

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-H-1698)

Complainant

v.

Leung's Inc.  
d/b/a El Faro Supermarket,

Respondent.

Docket No. T-17-2998

Decision No. TB2752

Date: May 24, 2018

**INITIAL DECISION**

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Leung's Inc. d/b/a El Faro Supermarket, located at 4338 Northwest 7th Street, Miami, Florida 33126, for four 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 twenty-four month period. Specifically, CTP alleges that Respondent violated the Act by impermissibly selling tobacco products 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.

**Procedural History**

CTP began this matter by serving an administrative complaint, seeking a \$2,200 civil money penalty, on Respondent, at 4338 Northwest 7th Street, Miami, Florida 33126, 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 and stated that the inspector's narrative report was inaccurate. On May 11, 2017, Administrative Law Judge Bill Thomas issued an Acknowledgment and Pre-Hearing Order (APHO). Subsequently, CTP timely filed its pre-hearing exchange. Respondent did not file a pre-hearing exchange.

On December 15, 2017, this case was transferred to me. On December 20, 2017, I held a pre-hearing conference to resolve any issues in advance of a hearing. During the pre-hearing conference, Respondent stated that it wanted to cross-examine the inspector involved in the October 15, 2016 inspection of its establishment at issue in this case. Following the pre-hearing conference, I issued an Order Scheduling Telephone Hearing for January 17, 2018, noting that Respondent wished to cross-examine Inspector Krystle Kirkland-Mobley.

On January 17, 2018, a hearing was held in this case. The purpose of the hearing was to allow Respondent to cross-examine Inspector Krystle Kirkland-Mobley. On February 7, 2018, I informed the parties that the Court had received the transcript of the hearing, and set a March 9, 2018 deadline for the parties' post-hearing brief submissions. On February 20, 2018, Respondent filed its post-hearing brief. On March 9, 2018, CTP filed its post-hearing brief along with a Motion to Exclude Evidence and a Memorandum in Support of its Motion to Exclude Evidence. In a March 12, 2018 letter issued by my direction, Respondent was allowed until March 26, 2018 to file a response to CTP's Motion to Exclude Evidence. To date, Respondent has not filed a response.

### **Pending Motion**

On March 9, 2018, CTP filed a Motion to Exclude Evidence and a Memorandum in Support of its Motion to Exclude Evidence. In its motion and memorandum, CTP argues that Respondent's post-hearing brief seeks to introduce witness testimony and documentary evidence that was not submitted as part of a pre-hearing exchange. CTP asserts that Respondent's failure to submit this information in its pre-hearing exchange but include it for the first time in Respondent's post-hearing brief is "extremely prejudicial to CTP's ability to prepare its case for adjudication."

After reviewing Respondent's post-hearing brief and CTP's arguments, I see no reason to exclude Respondent's post-hearing brief. Respondent's post-hearing brief consists of argument - not evidence. With its post-hearing brief, Respondent did not submit a written declaration submitted under penalty of perjury or documentary evidence for the first time. 21 C.F.R. §§ 17.25(a)-(b), 17.37(b); APHO ¶¶ 4, 9-10. Here, I provided both parties an opportunity to submit post-hearing argument and both parties availed themselves to that opportunity. CTP has not pointed to a valid basis for me to exclude Respondent's post-hearing argument.

CTP may argue that I should not rely on Respondent's post-hearing assertions. I note that Respondent's post-hearing arguments are unsupported by any documentary or testimonial evidence. As there is no evidence to support Respondent's arguments in its post-hearing brief, I do not assign any weight can be assigned to those assertions.

As such, CTP's Motion to Exclude Evidence is **Denied**.

## **Analysis**

### **I. Violations**

CTP determined to impose a civil money penalty against Respondent pursuant to the authority conferred by the Federal Food, Drug, and Cosmetic Act (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 implementing regulations. 21 C.F.R. § 1140.14(a)(1).<sup>1</sup> Additionally, failure to verify, by means of photographic identification containing a purchaser's date of birth is a violation of implementing regulations. 21 C.F.R. § 1140.14(a)(2)(1).

