

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-H-6135)

Complainant,

v.

Maya Grocery LLC  
d/b/a Maya Grocery and Deli,

Respondent.

Docket No. T-18-126

Decision No. TB3151

Date: October 5, 2018

**INITIAL DECISION**

I hereby sustain the determination of Complainant, Center for Tobacco Products (“CTP”) of the United States Food and Drug Administration (“FDA”) to impose an \$11,182 civil money penalty against Respondent, Maya Grocery LLC d/b/a Maya Grocery and Deli, for six violations of federal tobacco regulations within a 48-month period.

**I. Background**

CTP began this matter by serving an administrative complaint on Respondent, Maya Grocery LLC d/b/a Maya Grocery and Deli, at 284 Trenton Avenue, Paterson, New Jersey 07503, and by filing a copy of the complaint with the FDA’s Division of Dockets Management. CTP seeks to impose an \$11,182 civil money penalty against Respondent 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. CTP alleges that Respondent violated the Act by impermissibly selling cigarettes or smokeless tobacco to minors, failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, and opening packages of cigarettes intended for the sale of individual cigarettes. During an inspection conducted September 17, 2017, an

FDA-commissioned inspector documented the two current violations. CTP further alleges that Respondent Maya Grocery and Deli previously admitted to four violations of regulations found at 21 C.F.R. pt. 1140.

## **II. Procedural History**

On October 17, 2017, CTP served the complaint on Respondent Maya Grocery and Deli by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. On November 1, 2017, Respondent timely filed an answer denying the current allegations in the complaint.<sup>1</sup> *See* Answer ¶¶ 1-2. Specifically, Respondent stated, it “did not sell to any minor.” *Id.* ¶ 2. In a letter accompanying the Answer, dated October 23, 2017, Respondent indicated that it did “not have access for e-filing.” CRD Docket Nos. 3, 5 at 1. On November 13, 2017, I issued an Acknowledgment and Pre-Hearing Order (APHO) that set out the deadlines for the parties’ submissions in this case, and informal briefs for the parties to complete and submit.<sup>2</sup> In the APHO, I also granted Respondent a waiver from the electronic filing requirement. APHO ¶ 2.

On March 5, 2018, CTP timely filed its pre-hearing exchange. CTP’s exchange included an Informal Brief of Complainant (“CTP Br.”), a list of proposed witnesses and exhibits, and fourteen (14) numbered exhibits (“CTP Ex. 1- Ex. 14”). CTP’s exhibits included the written direct testimony of two witnesses: Ms. Laurie Sternberg, Senior Regulatory Counsel, Office of Compliance and Enforcement, CTP, FDA (“Sternberg Declaration”, “CTP Ex. 3”), and Ms. Tyhesia Evans (“Inspector Evans”), former FDA-commissioned inspector for the state of New Jersey (“Evans Declaration”, “CTP Ex. 4”). Respondent did not file a pre-hearing exchange.

### **A. Pre-Hearing Conferences (PHCs) and Respondent’s Request for a Spanish Language Interpreter**

On April 17, 2018, I scheduled a pre-hearing conference in this case by telephone. Ms. Miguela Urena appeared for Respondent Maya Grocery and Deli, and requested the assistance of a Spanish Language Interpreter for any further proceedings in the case. Complainant CTP did not appear for the PHC but provided good cause in response to my Order.

On May 22, 2018, I held the rescheduled pre-hearing conference by telephone. Both parties appeared and the court provided a Spanish Language Interpreter to assist Ms. Urena. During the prehearing conference call, we discussed the roles of the parties, the reasons for a prehearing conference and hearing, the exhibits submitted during the

---

<sup>1</sup> The Departmental Appeals Board, Civil Remedies Division, received Respondent’s Answer by U.S. Mail and e-mail from CTP on November 1, 2017.

