 3. Ms. Williams further argued that she was the clerk on duty at the time of the inspection on December 12, 2017, and that she did not sell any tobacco items to a minor. *Id.* Additionally, Ms. Williams argued that the video recording for the December 12, 2017 inspection was reviewed, and did not contain any footage of the December 12, 2017 inspection. Supplemental Answer at 2.

At the hearing, Ms. Williams attempted to testify as to her own recollection of what occurred on the dates at issue. I informed Ms. Williams that she could not testify at the

hearing because she did not submit any direct testimony under oath by the pre-hearing exchange date. The purpose of the hearing was to allow Respondent an opportunity to cross-examine Inspector Bowens-White. Both parties would have ample opportunity to submit additional argument by way of the post-hearing brief exchange. Tr. at 10-11. I informed the parties that Ms. Williams' statements would be treated as legal arguments and not sworn testimony. *Id.* at 14.

3. *Findings of Fact*

I find Respondent's arguments to be without merit. Respondent offered no evidence to rebut the testimony of Inspector Bowens-White regarding the sales at issue or the failure to verify the age of the purchaser. Ms. Williams argued that she received conflicting information of the alleged incidents, but according to CTP's complaint, the June 5, 2017 inspection documented two violations, the sale to a minor of the package of two Swisher Sweets Grape cigars and the failure of the clerk to verify photographic identification of the minor. The December 12, 2017 inspection only alleges a single violation of selling a package of two Swisher Sweets cigars to a minor. This illustrates that there is no conflicting story, as these are two separate incidents, in which only one incident includes the failure of Respondent to verify identification. Respondent also failed to submit the referenced December 12, 2017 video recording as evidence to substantiate its claim that the incident did not in fact occur.

The evidence of record establishes to my satisfaction that the violations alleged in the Complaint in fact occurred on the dates in question. The testimony of Inspector Bowens-White, plus the corroborating evidence is sufficient to establish that it is more likely than not that Respondent unlawfully sold covered tobacco products to minors and failed to verify that a purchaser was of sufficient age, in violation of 21 C.F.R. § 1140.14(b)(1) and 1140.14(b)(2)(i).

Therefore, I find that the facts as outlined above establish Respondent Woodville Chevron's liability under the Act for two violations within a 12-month period.

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Woodville Chevron is liable for a CMP 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 penalty amount, \$279, against Respondent for two violations of the Act and its implementing regulations within a 12-month period. Complaint at ¶ 1.

In its Answer, Respondent denied any obligation to pay a civil money penalty arguing that there is insufficient proof it violated the regulations.

I have found that Respondent committed two violations of the Act and its implementing regulations within a 12-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).

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

I have found that Respondent committed two violations of selling covered tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that one of the purchasers was 18 years of age or older. 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 \$279 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 two times violated the prohibition against selling covered tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(b)(1), and also failed to verify, by means of photo identification containing a date of birth, that a purchaser was 18 years of age or older, 21 C.F.R. § 1140.14(b)(2)(i).

D. Degree of Culpability

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

E. 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 has asserted “[w]e are very strict on I.D. our customers, we have the all the proper signs to let our customers know we do require I.D. when purchasing alcohol and

tobacco products” Answer at 3. However, this in itself is not a mitigation factor, since Respondent through its employee failed to actually prevent the sales at issue.

Respondent has violated the regulations on two separate occasions. These regulations were created as an initiative to avert minors from purchasing tobacco products. Thus, I find no basis for mitigation of the CMP sought by CTP, which I find proportional and appropriate in this case.

F. Penalty

Based on the foregoing reasoning, I find the penalty amount of \$279 to be reasonable and 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 \$279 against Respondent, Nishva Inc. d/b/a Woodville Chevron, for two 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 12-month period. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

/s/
Catherine Ravinski
Administrative Law Judge