In its Complaint, CTP alleges that Respondent committed four violations of the Act and its implementing regulations within a twenty-four month period. Respondent previously admitted to two violations: (1) Sale of tobacco products to a minor on March 19, 2015 and September 23, 2015; and (2) Failure to verify the age of a person purchasing tobacco products on March 19, 2015.<sup>2</sup> CTP initiated the current complaint following an October 15, 2016 inspection documenting two violations of the regulations - sale to a minor (21 C.F.R. § 1140.14(a)(1)) and failure to verify photographic identification (21 C.F.R. § 1140.14(a)(2)(1)). Respondent denies the allegations that it sold tobacco products to a minor and failed to verify the minor's identification. Answer at 1. Specifically, Respondent argues that the inspector's narrative report is inaccurate on at least five points and that there were only two prior violations within the last 24 months. *Id.* at 2.

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<sup>1</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

<sup>2</sup> 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.

CTP's case against Respondent rests on the testimony of Inspector Krystle Kirkland-Mobley plus corroborating evidence. CTP Exhibits (Exs.) 4, 6, 7, 9. During the hearing, CTP's exhibits 1 through 14 were admitted into the record without objection. Hearing Transcript at 6. The sole witness presented for cross examination at the hearing was Inspector Kirkland-Mobley. Ms. Kirkland-Mobley is an FDA-commissioned officer with the state of Florida whose duties include determining whether retail outlets are in compliance with federal tobacco product requirements. CTP Ex. 4, ¶¶ 1-3. Ms. Kirkland-Mobley's inspections entail accompanying minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id.* ¶¶ at 3-4.

Ms. Kirkland-Mobley's declaration states that she conducted an inspection of Respondent's place of business on October 15, 2016. CTP Ex. 4, ¶ 8. Her declaration further states that she accompanied a minor into Respondent's establishment on October 15, 2016, where she witnessed the minor purchase a package of cigarettes from an employee without presenting identification. *Id.* On cross-examination, Ms. Kirkland-Mobley confirmed that she accompanied the minor into Respondent's establishment and observed an employee sell a tobacco product to a minor. Hearing Transcript at 7-8.

Throughout this case, Respondent has denied the allegations and questioned the accuracy of the inspector's narrative report. Answer; Post-hearing Brief of Respondent. As previously stated, Respondent's arguments are unsupported by evidence written direct testimony. Absent documentary evidence or written direct testimony, Respondent's arguments are unpersuasive. 21 C.F.R. § 17.33(c).

The testimony of Ms. Kirkland-Mobley plus the corroborating evidence consisting of a photograph of the pack of cigarettes that were obtained from the minor on October 15, 2016 are compelling evidence that Respondent unlawfully sold cigarettes to a minor and failed to verify the age of the minor using photographic identification. The evidence of record sufficiently identifies the cashier who made the sale to the minor, and the sworn testimony of the inspector establishes to my satisfaction that the violations charged in this case in fact took place on the date in question. 21 C.F.R. § 17.33(b).

I find that the facts as outlined above establish Respondent Leung's Inc. d/b/a El Faro Supermarket's liability under the Act.

## **II. Civil Money Penalty**

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Leung's Inc. d/b/a El Faro Supermarket 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, \$2,200, against Respondent for four violations of the Act and its implementing regulations within a twenty-four month period.

I have found that Respondent committed four violations of the Act and its implementing regulations within a twenty-four 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. Nature, Circumstances, Extent and Gravity of the Violations**

I have found that Respondent committed four violations of the Act and its implementing regulations within a twenty-four month period. 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.

**ii. 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 \$2,200 Civil Money Penalty sought by CTP; nor has Respondent presented evidence as to the effect this penalty would have on its ability to do business.

**iii. History of Prior Violations**

The current action is the second civil money penalty action brought against Respondent for violations of the Act and its implementing regulations. As noted above, Respondent previously violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on March 19, 2015 and September 23, 2015, and failed to verify the age of a person purchasing tobacco products, 21 C.F.R. § 1140.14(a)(2)(1), on March 19, 2015. Instead of remedying these issues, Respondent repeated the same violations on October 15, 2016.

**iv. Degree of Culpability**

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

**v. Additional Mitigating Factors**

Respondent has not presented any evidence to mitigate the civil money penalty amount. As such, I find no reason to mitigate the penalty amount.

**vi. Penalty**

Based on the foregoing reasoning, I find a penalty amount of \$2,200 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 \$2,200 against Respondent, Leung's Inc. d/b/a El Faro Supermarket, for four 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 twenty-four month period.

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/s/  
Wallace Hubbard  
Administrative Law Judge