<sup>2</sup> I note that during the course of this proceeding, I ruled on discovery matters: CTP’s Motion to Compel Discovery (CRD Docket Nos. 9, 9a-9c.) and Motion to Extend Deadlines (CRD Docket No. 10).

exchange, and the cross-examination of witnesses that CTP offered. I clarified that although Ms. Urena is not an attorney, she can represent Respondent. I noted that CTP offered two witnesses in this case, Ms. Sternberg and Inspector Evans. I also noted that Respondent did not submit an exchange or offer any witnesses by the exchange deadline.

I explained that the sole purpose for holding a hearing in this case was to allow the parties an opportunity to cross-examine witnesses, proposed by the other party, on their sworn direct testimony of record. Respondent declined to cross-examine Ms. Sternberg,<sup>3</sup> but wished to cross-examine Inspector Evans. I emphasized that cross-examination of a witness is intended show that direct testimony of record is not worthy of belief. Respondent's questions should be limited in scope and related to statements made in Inspector Evans's sworn declaration. Respondent may not testify, argue with, or engage in dialogue with the witness. Finally, I suggested that Respondent review CTP Ex. 4 (Evans Declaration), CTP Ex. 8 (photograph of tobacco product sold to Minor A), and CTP Ex. 9 (photograph of evidence in a bag), to determine what questions she would like to ask Inspector Evans on cross-examination.

### **B. In Person Telephone Hearing**

On June 26, 2018, I held a hearing in this case. Both parties appeared, and a Spanish Language Interpreter assisted Ms. Urena with translation. In the absence of objections to CTP's proposed exhibits, I admitted CTP Ex. 1 through CTP Ex. 14 into the record. *See* Hearing Transcript ("Tr.") at 8. Respondent cross-examined Inspector Evans. Tr. at 9-29. CTP's attorney had no questions on redirect for Inspector Evans. *Id.* at 29.

On July 17, 2018, I issued an order informing the parties that the Civil Remedies Division had received the transcript of the hearing, and set the deadline for the parties' post hearing brief submissions as August 15, 2018. On July 20, 2018, CTP filed a Notice of Waiver of Post-Hearing Brief. Respondent did not file a post-hearing brief. As the briefing period has elapsed, I now render my decision.

### **III. Issues**

- a. Whether Respondent Maya Grocery and Deli sold cigarettes to a minor, and failed to verify that the cigarette purchaser was of sufficient age, on September 17, 2017, in violation of 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(a)(2)(i).<sup>4</sup>
- b. Whether the civil money penalty of \$11,182 is a reasonable remedy.

---

<sup>3</sup> Ms. Sternberg's declaration is undisputed.

<sup>4</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

#### IV. Applicable 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). The FDA and its agency, CTP, may seek the imposition of remedies against any person who violates the Act's requirements as they relate to the sale of tobacco products. 21 U.S.C. § 333(f)(9). Under 21 C.F.R. § 1140.14(a)(1), no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no cigarette or smokeless tobacco purchasers are younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(4) no retailer may open packages of cigarettes intended for the sale of individual cigarettes.

The Act establishes factors that a presiding officer must consider in determining the civil money penalty amount. The presiding officer must "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).

#### V. Analysis

##### **A. Allegations, Parties' Contentions, Hearing/Scope of Cross-Examination, and Findings of Fact**

###### *1. Allegations*

After a thorough review of the evidence submitted by the parties and the information elicited during the hearing, I find that Respondent committed six violations of the Act and its implementing regulations as alleged in the Complaint. The sale of cigarettes or smokeless tobacco to an individual who is under the age of 18, failure to verify the photographic identification of an individual who is not over the age of 26, and opening packages of cigarettes intended for the sale of individual cigarettes, are violations of implementing regulations. 21 C.F.R. § 1140.14(a)(1), (a)(2)(i), (a)(4).

###### *2. Parties' Contentions*

CTP's case relies on the testimony of former FDA-commissioned Inspector Evans, whose duties included undercover buy inspections to determine retailers' compliance with age and photograph identification requirements relating to the sale of tobacco products. CTP Ex. 4 ¶¶ 2-4. The Evans Declaration (CTP Ex. 4), Narrative Report ("CTP Ex. 6"), and Inspection Results ("TIMS Form", "CTP Ex. 7"), corroborate CTP's current allegations.

CTP alleged that Respondent committed six violations of the Act and its implementing regulations over a 48-month period. *See* Complaint ¶ 1; CTP Br. at 9, 12. Specifically, CTP alleges that at approximately 10:59 a.m. on September 17, 2017, at Respondent's

business establishment, 284 Trenton Avenue, Paterson, New Jersey 07503, Inspector Evans documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age. Complaint ¶ 7; CTP Ex. 4 ¶¶ 9-10; CTP Br. at 5. Inspector Evans 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. Complaint ¶ 7; CTP Ex. 4 ¶ 9; CTP Br. at 6. Inspector Evans testified that while she remained outside the establishment during the transaction, she "maintained a direct line of sight to Minor A and the sales counter." CTP Ex. 4 ¶ 9. Inspector Evans also testified that shortly after the inspection, she processed the evidence in accordance with the standard procedures at the time of the inspection, and recorded the inspection results in the TIMS form. *Id.* ¶¶ 10-11.

CTP also alleged that in a previous civil money penalty action, Respondent admitted to four violations of the Act. Complaint ¶¶ 9-10; *see* CTP Br. at 2-3. The previous action concluded when Respondent admitted the allegations contained in the Complaint and paid the agreed upon civil money penalty. *See* Complaint ¶ 10; CTP Ex. 2. Respondent denied the current allegations, and requested a hearing to cross-examine Inspector Evans. *See* Answer ¶¶ 1-2.

### 3. *Hearing and Scope of Cross-examination*

Before cross-examination, I gave the Spanish Language Interpreter a thorough overview of the issues discussed at the pre-hearing conference. *See* Tr. at 4-7. As Ms. Urena was proceeding without legal representation, and with the assistance of a court-provided Spanish Language Interpreter, I gave her considerable leeway during the cross-examination. However, Ms. Urena repeatedly asked questions that went beyond the scope of Inspector Evans's sworn direct testimony. *See generally id.* at 21-24, 26.

In addition, Ms. Urena persisted in asking the same questions "over and over" after Inspector Evans had provided answers. *See e.g.* Tr. at 25. Counsel for CTP made a number of objections during the hearing. Thus, I was obligated on several occasions to instruct Ms. Urena to limit the scope of her questions to the statements made in Inspector Evans's declaration, and to discontinue repeating the same questions that she already asked and Inspector Evans had answered. *Id.*

During the June 26, 2018 hearing, Ms. Urena cross-examined Inspector Evans regarding her sworn direct testimony (CTP Ex. 4), as well as the contents of the accompanying the TIMS (CTP Ex. 6), and Inspection Results (CTP Ex. 7). I will not recite every detail of Ms. Urena's cross-examination; rather I will present relevant excerpts. It appears that Ms. Urena was primarily concerned with whether Inspector Evans had other evidence beyond that already contained in the record proving that Respondent sold cigarettes to a minor on September 17, 2017. For example, Ms. Urena asked Inspector Evans whether she has "a video that proves that [Respondent] sold cigarettes to a minor." Tr. at 9. Ms. Urena also asked whether Inspector Evans had another witness to the sale. *Id.* at 9-10. Then she asked whether Inspector Evans took pictures of Respondent selling cigarettes to

a minor or whether Inspector Evans had a recording or audio of the sale. *Id.* at 10. She also asked whether the minor mentioned her by name as the person who sold the cigarettes. *Id.* at 11. Inspector Evans answered “no” to these questions. *Id.* at 9-11.

Ms. Urena also asked whether Inspector Evans had an independent recollection of the time that she came to the store. Tr. at 11. Inspector Evans testified that other than the actual report, she does not have a personal recollection of the time. *Id.* Ms. Urena then asked Inspector Evans about why she did not make a recording of the inspection. *Id.* at 11-12. Inspector Evans explained, “Recording is not part of my job, only picture-taking.” *Id.* at 12. When Ms. Urena attempted to press further, CTP’s counsel objected based on “asked and answered” and I sustained the objection. *Id.*

Ms. Urena asked Inspector Evans whether she was aware of the video recording of the sale and whether she checked it. Tr. at 14-15. CTP’s counsel objected to the question as beyond the scope of the Evans Declaration. *Id.* at 15. CTP’s counsel further objected because while Ms. Urena responded to a request for production of documents earlier in the case, she did not produce a videotape of the alleged sale to CTP. *Id.* I explained to Ms. Urena that Inspector Evans had no obligation to question her about the video during the inspection, and that if she wanted the video to be part of the evidence, she should have produced it when she responded to CTP’s production request. *Id.* at 16.

#### 4. Findings of Fact

Inspector Evans testified credibly and thoroughly about the September 17, 2017 inspection at which she observed Respondent selling cigarettes to a minor. Inspector Evans testified that based on the report, “. . . I observed the minor. I witnessed the minor entering that establishment, and I observed the sale.” Tr. at 19. Inspector Evans also confirmed, “[t]he brand of cigarettes was Newport, and also was stated and photographed as part of my report.” *Id.* at 20. Ms. Urena then attempted to ask additional questions outside the scope of the Evans Declaration, CTP’s counsel objected, and in order to avoid undue delay, I read the relevant part of sworn testimony from the record:

THE COURT: Let me read to you, because I can’t believe that anybody really read this report, but here it is.

The inspector’s report says that she stood outside of the store; that she had a clear, unobstructed view into the store. She did not enter because she did not wish to suggest that it was an undercover buy by a minor and put a damper on it. She said that she had a direct line of sight of Minor A, and she saw a female adult employee with black or dark brown hair selling a package of Newport cigarettes to the minor, not asking the minor for identification, and not providing the minor with a receipt. After that, she left the store and prepared a report in the car and made the photographs that are also contained as part of her testimony.

Tr. at 20-21. Ultimately, Ms. Urena was unable to elicit any information during the cross-examination to show that Inspector Evans' sworn testimony was unworthy of belief. Ms. Urena did not submit any evidence during the pre-hearing exchange to rebut CTP's evidence.

At the close of the hearing, I informed Ms. Urena that next, a transcript of the proceedings would be prepared. She would be notified when the transcript was available for review. At that time, she would have ample opportunity submit a post-hearing final brief. In that brief, she would be able to make any arguments she wished, including her reasons for believing that the process is unfair, why it should be conducted in a different way, and why videos should be required. Tr. at 23-24. Despite due notification, Ms. Urena did not file a post-hearing final brief.

Based on all of the evidence and testimony in the record as currently constituted, I find that Respondent committed six violations of the Act and its implementing regulations over a 48-month period. As Respondent conceded the previous allegations, there is no dispute as to the material facts of the previous civil money penalty action. Accordingly, the only issue before me is whether the CMP of \$11,182 that CTP seeks is a reasonable remedy.

## **B. Civil Money Penalty**

After considering the factors under the applicable statute, I find that the CMP of \$11,182 that CTP seeks against Respondent, for six violations of the Act and its implementing regulations over a 48-month period, is reasonable. CTP can seek a civil money penalty from Respondent for violating the Act. 21 U.S.C. § 333(f)(9). When determining an appropriate penalty, the presiding officer shall evaluate any circumstances that mitigate or aggravate the violation referring to the factors identified in (but not limited to) the applicable statute. 21 C.F.R. § 17.34. Under the applicable statute, I must consider "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).

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

I find that Respondent committed six violations of the Act with a 48-month period. While Respondent denies the September 17, 2017 allegations, Respondent did not provide any evidence to rebut Inspector Evans's testimony or the documentation in the evidentiary record. I find Respondent's repeated inability to comply with federal tobacco regulations to be serious in nature. Accordingly, I find that the civil money penalty of \$11,182 is reasonable under these circumstances.

## *2. Respondent's Ability to Pay and Effect on Ability to do Business*

While Respondent submits that the civil money penalty is too high, Respondent has not provided any evidence that it does not have the ability to pay the \$11,182 penalty. Further, Respondent has not presented any evidence regarding the effect of the civil money penalty on its ability to do business. Respondent may continue to sell tobacco products so long as it complies with the Act's prohibition of selling tobacco products to minors and opening packages of cigarettes intended for the sale of individual cigarettes.

## *3. History of Prior Violations*

Respondent has a history of violating FDA tobacco regulations. This is the second civil money penalty action against Respondent for violations of the Act and its implementing regulations. On November 17, 2016, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-564, FDA Docket Number FDA-2016-H-3614, for four violations of 21 C.F.R. pt. 1140 within a twenty-four month period. Complaint ¶ 9; *see also* CTP Ex.1 ¶¶ 1, 8, 10. CTP documented two violations on January 2, 2016 (sale to minor and failure to verify age of purchaser), two on April 23, 2016 (sale to minor and failure to verify age of purchaser), and one on April 25, 2016 (open packages of cigarettes intended for individual cigarettes). Complaint ¶ 9; CTP Ex.1 ¶¶ 8, 10. 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. Respondent admitted the prior violations, paid the agreed upon penalty, and expressly waived its right to contest such violations in subsequent actions. Complaint ¶ 10; CTP Ex. 2. While I commend Respondent for taking responsibility for its prior violations, Respondent's repeated inability to comply with FDA tobacco regulations is troubling and supports the imposition of a higher penalty.

## *4. Degree of Culpability*

I find that Respondent committed six violations of the Act as alleged in the complaint. The record shows that Respondent sold cigarettes or smokeless to minors in violation of 21 C.F.R. § 1140.14(a)(1) on January 2, 2016, April 23, 2016, and September 17, 2017. The record also shows that on those same dates, Respondent failed to verify the identification of the purchasers in violation of 21 C.F.R. § 1140.14(a)(2)(ii). Finally, the record shows that Respondent had open packages of cigarettes intended for the sale of individual cigarettes on April 25, 2016. Based on Respondent's admissions regarding the previous civil money penalty action, the documentary evidence of record, and the additional testimony given at the June 26, 2018 hearing, I find Respondent fully culpable for six violations of the Act and its implementing regulations.

## *5. Additional Mitigating Factors*

After reviewing Respondent's evidence in the record and the information elicited during hearing, I do not find any mitigating factors. While Respondent checked a box in the



answer that the civil money penalty was too high, it did not provide any additional evidence for me to evaluate. *See Answer ¶ 3.* Respondent did not submit any evidence during pre-hearing exchange, for example, policies and procedures to deter violations of the Act, evidence of employee training, or evidence of financial hardship. Furthermore, Respondent did not avail itself of the opportunity to present arguments of any unfairness of the process by submitting a post-hearing brief. Based on the gravity of Respondent's violations, lack of evidence regarding respondent's ability to pay and continue business, history of prior violations, culpability, and lack of mitigating factors, I find the full penalty is appropriate and supported by the evidence.

## **VI. Penalty**

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

## **VII. Conclusion**

For these reasons and pursuant to 21 C.F.R. § 17.45, I impose a civil money penalty of \$11,182 against Respondent Maya Grocery LLC d/b/a Maya Grocery and Deli, 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. Pursuant to 21 C.F.R. § 17.45(d), this decision becomes final and binding upon both parties after 30 days of the date of its issuance.

/s/

---

Catherine Ravinski  
Administrative Law Judge